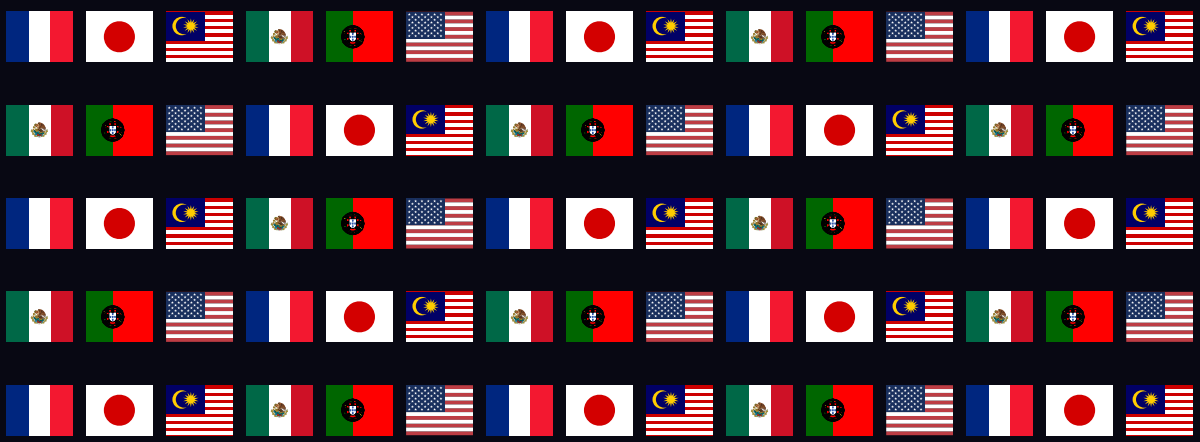
HEALTHCARE ENFORCEMENT & LITIGATION

Mexico



LEXOLOGY
Getting The Deal Through

Consulting editor
Mintz

Healthcare Enforcement & Litigation

Consulting editors

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Mintz

Quick reference guide enabling side-by-side comparison of local insights into the applicable regulatory, enforcement and litigation framework (for pharmaceutical products and medical devices, relationships between healthcare professionals and suppliers, and healthcare delivery); private enforcement, cross-border enforcement and extraterritoriality; and recent trends.

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OVERVIEW

Healthcare funding

In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

Law stated - 01 July 2022

Delivery

In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

Law stated - 01 July 2022

Key legislation

Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

Key legislation includes the following:

- the General Health Law;
- the General Health Law Regulations;
- the Health Supplies Regulation;
- the Official Mexican Standards (NOMs); and
- the Mexican Pharmacopoeia (Farmacopea Mexicana).

Law stated - 01 July 2022

Responsible agencies

Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

The regulatory authorities in this field are the following.

Federal Commission for Protection against Sanitary Risk

Until recently, the Federal Commission for Protection against Sanitary Risk (COFEPRIS) was a decentralised agency of the Ministry of Health, in charge of the control and surveillance of all aspects related to sanitary regulation (in connection with drugs, medical devices, health services, food supplements, food and beverages, cosmetics, pesticides, clinical studies, and so on). COFEPRIS had administrative, technical and operational autonomy, as well as its own legal personality and assets. It is now under the authority of the Undersecretary for Prevention and Promotion of Health. The General Health Law entitles COFEPRIS to recover income derived from insurance rescue and other exceptional incomes.

General Health Council

The General Health Council is an agency controlled by the Executive and is funded by the federal government.

Law stated - 01 July 2022

Scope of enforcement

What is the scope of their enforcement and regulatory responsibilities?

In accordance with the General Health Law, COFEPRIS is in charge of the following:

- the sanitary regulation, surveillance and control of public social security institutions and private institutions;
- the sanitary control of products and services, and their importation and exportation;
- the sanitary control of the processing, use, maintenance, import, export and disposal of medical equipment, prosthetics, orthotics, functional aids, diagnostic agents, dental supplies, surgical materials, healing and hygienic products;
- preparing and issuing NOMs relating to health facilities, products and services;
- evaluating, issuing or revoking sanitary authorisations;
- exercising control and sanitary surveillance of drugs and other health supplies;
- disposal of organs, tissues, human cells and their components, toxic or dangerous substances, biotechnological products and raw materials;
- exercising control and surveillance of the advertising of sanitary activities, products and services; and
- imposing sanctions and implementing security measures.

The General Health Council is responsible for:

- preparing, updating and circulating the National Compendium of Health Supplies through the creation of groups of experts from all public health institutions, which decide on the inclusion of new medicines, therapies, devices and other products in the compendium;
- preparing and updating the Guidelines for the Evaluation of Health Supplies; and
- preparing the Guidelines for Interchangeability Tests of medicines that are submitted to COFEPRIS for the granting of marketing authorisations of generics.

Law stated - 01 July 2022

Regulation of pharmaceutical products and medical devices

Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

The regulatory authorities in this field are the following.

COFEPRIS

Until recently, COFEPRIS was a decentralised agency of the Ministry of Health, in charge of the control and surveillance of all aspects related to sanitary regulation (in connection with drugs, medical devices, health services, food supplements, food and beverages, cosmetics, pesticides, clinical studies, and so on). COFEPRIS had administrative, technical and operational autonomy, as well as its own legal personality and assets. COFEPRIS is now under the authority of the Undersecretary for Prevention and Promotion of Health. The General Health Law entitles COFEPRIS to recover income derived from insurance rescue and other exceptional incomes.

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- preparing and updating the Guidelines for the Evaluation of Health Supplies; and
- preparing the Guidelines for Interchangeability Tests of medicines that will be submitted before COFEPRIS for the granting of marketing authorisation as generics.

In accordance with the General Health Law, COFEPRIS is in charge of the following:

- the sanitary regulation, surveillance and control of public social security institutions and private institutions;
- the sanitary control of products and services, and their importation and exportation;
- the sanitary control of the processing, use, maintenance, import, export and disposal of medical equipment, prosthetics, orthotics, functional aids, diagnostic agents, dental supplies, surgical materials, healing and hygienic products;
- preparing and issuing NOMs relating to health facilities, products and services;
- evaluating, issuing or revoking sanitary authorisations;
- exercising control and sanitary surveillance of drugs and other health supplies;
- disposal of organs, tissues, human cells and their components, toxic or dangerous substances, biotechnological products and raw materials;
- exercising control and surveillance of the advertising of sanitary activities, products and services; and
- imposing sanctions and implementing security measures.

Law stated - 01 July 2022

Other agencies

Which other agencies (eg, competition or securities regulators, prosecutors) have jurisdiction over healthcare, pharmaceutical and medical device cases?

The following agencies have jurisdiction over healthcare, pharmaceutical and medical device cases:

- the Mexican Institute of Industrial Property;
- the Federal Agency for the Protection of Consumers;
- the Federal Economic Competition Commission; and
- the Federal District Attorney's office.

Law stated - 01 July 2022

Simultaneous investigations

Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

Multiple government agencies can simultaneously conduct investigations on the same subject, provided that the corresponding actions are independent of each other and are intended for different purposes.

Law stated - 01 July 2022

REGULATION OF PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

Monitoring powers

What powers do the authorities have to monitor compliance with the rules on drugs and devices?

Pharmaceutical products

Pharmaceutical products are subject to the following provisions.

New molecules

Essentially, applicants for marketing authorisations must prove the safety and efficacy of their products through standard clinical trials, according to the rules set out by the General Health Law, its regulations and NOMs of good manufacturing of medicines and active ingredients. Concurrently, they also have to request approval of their products as new molecules from the New Molecules Committee of COFEPRIS. According to the Health Law Regulations article 2 section XV, a new molecule is:

- an active ingredient or drug not approved worldwide (a new molecular entity);
- an active ingredient or drug already available in other countries but with limited clinical experience or disputed information, that has not be approved in Mexico;
- a drug that is a non-marketed combination of two or more active ingredients; or
- an active ingredient or drug already available on the market, but to be marketed for a new therapeutic indication.

R&D companies benefit from a special procedure for drugs that have been previously approved by a regulatory authority abroad to be approved for the first time in Mexico.

Generics

Applicants for marketing authorisations have to prove that their products are bioequivalent to the innovator product. They have to provide information concerning dissolution profiles or bioavailability studies regarding the reference product. COFEPRIS periodically issues a reference list of medicinal products. Recently, the NOM setting the test to prove that a generic drug is interchangeable with a reference drug was updated (NOM-177-SSA1-2013). Legally, COFEPRIS should not grant marketing authorisation for generics breaching exclusivity rights.

There is a linkage system between COFEPRIS and the Mexican Institute of Industrial Property (IMPI), which aims to prevent the granting of marketing authorisations in violation of patent rights. According to the Intellectual Properties Regulations, every six months IMPI must publish a gazette that includes patents covering allopathic medicines (the Linkage Gazette). The initial IMPI position was that only patents relating to a compound were relevant to linkage review (excluding formulation and use patents). On 31 July 2012, for the first time IMPI included formulation patents in the Linkage Gazette, in accordance with a 2010 ruling of the Mexican Supreme Court (Jurisprudence No. 2a/J7/2010, Federal Judicial Gazette, No. XXXI, page 135).

Use patents are included in the Linkage Gazette by a court order, since IMPI considers that they should not be included in the linkage system.

Under the linkage regulations, at the filing of the application, the applicant must prove that he or she is the owner or licensee of the patent of the active ingredient of the product (recorded before IMPI), or state under oath that their application does not violate the list of products published in the Linkage Gazette and observes patent law.

Biologics

Amendments to the legal framework to regulate the approval of biologics are recent and being tested. Under the General Health Law, applicants have to prove the quality, safety and efficacy of their products, and that they meet their regulations and applicable NOMs, particularly those for good manufacturing practices for medicinal products (NOM–059–SSA1–2015) and for active ingredients (NOM-164-SSA1-2015).

In accordance with NOM–257–SS1–2014, all biological drugs that were authorised before the legal reform and that are still on the market must enter a regularisation process to comply with the latest standards for biologics. NOM 257 emphasises that key points to ensure the safety, efficacy and quality of biologics are already regulated in other NOMs currently in effect, such as those for clinical trials and pharmacovigilance. NOM 257 empowers the Assessment Subcommittee on Biotech Products (SEPB) to assess technical and scientific data in connection with clinical trials, approval or renewal of innovator biologics or follow-on biologics (biocomparables), and to issue opinions to characterise biologics as innovators, reference products or biocomparables.

NOM 257 provides transitional provisions for the renewal of marketing authorisations of biologics granted before the amendments to the Health Law Regulations for Biologics issued in 2011 came into force. These provisions establish that:

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

These provisions will be applicable only for those renewal applications submitted before 31 December 2015. COFEPRIS, however, missed an opportunity to address the current uncertainty in respect of Regulatory Data Protection for Biologics, as NOM 257 does not provide for guidelines in this regard.

Biocomparables (follow-ons)

Applicants must submit clinical tests, and when appropriate in vitro tests, to prove the safety, efficacy and quality of this product comparable (similar) to those of the reference biologic. The pre-clinical and clinical test used by an applicant for a biocomparable must use the corresponding reference biologic to perform comparative and physico-chemical studies. For this, the applicant must submit:

- in-vitro studies;
- the report of a comparative pharmacokinetic test, if determined by the Ministry of Health, to show pharmacokinetic comparability on key parameters between both the follow-on and the reference biologic;
- pharmacodynamics test reports; and
- comparative efficacy and safety clinical test to show the similarity between both the follow-on and the reference biologic.

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

Orphan drugs

Orphan drugs were recently introduced into the General Health Law and the Mexican Pharmacopeia. In practice, they are approved by a particular procedure, following rules for new molecules when applicable and appropriate. Specific rules are still pending. The draft of the NOM compiling requirements for granting marketing authorisation includes orphan drugs.

Medical devices

The primary legislation for medical devices and diagnostics are the General Health Law, its regulations and the NOM for good manufacturing practices regarding medical devices (NOM–241–SSA1–2012). In general, it would be fair to say that regulation regarding medical devices is lighter than that for drugs and other substances. According to their use, the General Health Law classifies medical devices into:

- medical equipment;
- prosthetics, orthotics and functional supports;
- diagnostic agents;
- dental supplies;
- surgical and healing materials; and
- hygiene products.

Marketing authorisation requirements for these devices depends on the level of risk involved in their use, according to a threefold classification:

- Class I: products that are well known in medical practice and for which safety and efficacy have been proven. They are not usually introduced into a patient's body;
- Class II: products that are well known in medical practice, but may have material or strength modifications. If introduced, they remain in a patient's body for less than 30 days; and
- Class III: products either recently accepted in medical practice or that remain in a patient's body for more than 30 days.

COFEPRIS analyses both medical devices and, if applicable, software that enables them to work. Conversely, mobile medical applications are a new area that COFEPRIS may address in the future with particular regulations, especially if they represent health risks. As an incentive, applicants can benefit from a special procedure for certain devices that have been previously approved by the US Drug and Food Administration and Health Canada to be approved in Mexico. This procedure is essentially based on a dossier filed with the foreign regulatory agency, to reduce approval time frames by up to 30 working days. Industry participants have welcomed these new rules, but they are still being tested.

Powers to monitor compliance

COFEPRIS can request reports from marketing authorisation holders, and make on-site inspection visits in the manufacturing, distribution or storage facilities, essentially to verify that their products meet the approved specifications and do not represent a risk to public health and to ensure that good manufacturing practices, stability, pharmacovigilance and labelling standards are complied with. COFEPRIS can initiate ex officio legal proceedings to sanction non-compliance. Ultimately, these legal proceedings can result in the revocation of the marketing authorisation.

COFEPRIS is also entitled to implement measures on behalf of public health, such as the seizure of products and ordering a partial or total suspension of activities, services or adverts.

Under certain conditions, COFEPRIS has statutory authority to revoke any manufacturing approval or impose sanctions, ranging from a fine of up to 16,000 times the minimum wage to the closure of the establishment. The imposition of administrative sanctions does not exclude civil and criminal liability. Administrative infringements can incur penalties ranging from a fine up to 20,000 times the minimum wage to the final closure of the establishment. Repeated infringements are considered a criminal offence.

COFEPRIS has broad jurisdiction to seize counterfeit or illegal medicines. The General Health Law classifies the manufacturing and sale of counterfeit or falsified medicine as a crime. In addition, COFEPRIS commonly enters into collaboration agreements with the office of the Attorney General of Mexico (FGR) and the Customs Office in order to investigate and prevent counterfeit and illegal medicines.

COFEPRIS has a permanent pharmacovigilance programme. Under the Health Law Regulations and NOMs, COFEPRIS's monitoring is focused, among other things, on the following:

Ensuring compliance with good manufacturing practices and standard operating procedures.

Ensuring that activities performed do not exceed either authorised limits or differ from those authorised activities.

Ensuring that companies perform validation analyses of their manufacturing processes and systems involved.

COFEPRIS is entitled to implement measures to protect public health, such as:

- seizure of products; and

- ordering the partial or total suspension of activities, services or adverts;
- revoke a company's manufacturing approval;
- impose sanctions, ranging from a fine of up to 16,000 times the minimum wage (about US$135,000) to the closure of an establishment; and
- make on-site inspection visits to manufacturing, distribution and storage facilities.

The imposition of administrative sanctions does not exclude civil and criminal liability. Affected parties are entitled to appeal decisions by COFEPRIS through the applicable administrative or judicial venues.

Law stated - 01 July 2022

Investigation time frames

How long do investigations typically take from initiation to completion? How are investigations started?

Investigations conducted by COFEPRIS can be initiated either by the complaint of an individual or by COFEPRIS itself. However, the duration of the investigation varies depending on the complexity of the case. Certain investigations related to the counterfeiting and commercialisation of illegal medicines are generally conducted in a matter of a few days.

Law stated - 01 July 2022

Access to investigation materials

What rights or access does the subject of an investigation have to the government investigation files and materials?

In most contentious administrative and judicial proceedings, the subject of an investigation has full access to the files and materials, except for the information expressly classified as confidential due to the request of an authority or another individual. Third parties are usually restricted from accessing files and materials submitted before COFEPRIS by companies or individuals during the prosecution of administrative proceedings.

Law stated - 01 July 2022

Investigations abroad

If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

No, but under article 168 of the Health Law Regulations, to hold a marketing authorisation foreign applicants must have:

- an approval from COFEPRIS for a manufacturing facility or laboratory for medicines or biologic products for human use in Mexico; or
- an equivalent approval (eg, a licence, certificate or another permit document) for any of these facilities abroad from the competent authority in the country of origin.

Law stated - 01 July 2022

Enforcement proceedings

Through what proceedings do agencies enforce the rules?

Most agencies hold their own administrative proceedings, and the possibility of applying later to a court remains available. COFEPRIS is entitled to revoke sanitary authorisations in the following cases:

- when the corresponding products or activities constitute a risk of harm to human health;
- when exercising an authorised activity exceeds the limits set in the respective authorisation;
- when the authorisation is used for different purposes;
- for non-compliance with the Health Law or Regulations;
- when the product covered by the authorisation does not meet or no longer meets specifications or requirements established by the Health Law, NOMs and other general provisions;
- when information or documents provided by the applicant is false;
- when the reports provided by authorised third parties are false; and
- when the products no longer possess the attributes or characteristics under which they were authorised or lose their preventive or therapeutic properties.

There is also an available action called accion popular , whereby any individual with or without proper legal standing can file a complaint before COFEPRIS, arguing and proving that there are certain health risks associated with a product in the market. However, the claimant's procedural rights are very limited, and these actions are intended to end a health risk and not to obtain compensation.

In coordination with COFEPRIS, the FGR is entitled to investigate and prevent the commercialisation of illegal medicines and also to implement measures on behalf of public health, such as the seizure of products.

The Federal Agency for the Protection of Consumers (PROFECO) can start proceedings for violations of NOMs. Individuals are entitled to file complaints against the providers of a service or manufacturers of a product. PROFECO, non-profit associations and a common representative of a group of at least 30 members can now pursue class actions. The federal procedural laws have been amended to allow class actions before the federal courts.

The Federal Economic Competition Commission (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 the conclusion of the investigation stage, COFECE will determine 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 is not as common as in other jurisdictions, such as the United States. Additionally, COFECE can file criminal complaints.

Individuals can file patent infringement and unfair competition claims with IMPI, which is entitled to implement preliminary measures while investigating the infringement, which includes:

- the recall of infringing goods, or preventing their circulation;
- infringing articles to be withdrawn from circulation, including tools used in the manufacture, production or obtaining of infringing articles;
- the alleged transgressor or third parties to suspend or cease all acts that violate the law; and
- suspension of services or closure of an establishment, when other measures are insufficient to prevent or avoid a violation of rights protected by law.

On 1 July 2020, and as a result of the entry into force of the United States–Mexico–Canada Agreement (USMCA), which replaced the North American Free Trade Agreement (NAFTA), the new Federal Law for Protection of the Industrial Property (the IP Law), was enacted. The new IP Law came into force on 5 November 2020. The current system requires parties to first obtain a final declaration of infringement from IMPI before requesting compensation in the civil courts. The new IP Law offers two new options to file a claim for patent infringement:

- File a civil action directly with the civil courts. This gives the civil courts the authority to resolve disputes in accordance with the IP Law. However, if the validity of the IP right is challenged, the civil procedure will be suspended until the IMPI decides on the invalidity action.
- File an infringement action with the IMPI and request the determination of damages in a special incidental proceeding once the infringement is declared. The decision on damages can then be enforced by the civil courts. However, according to the transitory provisions of the new law, this option will only be available when the IMPI is ready to implement it. There are currently no clear indications of when this may occur.

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

Patent holders can enforce border measures and the remedies provided by the 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 products.

Law stated - 01 July 2022

Sanctions

What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

COFEPRIS can initiate ex officio legal proceedings to sanction non-compliance. Ultimately, these legal proceedings can result in the revocation of the marketing authorisation. It is also entitled to implement measures on behalf of public health, such as the seizure of products and ordering the partial or total suspension of activities, services or adverts.

Under certain conditions, COFEPRIS has statutory authority to revoke any manufacturing approval or impose sanctions, ranging from economic fines to closure of the establishment. The imposition of administrative sanctions does not exclude civil and criminal liability.

COFEPRIS has broad jurisdiction to seize counterfeit or illegal medicines. The General Health Law classifies the manufacturing and sale of counterfeit or falsified medicine as a crime. In addition, COFEPRIS commonly enters into collaboration agreements with the FGR and the Customs Office in order to investigate and prevent counterfeit and illegal medicines.

COFEPRIS can make on-site inspection visits to manufacturing, distribution or storage facilities.

In coordination with COFEPRIS, the FGR is entitled to investigate and prevent the commercialisation of illegal medicines and also to implement measures on behalf of public health, such as the seizure of products.

COFEPRIS has a permanent pharmacovigilance programme. Under the Health Law Regulations and NOMs, COFEPRIS's monitoring is focused, among other things, on the following:

- ensuring compliance with good manufacturing practices and standard operating procedures;
- ensuring that activities performed do not exceed either authorised limits or differ from those authorised activities; and

- ensuring that companies perform validation analyses of their manufacturing processes and systems involved.

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- the alleged transgressor or third parties to suspend or cease all acts that violate the law; and
- suspension of services or closure of an establishment, when other measures are insufficient to prevent or avoid a violation of rights protected by law.

Law stated - 01 July 2022

Actions against employees

Can the authorities pursue actions against employees as well as the company itself?

Yes, the General Health Law includes a chapter (Title Eighteenth, Chapter VI) of specific offences in which both individuals and the responsible legal entity may be the subject of an enforcement action.

Law stated - 01 July 2022

Defences and appeals

What defences and appeals are available to drug and device company defendants in an enforcement action?

Company defendants are entitled to file a nonconformity recourse against the decisions issued by COFEPRIS within 15 working days following the issuance of the decision. Likewise, a decision issued by an administrative authority can be appealed through a review recourse before the corresponding authority, within 15 working days of the issuance of the decision. The decision issued in the review recourse can be challenged by means of a nullity trial before an administrative court (the Federal Court for Administrative Affairs) and lastly before an administrative Federal Circuit Court.

Law stated - 01 July 2022

Minimising exposure

What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Companies should focus on the diagnosis of the problem and its resolution through institutional proceedings, appealing adverse decisions when applicable.

Law stated - 01 July 2022

Recent enforcement activities

What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

In past years, COFEPRIS's enforcement activities have been focused on the seizure of illegal medicines, which has resulted in the closure of the establishment and suspension of activities.

Recently, COFEPRIS has been targeting companies that promote, through digital means, the sale of prescription drugs, both innovative medicines approved in our country but that are manufactured and acquired abroad and generics that have not been authorised in our country, and that are characterised by having prices considerably lower than those available in Mexico to individuals. Said acquisitions are made unlawfully through import permits for purported personal use and in many other cases they do not even register the same as it is a minimum quantity. In these cases, the affected companies have filed acciones populares claiming the illegal importation and commercialisation of their products and the generics on the ground of unfair competition, noncompliance with the regulatory requirements and, of course, the infringement of industrial property rights.

Law stated - 01 July 2022

Self-governing bodies

Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

The National Chamber of the Pharmaceutical Industry exercises institutional representation of the pharmaceutical industry before the Mexican authorities. Affiliate members are required to comply with the codes issued by the organisation.

Law stated - 01 July 2022

RELATIONSHIPS BETWEEN HEALTHCARE PROFESSIONALS AND SUPPLIERS

Relationship rules

What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

There are several bodies of law that refer in general terms to the relationship between the pharmaceutical industry and healthcare professionals, such as the Health Law and Health Law Regulations (including those that concern the sanitary control of activities, establishments, products and services).

Industry Codes of Practice complement these regulations. The Council of Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA) has issued the following self-regulatory instruments:

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

The latest versions of these Codes have been in force since 1 April 2013. Affiliate members of the National Chamber of

the Pharmaceutical Industry (CANIFARMA) are required to follow these Codes. CETIFARMA supervises members' and adherents' compliance.

Law stated - 01 July 2022

Enforcement

How are the rules enforced?

Scientific and educational events

The GPP Code states that the main purposes of congresses, lectures, symposia, meetings and other similar scientific or educational events sponsored, financed or supported by pharmaceutical companies or any other third party must be:

- scientific exchange;
- medical education; and
- information about medicines.

Whenever support for continuing education or independent educational programmes is being provided, the education of healthcare professionals should be encouraged, primarily to improve their knowledge of patient care. In each case, programmes must comply with the guidelines of the applicable laws. They must have strict policies that scientific content is sustained, if required, on clinical evidence. Also, most importantly, they must be accredited and certified by the corresponding academic authorities. Under no circumstances will support be offered in order to influence the decision-making process involved in prescribing medicines or buying, including, excluding or modifying official product catalogues.

Samples

According to the GPP Code, samples are provided directly, in fair amounts and without cost to healthcare professionals, so that they may get to know and be familiar with the products or to initiate treatment. According to article 49 of the Health Law Regulations concerning advertising, providing free samples of products does not require approval, provided that they meet the requirements of the approved medicinal product. These samples should be contained in a package with a smaller number of units than the approved product.

The GPP Code establishes guidelines for sampling. It prohibits members from offering or supplying samples with the aim of seeking or rewarding prescription practices. The Code also forbids any trade of samples. Members are required to have full and up-to-date control of their samples, including their manufacture, storage, delivery to regional coordinators or others, and provision to medical representatives and physicians. We always recommend that our clients have strict control of product samples as there have been cases of resale of said samples.

Gifts and donations

The GPP Code essentially states that companies must act responsibly regarding sponsorships and donations. No gifts of significant commercial value or incentives of any kind may be offered to healthcare professionals as an inducement to use, prescribe, purchase or recommend a specific product or influence the results of a clinical study. Similarly, no gifts, bonuses, pecuniary advantages, benefits in kind or any sort of incentive may be offered or promised to healthcare professionals, administrative staff or government employees involved in the cycle of prescription, purchase, distribution, dispensing and administration of medicines, except in the case of inexpensive promotional aids related to

the practice of medicine or pharmaceutical activities. The GPP Code delineates an inexpensive promotional aid as that one that does not exceed the equivalent of 10 times the minimum wage (around US$85.00).

Concerning healthcare professionals in government institutions, article 47 of the Federal Law of Responsibilities for Government Officers expressly forbids these officers from requesting, accepting or receiving any gifts or donations from persons whose commercial or industrial activities are directly linked, regulated or supervised by government officers.

Law stated - 01 July 2022

Reporting requirements

What are the reporting requirements on such financial relationships? Is the reported information publicly available?

The GPP Code establishes that collaboration between the pharmaceutical industry and patient organisations must have a written agreement in place that includes:

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

In these agreements, members must follow their applicable guidelines and codes of ethics and conduct, have transparent practices and use deontological instruments approved by CETIFARMA and CANIFARMA. The Code requires members to set forth criteria and procedures for the approval and implementation of these kinds of collaborations. Any other kind of sponsorship provided by social, governmental or private sector organisations should not be excluded.

Law stated - 01 July 2022

REGULATION OF HEALTHCARE DELIVERY

Authority powers

What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

The Ministry of Health and the governments of the states are in charge of monitoring health professionals when providing the following services:

- conducting sanitary evaluations and verification visits and, as a result, issuing an official report that states whether the subject of the investigation complied with laws, regulations and Official Mexican Standards (NOMs). In the case of non-compliance, the health authority in charge of the investigation will initiate the corresponding administrative proceeding; and
- applying sanctions and safety measures when appropriate and verifying compliance.

Physicians are also subject to liability for malpractice. Patients can opt between filing a civil action or requesting medical arbitration from the National Commission of Medical Arbitration (CONAMED). The latter is a quick alternative where a non-judicial solution is proposed. Decisions by CONAMED can be enforced through a judicial process.

Law stated - 01 July 2022

Investigation time frames

How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

The duration of the investigation varies depending on the complexity of the case. The establishment or site requiring an evaluation or verification visit is determined by any of the following:

- random selection;
- a previous contingency or health emergency;
- programmes determined by the health authority;
- a claim by a third party;
- the request of the owner; and
- any follow-ups to an administrative procedure initiated by the health authority.

Law stated - 01 July 2022

Access to investigation materials

What rights or access does the subject of an investigation have to the government investigation files and materials?

The subject of an investigation has full access to the files and materials, except for any information that has been expressly classified as confidential upon the request of the authority or another individual.

Law stated - 01 July 2022

Enforcement agencies

Through what proceedings do agencies enforce the rules?

Most agencies hold their own administrative proceedings while applying to a court later remains available. The Ministry of Health and the governments of the states are in charge of performing regular sanitary evaluations and verification visits to public and private institutions that, depending on the results, can lead to the application of sanctions and safety measures. The imposition of administrative sanctions does not exclude civil and criminal liability.

Law stated - 01 July 2022

Sanctions

What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

If the sanitary conditions of the establishment, raw materials, process, procedures or products present a significant risk to health or lack the essential requirements of the law and other applicable provisions, verifiers should take immediate security measures with the approval or consent of the health authority on which they depend. The competent health authorities may order the application of the following security measures:

- isolation;
- quarantine;
- personal observation;
- vaccination of persons;
- vaccination of animals;
- destroying or controlling insects or other vermin;
- the suspension of work or services;
- the suspension of advertising in health;
- the issue of advertising messages that warn of potential damage to health;
- the seizure and destruction of objects, products or substances;
- eviction from houses, buildings, facilities and any property in general; and
- other health measures as determined by the competent health authorities.

The sanitary authority has statutory powers to impose sanctions, ranging from economic fines to closure of the establishment. The imposition of administrative sanctions does not exclude civil and criminal liability.

Law stated - 01 July 2022

Defences and appeals

What defences and appeals are available to healthcare providers in an enforcement action?

Healthcare providers are entitled to file administrative, civil and criminal complaints against sanctions or adverse decisions. The National Commission of Medical Arbitration provides guidance and assistance to healthcare providers during the process of a complaint filed against them for medical negligence and during the medical arbitration proceeding.

Law stated - 01 July 2022

Minimising exposure

What strategies should healthcare providers adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Healthcare providers should focus on the diagnosis of the problem and its resolution through institutional proceedings, appealing adverse decisions when applicable.

Law stated - 01 July 2022

Recent enforcement activities

What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

Enforcement activity has been focused on the inspection of private clinics. This has resulted in the closure of establishments and suspension of activities due to a significant risk to health, the lack of essential requirements for the establishments' operation and uncertified medical personnel.

Law stated - 01 July 2022

Self-governing bodies

Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

Healthcare providers in Mexico are grouped and represented by different private associations depending on their specialisation and field of work.

Law stated - 01 July 2022

Remedies for poor performance

What remedies for poor performance does the government typically include in its contracts with healthcare providers?

Contracts for the acquisition of health supplies and health services provisions usually include the following sanctions:

- Penalties for delays in compliance with agreed dates of delivery or service provision, which shall not exceed the amount of the guarantee of compliance of the contract, and will be determined according to the goods or services not delivered or rendered on time.
- When a supplier totally or partially breaches any of the obligations expressly established in a contract, government entities can terminate the contract in advance without liability and without any judicial resolution.

Contracts for the acquisition of medicines or health supplies provide that the government institution may request that the supplier exchange goods with defects or the total devolution of the goods, where, after delivering the new batches, the same defect is detected.

The supplier of the goods is obliged to respond at its own risk regarding claims that failure or negligence on its part has caused problems for government institutions or third parties.

Law stated - 01 July 2022

PRIVATE ENFORCEMENT

Causes of action

What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

Besides civil and criminal actions, to enforce a healthcare regulation or law, citizens or other private bodies can file a constitutional action against a particular act or omission of the authority, grounding their legal standing in article 4 of the Mexican Constitution, which provides the human right of due access to healthcare.

Law stated - 01 July 2022

Framework for claims

What is the framework for claims of clinical negligence against healthcare providers?

Patients or relatives of patients who have received medical, public or private care that potentially caused them harm because of malpractice are entitled to file complaints against healthcare providers. The National Commission of Medical Arbitration (CONAMED) provides guidance and expert advice to patients and healthcare providers about their rights and obligations. It also receives and investigates cases related to irregularity or denial in providing justified or urgent medical services by public institutions.

Patients are entitled to file a complaint before CONAMED, in which case such authority will be a mediator between the patient and the healthcare provider with the purpose of achieving a settlement agreement. If this is not the case, the patient can choose between submitting to a medical arbitration proceeding before CONAMED or filing a civil action. Decisions issued by CONAMED may include:

- an order for the provision of adequate medical care; and
- an order that the patient receives reimbursement, compensatation or both.

Law stated - 01 July 2022

Seeking recourse

How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

Individuals are entitled to file complaints against the providers of a service or manufacturers of a product before the Federal Agency for the Protection of Consumers (PROFECO), on the grounds that the product of interest does not comply with the essential requirements provided by the applicable regulations and NOMs or the advertised characteristics and functionality. PROFECO, non-profit associations and a common representative of a group of at least 30 members can now pursue class actions. The federal procedural laws have been amended to allow class actions before the federal courts.

The Federal Economic Competition Commission (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 will determine 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 is not as common as in other jurisdictions, such as the United States. Additionally, COFECE can file criminal complaints.

Law stated - 01 July 2022

Compensation

Are there any compensation schemes in place?

There are no specific compensation schemes in place; however, the applicable laws aim to establish the bases and proceedings for recognising the right to compensation of those who suffered damages.

Law stated - 01 July 2022

Class and collective actions

Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

The federal procedural laws have been 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, apparently, there are no precedents of class actions for product liability.

In addition, there is an action available called accion popular , whereby any individual with or without proper legal standing can file a complaint before COFEPRIS, arguing and proving that there are certain health risks in a product in the market. However, the claimant's procedural rights are very limited, and these actions are intended to stop health risks, not to obtain compensation.

Law stated - 01 July 2022

Review

Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

Yes. Acts, omissions and decisions of both public and private institutions can be the subjects of administrative, civil and criminal complaints from interested parties before courts. Actions should be filed as soon as possible to duly attend to and repair the claimed act or omission. In these types of cases, the legal standing of the complainant is grounded in the human right of due access to health. In relevant cases, it has been decided that the state will always be responsible for appropriate health attention, even if the claimed act or omission derives from a private institution.

Law stated - 01 July 2022

Whistle-blowers

Are there any legal protections for whistle-blowers?

No, in Mexico we do not have a figure equivalent to a whistleblower. The Federal Law on the Administrative Responsibilities of Public Servants provides that public servants must inform their superiors in writing about any conclusive doubts that arise from the origin of the orders they receive that could constitute an infringement of any legal or administrative provision. However, the law fails to consider the protection that should be granted to the public servant, or the process that should be implemented in order to preserve the confidentiality of the denouncement.

Law stated - 01 July 2022

Does the country have a reward mechanism for whistle-blowers?

No.

Law stated - 01 July 2022

Are mechanisms allowing whistle-blowers to report infringements required?

Yes. The Ministry of Public Administration is the authority in charge of verifying that public servants act in accordance with the applicable laws during the exercise of their functions, and is the authority in charge of implementing the corresponding sanctions.

Law stated - 01 July 2022

CROSS-BORDER ENFORCEMENT AND EXTRATERRITORIALITY

Cooperation with foreign counterparts

Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

Yes. In accordance with the Health Law, its Regulations and the international treaties subscribed by Mexico, the Ministry of Health is in charge of institutional relationships with the health dependencies of other governments and international organisations in order to facilitate the provision of technical advice, information and assistance in everything related to sanitary regulation, control and health promotion.

Additionally, the Ministry of Health notifies the World Health Organization of all the measures it has taken, temporarily or permanently, in international health, as well as of any case that is of interest in the surveillance of the diseases listed in the International Health Regulations.

Law stated - 01 July 2022

Triggering investigations

In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

When the Ministry of Health receives an international communication, alert or requirement on health matters, in coordination with the corresponding administrative entities (ie, the Ministry of Foreign Affairs and the Ministry of the Interior) it will conduct inspection visits in order to verify compliance or noncompliance with international sanitation rules, which could lead to an administrative procedure in accordance with the applicable laws.

Law stated - 01 July 2022

Pursuing foreign entities for infringement

In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

Mexican healthcare laws, regulations and official standards are equally enforceable against foreign companies and nationals.

Law stated - 01 July 2022

UPDATE AND TRENDS

Key developments of the past year

What are the authorities' enforcement priorities likely to be in the coming year? Are there any noteworthy cases pending? Are there any current developments or emerging policy or enforcement trends that should be noted?

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 the Industrial Property (the IP Law), was enacted. The new IP Law represented an important legislative change as it aimed to match the domestic law with the standards set by the new trade and cooperation agreements signed by Mexico in recent years. It came into force on 5 November 2020. Due to this, amendments to the health laws are expected.

Although in the past, the Mexican government was in charge of the acquisition of medicines for public health institutions, on 31 July 2020, the Mexican government and the United Nations Office for Project Services (UNOPS) executed an agreement between the Institute of Health for the Welfare of the United Mexican States (INSABI) and UNOPS for the acquisition of medicines and medical supplies for the period 2021–2024, under the modality of an open international public tender for the consolidated purchase of medicines under the procurement policies and procedures of UNOPS; that is, the Mexican government transfers to UNOPS all the resources for such procurement and UNOPS is in charge of implementing, tendering and contracting said activities, as well as managing the respective contracts with third parties.

In connection with the above, at the end of January 2020, the Ministry of Health published an official administrative decree, establishing new relevant provisions on the applications for marketing authorisation and importation of medicines into Mexico. The Ministry of Health confirmed that it recognises various foreign regulatory health authorities' requirements and evaluation procedures to authorise the sale, distribution and use of allopathic and biological medicines in their respective countries as being equivalent to those of the quality, safety and efficacy standards of the General Health Law, the Health Supplies Regulation and other applicable provisions that products must meet to be granted marketing authorisation in Mexico by the Federal Commission for Protection Against Sanitary Risks (COFEPRIS).

Additionally, the Mexican authorities are being authorised to import medicines that do not have a marketing authorisation in Mexico, provided said importing is carried out due to the necessity of guaranteeing the supply of medicines for the correct and timely provision of health services to the population.

On 18 November 2020, the Ministry of Health issued another decree ordering COFEPRIS to resolve applications for marketing authorisation of medicines and health supplies coming from abroad within just five working days, stating that applicants, importers and marketers are not exempt from complying with the applicable provisions to maintain marketing authorisation and that COFEPRIS must still carry out the necessary actions to guarantee the safety, quality and efficacy of the medicines.

On 22 June 2021, the Ministry of Health published a Decree amending the Equivalence Decree published in January 2020. The Decree of 22 June 2021 included the following amendments:

- The inclusion of medical devices as health supplies that can be imported without marketing authorisation.
- New regulatory agencies for medical devices have been added.
- Contrary to the Decree of January 2020, the Decree of 22 June 2021 expressly mentions biosimilar drugs as health supplies that can be imported without marketing authorisation.
- In compliance with the recent amendments to the Health Law Regulation, the Decree of 22 June 2021 allows the submission of documentation in English, without the need for providing a translation into Spanish.

- The deadline to comply with the requirement to request corresponding marketing authorisation after importation was extended from five to 10 days.
- The deadline for COFEPRIS to respond to an approval application was reduced from 60 to 45 days.
- Some requirements regarding the information to be submitted as part of the eventual marketing authorisation application, such as the quality data (chemical, pharmaceutical and biological) and non-clinical and clinical data, have been reduced.

In addition, Section IV of the Technical Annex of the Decree of 22 June 2021 included changes and inclusions, such as additional details on the approval process, which was not entirely described in the previous Decree.

Since its certification as the first National Regulatory Authority for Medicines with Level IV in Latin America before the PanAmerican Health Organization, and its recognition of the World Health Organization, COFEPRIS is carrying out the corresponding steps to improve the efficiency of the regulation of medicines, encourage the recognition of other jurisdictions' regulatory decisions, and to formulate and implement strategies to strengthen its regulatory system.

Law stated - 01 July 2022

Jurisdictions

France	LexCase
Japan	Mori Hamada & Matsumoto
Malaysia	Raja, Darryl & Loh
Mexico	OLIVARES
Portugal	Morais Leitão, Galvão Teles, Soares da Silva & Associados
USA	Mintz