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Medicinal product regulation and product liability in Mexico: overview

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REGULATORY OVERVIEW

1. What are the main legislation and regulatory authorities for pharmaceuticals in your jurisdiction?

Legislation

The main legislation for pharmaceuticals is the:

- General Health Law (*Ley General de Salud*).
- General Health Law Regulations (*Reglamentos de la Ley General de Salud*).
- Health Supplies Regulation (*Reglamento de Insumos para la Salud*).
- Official Mexican Standards (*Normas Oficiales Mexicanas*) (NOMs)).
- Mexican Pharmacopoeia.

Regulatory authorities

The regulatory authorities in this field are the:

- Federal Commission for Protection against Sanitary Risk (*Comisión Federal para la Protección contra Riesgos Sanitarios*) (COFEPRIS).
- General Health Council.

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 to 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 its own legal personality and assets. COFEPRIS is now under the authority of the Undersecretary for Prevention and Promotion of Health.

Under the General Health Law, COFEPRIS is responsible for:

- The sanitary regulation, surveillance and control of public social security institutions and private health care institutions.
- The sanitary control of medical 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, and healing and hygiene products.
- Preparing and issuing NOMs relating to health facilities, products and services.
- Evaluating, issuing and revoking sanitary authorisations.
- Exercising control and sanitary surveillance of pharmaceuticals and other health products.
- The 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.
- Imposing sanctions and implementing security measures.

The General Health Council is an agency controlled by the Executive and funded by the federal government which 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.
- Preparing the Guidelines for Interchangeability Tests of medicines that are submitted to COFEPRIS for the granting of marketing authorisations of generics.

2. Briefly outline any additional or alternative regulation of large molecule (biological) medicines and discuss how combination products and gene therapies are classified and regulated in your jurisdiction.

Both biologics and combination products must have marketing authorisation from COFEPRIS. Roughly, biologics are classified as:

- Biologics of reference (usually innovators).
- Biocomparables, a term used instead of biosimilars, in view of social context issues with the term "similars" in Spanish (*similares*).

Given their particular features, combination products can be classified as either drugs (drug/biologic) and/or medical devices (drug/device). Requirements and application time frames differ in each case. A combination product may require separate drug or biologic and medical device approvals (*see Question 3 and Question 9*).

There are no specific regulations on gene therapies. These are currently regulated by the provisions applicable to biological drugs.

3. Briefly outline how medical devices and diagnostics are regulated in your jurisdiction. Is there any specific regulation of medical software, health care IT, e-health (such as mobile health apps), or laboratory diagnostic testing kits?

The primary legislation for medical devices and diagnostics is the General Health Law, its regulations and the NOM for good manufacturing practices regarding medical devices (NOM-241-SSA1-2012).

Depending on their use, medical devices are classified into:

- Medical equipment.
- Prosthetics, orthotics and functional supports.
- Diagnostic agents.
- Dental supplies.
- Surgical and healing materials.
- Hygiene products.

(*Article 262, General Health Law.*)

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

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

There are no specific regulations on medical software, health care IT, e-health or laboratory diagnostic testing kits. Due to the current gap in legislation, COFEPRIS has implemented a process to review these types of products on a case-by-case basis.

PRICING, GOVERNMENT FUNDING AND REIMBURSEMENT

4. What is the structure of the national health care system, and how is it funded? Explain briefly how medicines are introduced into that system.

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

The public sector comprises of:

- Social security institutions exclusively directed to formal workers, which are funded by contributions from the federal government, employers and employees, such as:
  - 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 force; and
  - PEMEX Medical Services, for Mexican petroleum workers.
- Public institutions exclusively directed to attend people not covered by social security, such as the Instituto de Salud para el Bienestar (INSABI), which is 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 usually 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.

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

Social security institutions, such as 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, such as INSABI, aim to deliver free medical care and medicines, although patients may be required to contribute personally under certain conditions. To date, there are no reports indicating that INSABI users are being charged for medication.

5. How are the prices of medicinal products regulated?

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. 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.

In 2008, the government created the Committee for the Negotiation of Drug Prices (CNDP) to:

- Support public acquisitions through a process of transparent negotiation between public insurers and pharmaceutical companies.
- Evaluate cost-benefits of new medicines and therapies in view of prices and other comparable products in the market.

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

6. When is the cost of a medicinal product funded by the government or reimbursed? How is a pharmacist compensated for dispensing services?

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 CNDP analyses the:

- Effectiveness of the products and relevant therapeutic alternatives.
- 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 this 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.

CLINICAL TRIALS

7. Outline the regulation of clinical trials.

Legislation and regulatory authorities

The main legislation for clinical trials is the:

- Health Law Regulations for Health Research (*Reglamento de la Ley General de Salud en Materia de Investigación para la Salud*) (RLGSMIS).
- NOM for Health Research in Human Beings (NOM-012-SSA3-2012).

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

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

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

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

Authorisations

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

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

Consent

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

Trial pre-conditions

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

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

Procedural requirements

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

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

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

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

- Good manufacturing practices for Active ingredients (NOM-164-SSA1-2015).

Sponsors and investigators must also comply with privacy and data protection laws (*see Question 17*).

Transparency and reporting requirements

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

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

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

MANUFACTURING AND DISTRIBUTION

8. What is the authorisation process for manufacturing and distributing medicinal products?

Application

Companies manufacturing and/or distributing medicinal products must obtain an authorisation from COFEPRIS.

COFEPRIS can also issue health permits for the temporary distribution of drugs for strategic purposes.

Conditions

The requirements for manufacturing approval are set out mainly in the General Health Law, its regulations and NOMs setting good manufacturing practices for medicinal products (NOM-059-SSA1-2015) and health requirements for manufacturing (NOM-176-SSA1-1998). They regulate and provide guidelines and standards essentially for:

- Workforce conditions in the manufacturing facilities (including, for example, responsibilities, uniforms, and medical examinations).
- Legal and technical documentation.
- Facility requirements.
- Manufacturing, validity and quality controls and protocols.
- Standard operation procedure.
- Biosafety measures.
- Packaging.
- Equipment.
- Destruction and elimination of waste.

Foreign applicants

To hold an authorisation, applicants must have either an:

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

(*Article 168, Health Law Regulations.*)

Key stages and timing

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

Fee

Government fees for analysing a manufacturing approval application are about USD5,000.

Authorisations, variations, and renewals

Manufacturing approvals are granted without a specific expiration date. However, any modification of the list of manufactured products or change of address must be approved by COFEPRIS.

COFEPRIS can revoke sanitary authorisations in the following cases:

- The products or activities covered by the authorisation pose a risk of harm to human health.
- The exercise of the authorised activity exceeds the limitations set in the authorisation.
- The authorisation is used for different purposes.
- Non-compliance with the Health Law or Regulations.
- 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.
- The applicant provided false information or documents.
- Reports provided by authorised third parties are false.
- The products no longer possess the attributes or characteristics under which they were authorised or lose their preventive or therapeutic properties.

Monitoring compliance and imposing penalties

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 can carry out on-site inspection visits of manufacturing, distribution or storage facilities.

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

- Seizure of products.
- Ordering partial or total suspension of activities, services or adverts.
- Under certain conditions, revoke any manufacturing approval and/or impose sanctions, ranging from a fine of up to 16,000 times the minimum wage (about USD64,000) to closure of the establishment.

The imposition of administrative sanctions does not exclude civil and criminal liability. Affected parties can appeal decisions of COFEPRIS through the relevant administrative or judicial mechanisms.

MARKETING
Authorisation and abridged procedure

9. What is the authorisation process for marketing medicinal products?

Application

Manufacturers must obtain a marketing authorisation from COFEPRIS to sell any medicinal product. Requirements and time frames vary among new molecules, biologics, and follow-on products. There is a NOM compiling the requirements for granting marketing authorisations for medicinal products (NOM-257-SSA1-2014). In addition, there is a NOM about the specifications of stability test (NOM-073-SSA1-2015). This NOM specifically addresses the test for stability to be carried out on drugs in Mexico (Climate Zone II subtropical with possible high humidity according to the OMS classification).

New molecules. Essentially, applicants for marketing authorisations must prove safety and efficacy of their products through standard clinical trials, according to the rules set out in the General Health Law, its regulations and NOMs of good manufacturing of medicines and active ingredients.

Concurrently, applicants must request approval of their products as new molecules by the New Molecules Committee of COFEPRIS. A new molecule is:

- An active ingredient or drug not approved worldwide (new molecular entity).
- An active ingredient or drug already available in other countries but with limited clinical experience or disputed information, without approval in Mexico.
- A drug that is a non-marketed combination of two or more active ingredients.
- An active ingredient or drug already available in the market, but to be marketed for a new therapeutic indication.

(*Article 2, section XV, Health Law Regulations*.)

R&D companies can benefit from a special procedure for drugs to be approved for the first time in Mexico that have been previously approved by a regulatory authority abroad (*see Question 11*).

Generics. Applicants for marketing authorisations must prove that their products are bioequivalent to the innovator product. They must provide information concerning dissolution profiles or bioavailability studies regarding the reference product. COFEPRIS periodically issues a list of reference medicinal products.

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. Under the IP Regulations, the IMPI must publish every six months a gazette that includes patents covering allopathic medicines (*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 the IMPI included formulation patents in the *Linkage Gazette*, in accordance with a 2010 ruling of the Mexican Supreme Court (*Jurisprudence No. 2a./J.7/2010, Federal Judicial Gazette, No. XXXI, page 135*).

Use patents are only included in the *Linkage Gazette* by court orders, since the IMPI consider that they should not be included in the linkage system.

Under the linkage regulations, on the filing of the application, the applicant must either:

- Prove that it is the owner or licensee of the patent over the active ingredient of the product (recorded with the IMPI).
- State under oath that their application does not violate the list of products published in the *Linkage Gazette* and complies with patent law.

Biologics. Amendments to the legal framework to regulate the approval of biologics are recent and being tested. Applicants must prove quality, safety and efficacy of their products, under the General Health Law, its 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).

According to NOM-257-SSA1-2014, all biologicals drugs that were authorised before the legal reform that are still on the market must enter a regularisation process to comply with the new standard for biologics. NOM 257 emphasises that key points to ensure safety, efficacy and quality of biologics are already regulated in other NOMs currently in effect, such as those for clinical trials and pharmacoviligance. NOM 257 empowers the Assessment Subcommittee on Biotech Products (*Subcomité de Evaluación de Productos Biotecnológicos*) (SEPB) to:

- Assess technical and scientific data in connection with clinical trials, approval or renewal of innovator biologics or follow-on biologics (biocomparables).
- Issue opinions to classify 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.
- Renewal applications for biocomparables will require prior assessment by the SEPB to identify the product of reference in order for applicants to submit the corresponding tests.

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

Biocomparables (follow-ons). Applicants must submit clinical tests and, when appropriate, in-vitro tests, to prove safety, efficacy and quality of the product comparable (similar) to those of the reference biologic.

COFEPRIS published guidelines for biocomparability tests for Etanercept, Filgrastim, Infliximab, Insulin and its analogous Rituximab and Somatropin. These guidelines are only recommendations, since the corresponding evaluation is conducted on a case-by-case basis.

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

Although industry participants welcomed amendments to approve biologics, specific rules to approve follow-ons have caused debate. There is currently no indication of a data protection period for biologics. The recognition of data package exclusivity rights for biologics can only currently be achieved through litigation (*see Question 11*). Accordingly, there are also concerns regarding the accurate application by COFEPRIS of the linkage provisions.

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

Key stages and timing

The following approval time frames apply:

- 180 calendar days for medicines, including an active pharmaceutical ingredient (API)/therapeutic indication already approved in Mexico.
- 240 calendar days for medicines that are not approved in Mexico but are approved abroad.
- 180 calendar days for new drugs (a meeting with the New Molecules Committee is required).

(*Article 166, Health Law Regulations.*)

The approval time frame for biologics and biocomparables is 180 calendar days (*Articles 177 and 177bis 4, Health Law Regulations*).

These time frames can be reduced if the application has been pre-examined by a third health institution approved by COFEPRIS to do so.

However, on 29 October 2020, the Mexican President issued a Decree (*Acuerdo por el que se instruyen a la Secretaría de Salud y a la Comisión Federal para la Protección contra Riesgos Sanitarios las acciones que en el mismo se indican*) ordering the Ministry of Health and COFEPRIS to take the necessary measures to expedite the granting of marketing authorisations of foreign health supplies based on the Equivalence Decrees. These decrees simplify the requirements for the processing of applications for marketing authorisation of foreign health supplies.

In response, the Ministry of Health issued a decree, published on 18 November 2020 in the *Official Federal Gazette*, ordering COFEPRIS to process applications for marketing authorisation of foreign medicines within five working days (*Acuerdo por el que se establecen medidas administrativas para agilizar el trámite de registro sanitario de medicamentos y demás insumos para la salud que provengan del extranjero*). The decree provides that application that are not resolved within this period will automatically be presumed to have been granted (*afirmativa ficta*).

The five-day period will be suspended if COFEPRIS requires documents, clarification or additional information from the applicant. Applicants, importers and distributors are not exempted from the requirements to maintain the marketing authorisation.

Fee

Government fees for assessing marketing authorisation applications are about:

- For new molecules/biologics: USD6,600.
- For generics/biocomparables: USD3,396.

Exceptions

All medicines must have a marketing authorisation to be sold in Mexico (*General Health Law; Health Supplies Regulation*).

Authorisations, variations, and renewals

Marketing authorisations must be renewed every five years. Applicants must prove continued compliance with good manufacturing practices, safety and efficacy standards, pharmacovigilance, labelling standards and all other applicable provisions.

Any modification to the authorised product, including transfers of rights, must be notified and approved by COFEPRIS on a case-by-case basis.

COFEPRIS has the power to revoke authorisations in certain circumstances (*see Question 8, Authorisations, variations, and renewals*).

Monitoring compliance and imposing penalties

Under the NOM for good manufacturing practices of medicinal products (NOM-059-SSA1-2015), a marketing authorisation holder is responsible for the quality of the approved product. Therefore, when manufacturing through third parties, the marketing authorisation holder must supervise the manufacturing of the product and set liabilities and duties of each party involved in agreements. There must be a programme to recall and destroy products that do not meet quality standards (*see Question 20*).

COFEPRIS can request reports from marketing authorisation holders, and make on-site inspection visits of manufacturing, distribution or storage facilities, essentially 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.

COFEPRIS can impose strong administrative sanctions for breaches of the legal framework (*see Question 8, Monitoring compliance and imposing penalties*).

Protection of confidential information

Information disclosed in an application for marketing authorisation is treated as classified and confidential. The marketing authorisation application process only involves COFEPRIS and the applicant. Third parties are not entitled to intervene in the process or to access related information.

However, COFEPRIS publishes on its website a list of marketing authorisation applications received over certain periods of time, indicating the name of the active ingredient, the pharmaceutical form, the name of the applicant and the date of filing. However, this information is not reliable or consistently updated.

Release requirements

Advertisements of medicinal products must be approved by COFEPRIS (*Article 79, Health Law Regulations*) (*see Question 16, Restrictions*).

10. What pharmacovigilance obligations and other commitments apply after a company has obtained marketing authorisation? Are there further conditions on how the medicinal product is distributed and made accessible to patients?

Post-marketing commitments and pharmacovigilance obligations

The Health Law Regulations and the NOM for pharmacovigilance provide that marketing authorisation holders must:

- Report to the health authorities any adverse event, or suspected adverse reaction, that they are aware of and which may have been caused by their products manufactured or marketed in Mexico.

- Have standard operating procedures.
- Obtain any report of suspected adverse reactions from any possible source.
- Record, validate and identify any reports of misuse or abuse reported by health professionals or patients.
- Record and monitor any information related to any product used during lactation and pregnancy.
- Investigate serious and unexpected cases.
- Estimate the frequency of suspected adverse reactions and investigate the possible risk factors with intensive pharmacovigilance studies (at the request of the health authorities).
- Ensure the confidentiality of the identity of patients and reporters.
- Submit periodic reports on adverse reactions.

Other conditions

Marketing authorisation holders must ensure compliance with good manufacturing practices, stability, labelling standards and all other applicable provisions. There must be a programme to recall and destroy products that do not meet quality standards (*see Question 20*).

COFEPRIS can conduct on-site visits at any time to inspect premises and verify such compliance, and can initiate ex officio legal proceedings to sanction non-compliance. Ultimately, these legal proceedings can result in the revocation of the marketing authorisation.

11. Is there an abridged procedure for marketing authorisation? Which medicinal products can benefit from it and what conditions and procedure apply? What information can the applicant access and rely on?

Generics and data package exclusivity

Generics can be approved by providing dissolution profiles or bioavailability studies relating to the innovator product (*see Question 9*). Therefore, the General Health Law and its regulations allow indirect reliance on innovators' dossiers by approving generics through interchangeability tests, with no protection period for information provided by the innovator. Mexican domestic law is silent about data package exclusivity (DPE).

On 19 June 2012, COFEPRIS published an internal decree on its website, providing guidelines to observe and protect DPE in Mexico. According to the guidelines (and minimum requirements under NAFTA), a marketing authorisation holder benefits from a five-year exclusivity period during which their information cannot benefit or be used to support a third party application for registration of a generic drug.

These guidelines show that COFEPRIS has been willing to recognise and protect DPE by reference to NAFTA and TRIPS. The decree provides a higher degree of confidence for innovators. However, certain issues are not clear and require further clarification, for example whether:

- The guidelines apply to biological products.
- Other key approvals, such as new formulations and indications, are protected.
- The proceedings and measures to enforce and observe DPE rights, which are not covered by the decree.

The main issue is the legal force of the decree in view of the lack of domestic statutory law recognising DPE.

The United States-Mexico-Canada Agreement (USMCA), which replaces NAFTA, entered into force on 1 July 2020. This treaty will have an impact on DPE in Mexico. However, the current text of the USMCA only recognises a five-year DPE for new chemical molecules. The provisions on new formulations or combinations and biologics were removed by amendments to the agreement, which will lead to issues to obtain DPE in Mexico for these products.

Additionally, the Mexico-EU Trade Agreement requires at least six years of DPE for both small molecules and biologics, although the agreement has not yet fully entered into force.

DPE is not automatically conferred on approval; a petition must be filed with COFEPRIS and in many cases it is necessary to start proceedings to obtain a court decision ordering DPE.

Expedited procedure

As an incentive, R&D companies can benefit from a special procedure for drugs to be approved for the first time in Mexico, if they have been previously approved by:

- The European Medicines Agency.
- The US Drug and Food Administration.
- Health Canada.
- The Swiss Agency for Therapeutic Products (Swissmedic).
- The Therapeutic Goods Administration of Australia.

In 2012, COFEPRIS published new rules to set out this new procedure. This is essentially based on the dossier filed with the foreign regulatory agency, to reduce approval time frames by up to 60 working days.

In January 2020, the Ministry of Health published an administrative decree that sets out new rules for the expedited review of applications for marketing authorisation and the importation of medicines into Mexico. The key provisions are as follows:

- The decree confirms that the requirements and evaluation procedures applied by various foreign regulatory health authorities (*see above*) to allow the sale, distribution and use of allopathic and biological medicines are equivalent to those under the General Health Law, Health Supplies Regulation and other instruments to show the quality, safety and efficacy required to obtain a marketing authorisation in Mexico.
- Regardless of the country of origin of a medicine, COFEPRIS must process marketing authorisation applications submitted in accordance with the decree within 60 working days. If COFEPRIS fails to provide a response within that time frame, the application will be presumed to have been denied.
- The Mexican authorities are authorised to 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 five working days after importation of the product. COFEPRIS must then decide on the application within 60 working days.

On 29 October 2020, the Mexican President issued a Decree ordering the Ministry of Health and COFEPRIS to take the necessary measures to expedite the granting of marketing authorisations of foreign health supplies based on the Equivalence Decrees (*see Question 9, Key stages and timing*) (*Acuerdo por el que se instruyen a la Secretaría de Salud y a la Comisión Federal para la Protección contra Riesgos Sanitarios las acciones que en el mismo se indican*).

Third institutions approved for pre-examination

A pre-examination of formal and substantive requirements of applications for marketing authorisations by an authorised health institution reduces approval time frames.

12. Are foreign marketing authorisations recognised in your jurisdiction?

Foreign marketing authorisations are not valid in Mexico. However, COFEPRIS has set a special procedure for drugs to be approved for the first time in Mexico, if these are already approved by equivalent regulatory authorities abroad. Under this procedure, the requirements for approval of these agencies are recognised as equivalent to those in Mexico (*see Question 11, Expedited procedure*).

Parallel imports and cross-border trade in medicines

13. Are parallel imports of medicinal products into your jurisdiction allowed? What are the general requirements for imports of medicinal products into your jurisdiction? Are particular foreign markets or products favoured?

Any import of drugs, health products or raw material for drugs must be approved by COFEPRIS. Marketing authorisation in Mexico is required. In certain circumstances, for example, clinical trials and orphan drugs, import of a minimal quantity of products without a marketing authorisation can be approved. COFEPRIS can also grant permission for the importation of raw materials or 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 purposes of scientific research, registration or personal use.
- For laboratory tests.

Additionally, the Ministry of Health published an official administrative decree in January 2020 which allows Mexican authorities to 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 other cases, an importer must comply with the requirements for the filing of marketing authorisation applications, including those related to the linkage system and data exclusivity (*see Question 9 and Question 11*).

Patent holders can enforce border measures and the remedies provided by the Federal Law for the Protection of Industrial Property (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 Health Law and its 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.

RESTRICTIONS ON DEALINGS WITH HEALTH CARE PROFESSIONALS

14. 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 regulated or supervised by government officers (*Article 47, Federal Law on Responsibilities for Government Officers*).

Doctors working for the IMSS or ISSSTE are considered to be government officers and are therefore not allowed to receive gifts or donations from pharmaceutical companies when on duty and working in the name or facilities of the IMSS or ISSSTE.

The General Health Law and its 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, 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 the National Chamber of the Pharmaceutical Industry* (*Camara Nacional De La Industria Farmacéutica*) (CANIFARMA)). The corresponding sanctions range from a warning to a fine.

The CETIFARMA GPP Code provides that 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 get to know and become familiar with the products or to initiate a treatment.

Similarly, CANIFARMA's Code of Ethics 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.

SELLING RESTRICTIONS

15. What are the restrictions on selling medicinal products? Are there specific regulations for the sale of medicinal products on the internet, by e-mail and by mail order?

Under the Health Regulations, 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 different types of establishments. Pharmacies must obtain a sanitary authorisation from COFEPRIS certifying that the establishment complies with the current sanitary requirements for the commercialisation and dispensing of medicines and/or health supplies to preserve the safety, quality and efficacy of products until they reach patients.

ADVERTISING AND PROMOTION

16. What restrictions apply to the advertising and promotion of medicinal products and the provision of samples, and how are adverts and promotional activity regulated?

Legislation and regulatory authority

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 practices. CETIFARMA has issued the following self-regulatory codes:

- Code of Ethics and Transparency of the Pharmaceutical Industry.
- GPP Code.
- GPI Code.

The latest versions of these Codes have been in force since 1 April 2013. Affiliate members of CANIFARMA are required to comply with these codes. CETIFARMA supervises members' and adherents' compliance.

There are also opinions issued by the Advertising Council, which include 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 and the Industrial Property Law.

Restrictions

Advertisements of medicinal products must be approved by COFEPRIS (*Article 79, Health Law Regulations*). An application for approval must include all details of the proposed advertisement. Advertisements directed to health care professionals only need to be notified to COFEPRIS.

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, Health Law Regulations*). Advertisements must mention applicable precautions and contraindications (*Article 43, RLGSMP*).

Advertisements directed to 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, Health Law Regulations*).

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.

COFEPRIS can order the suspension of any advertising activity in breach of the law. The responsible party and the media channel must comply with such an order within 24 hours of issue.

COFEPRIS can issue warnings to companies to modify advertisements that are suspected to be in breach of the law. If 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 minimum wage (about USD60,952).

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

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, Health Law Regulations*).

Samples of prescription-only medicinal products cannot be given to the general public. Any sample of a medicinal product must not be given to minors. Samples must also contain the words "Not for sale".

See *Question 14* for more information on the provision of samples to health care professionals.

In addition, the sale of medical samples is a crime punishable by one to nine years' imprisonment and a fine of between USD81,746 and USD204,355 (*Article 464 ter, Health Law Regulations*).

CETIFARMA members must have full and up-to-date control of their samples, including their manufacture, storage, delivery to regional co-ordinators, and provision to medical representatives and physicians.

On June 2019, COFEPRIS issued a decree revoking the following guidelines on pharmaceutical advertising:

- Guidelines for the administrative simplification of digital advertising procedures and authorisations (2014).
- Guidelines establishing the criteria for the processing of advertising authorizations for medicines (2014).
- Guidelines establishing the criteria for the processing of advertising authorisations for medicines, homeopathic medicines and herbal remedies (2017).
- Guidelines establishing requirements applicable to publicity that promotes healthy habits to avoid a possible health risk (2017).
- Guidelines establishing the criteria for the processing of advertising authorisations for over-the-counter medicines, homeopathic medicines and herbal remedies (2017).

COFEPRIS stated that the revocation was due to the fact that the guidelines did not comply with the formality and publicity requirements set out in the General Law of Regulatory Improvement.

Internet advertising

Electronic advertising falls under the general rules for advertising in Article 2 of the RLGSMP. COFEPRIS is currently increasing its monitoring of internet adverts for medicinal products, which had been less stringent than those by television or radio.

DATA PRIVACY

17. Do privacy and data protection laws impact on pharmaceutical regulation in your jurisdiction?

The Personal Data Protection Law has an impact on pharmaceutical regulation, for example, in the case of clinical trials and pharmacovigilance.

The sponsor of a clinical trial is the data controller of participants' personal data under the:

- Federal Law for the Protection of Personal Data Held by Private Parties (*Ley Federal de Protección de Datos Personales en Posesión de Particulares*), for information collected, used and handled by a private party.
- Federal Law for the Protection of Personal Information Held by Public Entities (*Ley Federeal de Protección de Datos Personales en Posesión de Sujetos Obligados*), for information collected by authorities or public entities and organisations that are funded by the government.

Data controllers must comply with requirements relating to consent, quality, purpose, loyalty, proportionality, responsibility, security and confidentiality.

The Federal Law for the Protection of Personal Information Held by Public Entities and NOM-012-SSA3-2012 provide that research participants must be granted rights of access, rectification, cancellation and opposition rights, in line with the Personal Data Protection Law. Investigators and committees of the trial institution must protect personal data of participants at the research and publishing stages. Investigators must obtain informed valid consent from research participants.

Under the Health Law Regulation on Research for Health, public authorities must maintain the confidentiality of reports they receive from investigators. Investigators must ensure that reports do not identify research subjects and maintain the confidentiality of their personal information.

The NOM for pharmacovigilance (NOM-220-SSA1-2002) also recognises the protection of personal data of research participants and health care professionals submitting reports, by deferring this to the Personal Data Protection Law.

PACKAGING, LABELLING AND TRACKING

18. Outline the regulation of the packaging and labelling of medicinal products.

Legislation and regulatory authority

Packaging and labelling of medicinal products are regulated by the:

- General Health Law.
- Health Law Regulations.
- NOM 072-SSA1-2012 relating to the labelling of medicinal products.

COFEPRIS is responsible for enforcing provisions concerning the packaging and labelling of medicinal products.

Information requirements

The labelling of medicinal products must include the following information:

- Distinctive brand name.
- Generic name.
- Pharmaceutical form.
- Drug concentration.
- Formulation.
- Formula description.
- Dose.
- Mode of administration.
- Conservation and storage information.
- Precaution and warning legends, including risks in case of pregnancy.
- Marketing authorisation number.
- Batch number.
- Expiration date.
- Manufacturer's and, if applicable, distributor's information, including address.
- Content.
- Maximum retail price.
- For biological drugs, the specifications of the live organism that was used for the preparation of the medicinal product and the name of the disease for which it is indicated, according to the revised international nomenclature.

Serialisation

Batches must be identified in accordance with the applicable NOMs. Medicine containers must have closure systems that make it clear to the user that they have not been opened prior to purchase and that prevent accidental manipulation.

Other conditions

The information can be additionally stated in another language, provided it does not contradict the information in Spanish.

A Decree amending Article 26 of the Health Law Regulations sets out rules on the labelling of drugs for use in the public sector. The decree will enter into force on publication in the *Official Gazette of the Federation*. Generally, the decree provides that the primary and secondary packaging of a medicine destined for the public sector must include the words "sale prohibited" or "property of the Public Health Sector." The other general provisions regarding labelling otherwise apply.

PRODUCT SAFETY, QUALITY AND LIABILITY

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

Under the Health Law Regulations and NOMs, COFEPRIS's monitoring is focused, among other things, on the following:

- 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.

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 and/or held for marketing.

- Impose measures to prevent harm, such as seizure and orders to recall products and adverts.
- Impose fines of up to 16,000 times the minimum wage (around USD64,000).
- Revoke marketing authorisations and other approvals.

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

In co-ordination with COFEPRIS, the FGR can:

- Investigate and prevent the commercialisation of illegal medicines.
- Implement measures to protect public health, such as 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.

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 US. Additionally, COFECE can file criminal complaints.

20. Are there any mandatory requirements relating to medicinal product safety?

The NOM for good manufacturing practices of medicinal products (NOM-059-SSA1-2015) requires marketing authorisation holders to implement an appropriate and efficient recall programme for products that do not meet quality standards. This programme must include activities planned for recalling products in a rapid and effective manner, storage, and a list of authorities to be notified according to the distribution of the product. Marketing authorisation holders must report to COFEPRIS any product recall decision, providing details of these products, causes and a store centre.

In addition, COFEPRIS has a permanent pharmacovigilance programme, based on notification of possible adverse effects by:

- Doctors and physicians, on a voluntary basis.
- Persons who conduct clinical trials, who must submit periodical reports (*see Question 7*).
- Pharmaceutical companies, which must submit periodical safety reports every six months or year after the granting of the marketing authorisation (*see Question 10*).

21. 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) has provisions regarding liability. The Federal Consumer Protection Law allows class actions (*see Question 24*).

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.

22. Who is potentially liable for defective medicinal products?

All persons involved in selling and/or distributing medicinal products can be liable in civil actions for harm derived from defective medicinal products. In this regard, the NOM for good manufacturing practices of medicinal products (NOM-059-SSA1-2015) states that the marketing authorisation holder is responsible for the quality of the approved product. This NOM provides that, 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.

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

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

Available defences include:

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

Liability for defective medicinal products cannot be excluded.

24. 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 of class actions for product liability.

In addition, through a specific action called "*accion popular*", 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 very limited, and these actions are intended to remove a health risk, not to obtain compensation.

25. 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 public precedents.

LOCAL ESTABLISHMENT, REPRESENTATION AND RESIDENCY REQUIREMENTS

26. What local requirements apply to businesses and individuals (such as the person responsible for releasing a product onto the market) acting within or in relation to the jurisdiction?

To obtain a marketing authorisation for a drug manufactured abroad, the applicant must appoint a legal representative domiciled in Mexico.

REFORM

27. Are there proposals for reform and when are they likely to come into force?

The United States-Mexico-Canada Agreement (USMCA), which replaces NAFTA, entered into force on 1 July 2020. The USMCA includes provisions related to pharmaceuticals and regulatory matters.

On 8 March 2018, 11 countries signed a free trade agreement formerly known as the Trans-Pacific Partnership (TPP), which has been renamed the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). The signing members are Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam. The CPTPP includes several provisions that will certainly have a positive impact in terms of enforcement and litigation.

Following the revocation of all relevant guidelines on pharmaceutical advertising (*see Question 16*), COFEPRIS will need to reassess the content of the applicable regulations, which are expected to be supplemented by both industry associations and regulatory authorities.

The Mexican Supreme Court of Justice approved a decision ordering the Ministry of Health and COFEPRIS to regulate the medicinal use of cannabis. On 12 January 2021, the General Health Law Regulation on Sanitary Control for the Production, Research and Medicinal Use of Cannabis and its Pharmacological Derivatives (Cannabis Regulation) was published in the *Federal Official Gazette*. The Cannabis Regulation entered into force on 13 January 2021. It is intended to regulate, promote, and monitor the use of cannabis and its derivatives for medicinal use. The Cannabis Regulation includes provisions on primary production, research, manufacturing of pharmacological derivatives and medicines, distribution, advertising, prescription, and commercialisation.

The new Federal Law for the Protection of Industrial Property (IP Law) was enacted on 1 July 2020, as a result of the entry into force of the USMCA. The new IP Law aims to align domestic IP law with the standards set by trade and co-operation agreements signed by Mexico in recent years. The new IP Law came into force on 5 November 2020.

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

Recent transactions

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

Languages. English, Spanish

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

Publications

- *Imports shine the spotlight on experimental use defence, 2013, Intellectual Asset Management magazine issue, IP Media Group.*
- *Maximising IP rights in the life sciences industry, 2012, Intellectual Asset Management magazine issue 54, IP Media Group.*
- *New Regulations Pending, 2011 edition of Life Sciences, Mexico Chapter: Biologic Drugs, Managing Intellectual Property Magazine.*
- *Supreme Court upholds the worth of formulation patents, 2010, IAM Life Sciences 250, Formulation patents in Mexico.*
- *Pharmaceutical trademarks, World Trademark Review, Country correspondent: Mexico, October/November 2009.*

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Professional qualifications. Bachelor Degree, National Autonomous University of Mexico (UNAM), 1995

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

Recent transactions

- Successfully litigated to correct the term of pharmaceutical patents granted under transitory Article 12 of the Law for the Promotion and Protection of Industrial Property.
- Obtained a declaration of infringement of patents protecting active ingredients, medical uses, pharmaceutical formulations and production processes of biotechnological drugs, to maintain market exclusivity for patent holders.
- Obtained the nullity of marketing authorisations of generic medicines for violating the Mexican linkage system on behalf of holders of patents protecting active ingredients, pharmaceutical formulations and medical uses.
- Successfully representing clients in civil actions for damages for infringements of industrial property rights.
- Acted in the action for unconstitutionality of Article 167bis of the Health Supplies Regulation, on the ground that it does not provide the right to patent holders to be heard during the prosecution of marketing authorisations.

Languages. English, Spanish

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

Publications

- *Preliminary injunctions and infringement actions, Intellectual Property and Pharmaceutical Research, January 2012.*
- *Approval of follow-on biologics in Mexico, Intellectual Asset Management, July/August 2011.*
- *Reform of preliminary injunctions, Managing Intellectual Property, October 2010.*
- *Trademark enforcement, World Trademark Review, June/July 2009.*
- *Composite trademarks, Managing Intellectual Property, January 2009.*
- *COFEPRIS ordered to cancel marketing authorisation, Managing Intellectual Property, March 2015.*

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

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

Recent transactions

- Obtained the enforcement of an unpublished patent against the grant of a marketing authorisation for a generic medicine.
- Participated in the first case in Mexico leading to the revocation of a marketing authorisation of a pharmaceutical product for violation of a formulation patent listed in the *Linkage Gazette*.
- Participated in the first case in Mexico enforcing a use patent in a public tender.

Languages. English, Spanish

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

Publications

- *Damages Claims Under the New IP Law in Mexico, Mexico Business, 2020.*
- *Infringement of second medical use patents, Managing Intellectual Property, 2015.*