Medicinal product regulation and product liability in Mexico: overview

REGULATORY OVERVIEW

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

Legislation

The primary legislation for medical products is:

- The General Health Law (*Ley General de Salud*) (General Health Law).
- The Health Law Regulations (*Reglamento de Insumos para la Salud*).
- The Official Mexican Norms (*Normas Oficiales Mexicanas*) (NOMs).
- Mexican Pharmacopoeia.

Regulatory authorities

The regulatory authority in this field is the Federal Commission for Protection against Sanitary Risk (*Comisión Federal para la Protección contra Riesgos Sanitarios*) (COFEPRIS) (*www.cofepris.gob.mx*) which is an administrative agency

of the Ministry of Health (*Secretaria de Salud*).

Briefly outline how biologicals and combination products are regulated in your jurisdiction.

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

- Biologics of reference (usually innovators).

- Biocomparables, a term used instead of biosimilars, in view of social context issues with the term in Spanish (*similares*).

Requirements and application timeframes differ in each case.

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

Briefly outline how medical devices and diagnostics are regulated in your jurisdiction. Is there any specific regulation of health IT issues and mobile medical applications?

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).

According to their use, Article 262 of the General Health Law classifies medical

devices into:

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

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 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 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 future by particular regulations, especially if they represent health risks.

As an incentive, applicants can benefit from a special procedure for certain devices to be approved in Mexico, which have been previously approved by the:

- US Drug and Food Administration.

- Health Canada.

This procedure is essentially based on the dossier filed with the foreign regulatory agency, to reduce approval timeframes by up to 30 working days. Industry participants have welcomed these new rules, but they are still being tested.

Pricing and state funding

What is the structure of the national healthcare system, and how is it funded?

The Ministry of Health:

- Governs the health system in Mexico.

- Manages social security and health insurance.

- Determines the National Formulary for the list of basic drugs (*Cuadro Básico de Insumos para la Salud*).

The Mexican healthcare system comprises public (social security institutions) and private insurers, out-of-pocket payments and informal arrangements.

The major public segments of the Mexican healthcare system are:

- The Mexican Institute of Social Security (*Instituto Mexicano del Seguro Social*) (IMSS). This represents 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).

- The *Seguro Popular*. This is a programme created in 2004 as part of a strategic reform to the General Health Law. It provides a public insurance scheme for those not covered by social security and other formal

arrangements. The *Seguro Popular* was created to cover people with lower incomes. The Federal Government pays 70% of the annual family premium, states provide 20% and patients provide 10%.

- Other social security institutes for particular sectors, for example for members of the military and Mexican Navy Force (*Instituto de Seguridad Social para las Fuerzas Armadas Mexicanas ISSFAM and Secretaria de Marina Armada de México SEMAR*), and for Mexican petroleum workers (PEMEX Medical Services).

Private health insurance generally covers professional, executive and higher levels of the private sector. Enrolment in private health insurance has increased considerably over the last five years.

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

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, overseen by the Ministry of Economy. Pharmaceutical companies' participation is voluntary. Under the price control 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.

When is the cost of a medicinal product funded by the state or reimbursed? How is the pharmacist compensated for his dispensing services?

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

For direct purchasing of patented products, CNDP analyses the effectiveness of the drugs and relevant therapeutic alternatives, and the feasibility and implications of an eventual substitution with equivalent medicines. Also, CNDP conducts an economic evaluation of the cost-effectiveness of patented medicines compared with those potential substitutes.

For ISSSTE, a prescribed medicinal product can be dispensed in a private drug store registered with this public insurer, provided that this is not available within ISSSTE facilities and under certain conditions. 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

Outline the regulation of clinical trials.

Legislation and regulatory authorities

The primary 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) and the 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.

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. Essentially, the main requirements for an application for authorisation from COFEPRIS are:

- 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.

- Preclinical 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 his responsibilities, and data from both him and his staff.

Medical assistance and financial indemnification for damage caused by the clinical trial must be provided to research participants.

Consent

Investigators have to collect informed consent from research participants in a formal written document, also signed by two witnesses. Basically, the validity requirements for 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 keep the right to give up the research anytime. Investigators must ensure post care for them, until it is clarified that there are no damages derived from the research.

Trial pre-conditions

Preclinical data must be collected to justify whether clinical trials can be

conducted. The RLGMIS 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 RLGMIS and the NOM for Health Research in Human Beings provide 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 for the Health Authorities must be compiled. Accordingly, 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).

- Active ingredients (NOM-164-SSA1-2015).

Manufacturing

What is the authorisation process for manufacturing medicinal products?

Application

Companies manufacturing medicinal products must obtain a manufacturing licence/approval (*licencia sanitaria*) from COFEPRIS.

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 instance, responsibilities, uniforms, and medical examinations).
- Legal and technical documentation.
- Facility requirements.
- Manufacturing, validity and quality controls and protocols.
- Standard operation procedure.
- Biosafety measures.
- Destruction and elimination of waste.

Foreign applicants

To hold a marketing authorisation, applicants must have either (*Article 168, Health Law Regulations*):

- An approval from COFEPRIS for a manufacturing facility or laboratory for medicines or biologic products for human use in Mexico.

- An equivalent approval (a licence, certificate or other permit document) for any of these facilities abroad from the competent authority in the country of origin.

Key stages and timing

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

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

Fee

Government fees for analysing a manufacturing approval application are around US$3,000.

Period of authorisation 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.

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 nor differ from those authorised activities.

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

COFEPRIS is entitled to implement measures on behalf of public health, such as:

- Seizure of products.

- Ordering partial or total suspension of activities, services or adverts.

Under certain conditions, COFEPRIS has statutory authority to revoke any manufacturing approval and/or impose sanctions, ranging from a fine of up to 16,000 times the minimum wage (about US$60,952), to closure of the establishment.

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

Marketing

Authorisation and abridged procedure

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 timeframes vary among new molecules, biologics, and follow-on products. A NOM compiling the requirements for granting marketing authorisations for medicinal products (NOM-257-SSA1-2014). In addition, the specifications of stability test (NOM-073-SSA1-2015)) specifically addressed 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 by the General Health Law, its regulations and NOMs of good manufacturing of medicines and active ingredients.

Concurrently, they have to request approval of their products as new molecules by the New Molecules Committee of COFEPRIS. A new molecule is (*Article 2, section XV Health Law Regulations*):

- 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 which 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.

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

Generics. Applicants for marketing authorisations have to prove basically 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 list of reference 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 (*see Question 11*).

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 IP Regulations, 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*).

The use patents are included in the Linkage Gazette by court orders, since IMPI consider 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 it is the owner or licensee of the patent of the active ingredient of the product (recorded with the 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. Applicants have to 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 the recent NOM-257-SS1-2014 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 Mexican Official Standard Rules 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*, known by its initials in Spanish as 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 characterise biologics as innovators, reference products or biocomparables.

NOM 257 provides transitional provisions for the renewal of those marketing authorisations of biologics granted before the amendments to the Health Law Regulations for Biologics issued back 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 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. 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 safety, efficacy and quality of this 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 case by case.

The pre-clinical and clinical test used by an applicant for a biocomparable must use the corresponding reference biologic to perform comparative and physic-chemical studies. For this, the applicant must have to submit essentially:

- 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 both the follow-on and the reference biologic.

- Pharmacodynamics test reports.

- Comparative efficacy and safety clinical test to show similarity between both 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. They 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 NOM compiling requirements for granting marketing authorisations includes orphan drugs.

Key stages and timing

Article 166 of the Health Law Regulations sets out the following approval timeframes:

- 180 calendar days for medicines, including an active pharmaceutical ingredient (API)/therapeutic indication already approved in Mexico.

- 240 calendar days for medicines not approved in Mexico but which are approved abroad.

- 180 calendar days for new drugs (a meeting with the New Molecules Committee is required).

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

These timeframes may vary in practice, but can be reduced if the application has been pre-examined by a third health institution approved by COFEPRIS to do so.

Fee

Government fees for analysing marketing authorisation applications are around:

- For new molecules/biologics: US$6,00.
- Generics/biocomparables: US$3,396.

Period of authorisation and renewals

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

Monitoring compliance and imposing penalties

According to 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 has to supervise the manufacturing of the product and establish in agreements liabilities and duties of each party involved. 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 in the 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*).

What commitments and pharmacovigilance obligations apply after a company has obtained marketing authorisation? Are there further conditions concerning how the drug is distributed and accessible to patients?

Post-marketing commitments and pharmacovigilance obligations

The Health Law Regulations and the NOM for pharmacovigilance establish that marketing authorisation holders basically 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.

- Receive 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.

Holders of marketing authorisations must submit reports periodically.

Other conditions

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

COFEPRIS is empowered to make 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.

Which medicinal products can benefit from the abridged procedure for marketing authorisation and what conditions and procedure apply? What information can the applicant 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.

Based on the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS) and the North America Free Trade Agreement (NAFTA), and the hierarchy of international treaties in the Mexican legal system, the authors' firm has devised a legal strategy to obtain recognition of data package exclusivity for products that deserve this protection, and obtained court precedents recognising and ordering COFEPRIS to observe data package exclusivity.

On 19 June 2012, COFEPRIS published an internal decree on its website, providing guidelines to observe and protect data package exclusivity in Mexico.

According to the guidelines (and a minimum term set by NAFTA), a marketing authorisation holder has a five year exclusive right, where his information cannot benefit or be used to support a third party application for registration of a generic drug.

These guidelines show that COFEPRIS is now willing to recognise and protect data package exclusivity, according to NAFTA and TRIPS, and the decree provides a higher degree of confidence for innovators, which has been done and obtained in some cases specifically new small molecules. However, certain issues are not clear and require further clarification, for example:

- Whether the guidelines apply to biological products.

- Whether other key approvals, such as new formulations and indications, are protected.

- The proceedings and measures to enforce and observe data package exclusivity rights, which are not covered in the decree.

The main issue is the weight and strength of the decree versus the lack of domestic statutory law recognising data package exclusivity (*see Question 26*).

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, which have been previously approved by the:

- European Medicines Agency.
- US Drug and Food Administration.
- Health Canada.
- Swiss Agency for Therapeutic Products (Swissmedic).
- Therapeutic Goods Administration in 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 timeframes by up to 60 working days. Industry participants have welcomed these new rules, but they are still being tested.

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 timeframes. A pre-examination does not bind COFEPRIS, but it should indicate the outcome of an application.

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,

already approved by equivalent regulatory authorities abroad. In this procedure, the requirements for approval of these agencies are recognised as equivalent to those in Mexico (*see Question 11*).

Parallel imports

Are parallel imports of medicinal products into your jurisdiction allowed?

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.

Regarding IP rights, parallel imports are allowed in Mexico in relation to trade marks where both:

- The product was legally introduced in the country of origin.
- The trade mark is owned by the same company or a related company in Mexico.

The Intellectual Property Law does not specifically address patents in this context. However, it is likely that the principle of exhaustion of rights also applies to patents.

For information on pharmaceutical patents, trade marks, competition law, patent licensing, generic entry, abuse of dominance and parallel imports, see *Pharmaceutical IP and Competition Law in Mexico: overview.*

Restrictions on dealings with healthcare professionals

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

Government officers must not request, accept or receive any gifts or donations from persons whose commercial or industrial activities they are directly linked to, or that they regulate or supervise (*Article 8, Federal Law of 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 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.

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* (CANIFARMA). The corresponding sanctions range from a warning to a fine.

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 which do regulate, and in some cases prohibit, these practices.

Sales and marketing

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?

Unless they are over-the-counter products, medicines must only be available in authorised drug stores and can only be sold to patients with a physician's prescription. Dispensers must keep original prescriptions regarding antibiotics.

For advertising on the internet, see *Question 16*.

Advertising

What are the restrictions on advertising medicinal products?

Legislation and regulatory authority

The primary legislation on advertising of medicinal products is the General Health Law, its regulations regarding Advertising (*Reglamento de la Ley General de Salud en Materia de Publicidad*) (RLGSMP), and opinions issued by the Advertising Council. The Industrial Property Law (IP Law) and the Federal Consumer Protection Law also have provisions on advertising.

COFEPRIS (health legal framework) and the Federal Attorney's Office of Consumer (PROFECO) (consumer legal framework) are regulatory authorities in this field.

The National Chamber of the Pharmaceutical Industry has a Code of Ethics that includes provisions on advertising. Although these provisions are not mandatory, failure to comply can result in a suspension of rights as a member of the Chamber or exclusion from it.

Restrictions

Only non-prescription medicines can be advertised to the general public, subject to approval by COFEPRIS. Media channels must require certified copies of the relevant marketing authorisations for medicines, before publishing related adverts.

Prescription medicines cannot be advertised to the general public (*Article 310, General Health Law*).

Any visual or audio advert for non-prescription medicines must bear the message "Consult your physician", and must mention any required precautions when use of the medicine represents any danger, in case of an existing pathology (*Article 43, RLGSMP*).

Prescription medicines can be advertised to health professionals. However, advertising directed to health professionals can only be published in specialised media and it must be based on medical prescription information (*Article 42, RLGSMP*).

The RLGSMP was amended on 19 January 2012, granting COFEPRIS strong powers to require media channels to remove any suspicious illegal advert within 24 hours, and to impose a fine up to 16,000 times the minimum wage (about US$60,952 ,000).

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 protection

Do data protection laws impact on pharmaceutical regulation in your

jurisdiction?

The primary legislation is the Personal Data Protection Law and its rules. This legal framework requires the person/entity in charge of compliance to observe consent, quality, purpose, loyalty, proportionality, responsibility, security and confidentiality requirements. It relates to the pharmaceutical legal framework, such as in the case of health research and pharmacovigilance.

The NOM for Health Research in Human Beings requires protection of access, rectification, cancellation and opposition rights (ARCO rights) of research participants, by deferring this to the Personal Data Protection Law. Investigators and committees of the institution where the research is conducted must protect personal data of participants, in the research stages and the publishing stages. Investigators must collect informed valid consent from research participants.

The NOM for pharmacovigilance also recognises the protection of personal data of research participants and of healthcare professionals submitting reports, by deferring this to the Personal Data Protection Law.

Packaging and labelling

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

Legislation and regulatory authority

Packaging and labelling of medicinal products is 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 the provisions concerning the packaging and labelling of medicinal products.

Information requirements

The labelling of medicinal products should include essentially the following information:

- Distinctive brand name.
- Generic name.
- Pharmaceutical form.
- Drug concentration.
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- Formula description.

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- 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.
- Maximum price to the public.
- In cases of drugs with a biological origin, 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.

Other conditions

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

Product liability

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

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 nor differ from authorised activities.
- Ensuring that companies perform validation analyses of their manufacturing processes and systems.

In case 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 up to 16,000 times the minimum wage (around US$61,952).

- Revoke marketing authorisations and other approvals.

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

Are there any mandatory requirements relating to medicinal product safety?

The NOM for good manufacturing practices of medicinal products (NOM-059-SSA1-2015) requires a programme to recall products that do not meet quality standards to be implemented in an appropriate and efficient manner. This programme should essentially include those 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 information on possible adverse effects of the drugs provided, among others, by:

- Doctors and physicians, on a voluntary basis.

- Those who conduct clinical trials. They must submit periodical reports according to the relevant phase (*see Question 7*).

- Pharmaceutical companies. They must submit periodical safety reports each six months or year, according to the year after the granting of the marketing authorisation (*see Question 10*).

For clinical trials and approved health products, severe harmful effects must be reported within 15 days of identification of the effects.

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

Legal provisions

In general terms, liability arises from provisions in federal or local civil codes in Mexico. Liability can also arise from statutory terms. The NOM for good manufacturing practices of medicinal products (NOM-059-SSA1-2015) has provisions regarding liability. Recently, the Federal Consumer Protection Law

has been amended to allow class actions (*see Question 24*).

Substantive test

Liability claims are mainly regulated by statutes and not by court precedents. Therefore, there is no clear substantive test. The standards to determine damages are high. According to precedents from the Federal Courts, the cause-effect relationship between actions/omissions and damage has to be fully proved.

Who is potentially liable for defective medicinal products?

All those involved in selling and/or distributing medicinal products can be liable in civil actions for harm derived from a defective medicinal product. 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. Accordingly, the NOM states that, when manufacturing through third parties, the marketing authorisation holder has to 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. In this case, patients can opt between filing a civil action or require medical arbitration from the National Commission of Medical Arbitration (CONAMED). The latter is a quick alternative where a non-judicial solution is proposed.

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

Equitable defences are available. Available defences include:

- Statutes of limitations (which ranges from two to ten years). Under the Civil Code, liability for any illicit action (excluding criminal offences) expires after two years.

- Assumption of the risk and contributory negligence.

How can a product liability claim be brought?

Limitation periods

Depending on the conduct and cause of action, the limitation periods are two to ten years for civil actions, and one to nine years for certain criminal actions.

Class actions

The federal procedural laws have been amended to allow class actions before the federal courts. The Federal Agency for Protection of Consumers (*Procuraduría Federal de Protección al Consumidor*) (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 cease a health risk and not to obtain compensation.

What remedies are available to the claimant? Are punitive 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 to make estimations in this regard.

Reform

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

Data package exclusivity

Since data package exclusivity periods were not expressly included in amendments to the General Health Law (as was expected, to bring domestic law in line with international treaties), a proposed amendment to the law was published in the *Gazette of the Congress* in February 2011. The proposed amendment concerns Article 376 of the General Health Law, and intends to create a five-year data package exclusivity period for innovator products. The following points should be considered:

- The word "interchangeable" in Article 376 should be removed, since there is no longer any distinction made between "generics" and "interchangeable generics".

- The proposal does not make specific distinctions between the protection of new chemical entities, formulations and new indications.

- The proposal limits the scope of data package exclusivity to five years, while NAFTA establishes the five-year period as a minimum.

- The proposal seems to be limited to allopathic medicines of a chemical nature, as there is no specific mention of biological drugs. In other jurisdictions, biological drugs obtain a longer protection period.

Transpacific Partnership

The **Trans-Pacific Partnership** (TPP) is a trade agreement among 12 Pacific Rim countries signed on 4 February 2016 in Auckland, New Zealand, after seven years of negotiations, which has not entered into force in Mexico.

The specific issues such as regulatory data protection (RDP), patent linkage and patent term compensations will impact the Mexican legal system in connection with the life science industry.

Despite this, bearing in mind the hierarchy of international treaties in the Mexican legal structure, the TPP will shape the legal framework for the life science industry and IP law. Mexico has a new and valuable opportunity to review and change its IP system and adopt higher and, more importantly, more efficient standards of IP protection.

However, the final approval of the TTP from the Mexican Congress remains uncertain, since United States formally withdraw from the TTP trade deal. Thus the expectation is that the TPP may be part of the legal system in Mexico in the future, is uncertainly.

North America Free Trade Agreement. The United States Government stating his intention to renegotiate the free trade agreement between the United States, Canada and Mexico.

The deal was intended to eliminate most trade tariffs between the three nations, increase investment and tighten protection and enforcement of intellectual property. It is still early to predict the outcome of eventual renegotiation of NAFTA.

RDP. The protection would be at least three years for new formulations, new indications or new methods of administration or at least five years for new chemicals. Parties may limit the period of protection for three and five years respectively. Currently, Mexico is granting "*de facto*" five years for chemicals. It will be interesting how the Mexican government will reconcile the possibility to limit the term of protection to five years, while NAFTA states a minimum of five years of data protection for chemicals.

One of the most debated issues during the negotiations is the term of data protection for biologics. It was established for at least eight years or five years plus, consisting of "other" measures, recognizing that market circumstances also contribute to effective market protection to deliver a comparable outcome in the market. Hopefully, in the case of biologics, Mexico will opt for the eight years period of protection instead of the five-plus scheme which has a wide range of discretion and interpretation. If the scheme of five years plus is adopted, we unfortunately expect further litigation for the term of data protection for biologics.

Linkage regulation. The text allows Mexico to maintain their actual patent linkage which does not include use patents. Therefore, the Mexican patent linkage will not be impacted very much by the TPP. However there are positive issues such as the recognition of second uses as a subject matter of patentability, which will help the enforcement of use patents and will help to confirm the inclusion of these types of patents through court orders.

Patent term adjustments. TPP contemplates patent term adjustments due to unreasonable delays in patent prosecution and unreasonable curtailment of patent protection due to regulatory processes. Taking into consideration that the current law expressly limits the life term of a patent to 20 years as from the filing date, in this case Mexican IP law and the Health Law should be amended.

Transitional periods. There are transitional periods for some countries to be obligated to comply with the TPP. In the case of Mexico, this is five years for any case of RDP and four and a half years for unreasonable curtailment in the life term of a patent due to regulatory delays.

For information on pharmaceutical patents, trade marks, competition law, patent licensing, generic entry, abuse of dominance and parallel imports, see *Pharmaceutical IP and Competition Law in Mexico: overview.*

Online resources

The COFEPRIS website (Federal Commission for Protection against Sanitary Risk (COFEPRIS) (*www.cofepris.gob.mx*) and the Mexican Institute of Industrial Property (IMPI) website (*www.impi.gob.mx*) contain official updated of life sciences related legislation, in Spanish. As far as the authors know, there are no websites that provide reliable and up to date English translations.

Contributor profiles

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

Recent transactions

- Participated in cases against the unconstitutionality and inefficiency of certain amendments to the Federal Law of Administrative Proceedings in Mexico, which have affected the venues for challenging resolutions by the Mexican Institute of Industrial Property.

- Sponsor of a proposal to modify the litigation system of industrial property, limiting the Mexican Institute of Industrial Property to an exclusive registration authority, 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, published by the IP Media Group*.

- *Maximising IP rights in the life sciences industry, 2012, Intellectual Asset Management magazine issue 54, published by the IP Media Group*.

- *New Regulations Pending, 2011 edition of Life Sciences, Mexico Chapter: Biologic Drugs; published by 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*.

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

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

Recent transactions

- First case in México in which a Circuit Court recognizes the application of the Linkage System in relation to use patent.

- First case in Mexico where a marketing authorisation of a pharmaceutical product was revoked for being in violation of a formulation patent listed in the Linkage Gazette.

- First case in Mexico of a use patent being effectively enforced in Mexico related to public tender.

- The unconstitutionality of Article 167bis of the Health Supplies Regulation, as it does not provide the right of the titleholder of a patent to be heard during the prosecution of the marketing authorisation.

Languages. English, Spanish

Professional associations/memberships. Mexican Association for IP Protection (AMPPI) member of Inter- American Association of Intelectual Property (ASIPI)

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.

Jurisdiction	Which authority issues patents? Is guidance available on its website?	Can the typical patent term of 20 years be extended?	Are there data and marketing exclusivity protection periods for medicinal products?
Mexico	The Mexican Institute of Industrial Property (IMPI) grants patents. Some brief guidance on patent requirements and proceedings is available in Spanish on IMPI's website (*www.impi.gob.mx*). There are no guidelines for examination issued by IMPI.	There are no provisions for exclusivity term extensions or supplementary protection certificates in domestic law.	The regulator, COFEPRIS, has published an internal decree providing guidelines to observe and protect data package exclusivity in Mexico, according to international treaties. However, certain inconsistencies and legal loopholes remain.

Pharmaceutical IP and competition law in Mexico: overview

Patents

What are the legal conditions to obtain a patent and which legislation applies? Which products, substances and processes can be protected by patents and what types cannot be patent protected?

Conditions and legislation

Patent applications are regulated by the Industrial Property Law and its regulations. Patentable inventions must (*Article 16, Industrial Property Law*):

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

Scope of protection

Products and processes can be the subject of patent protection under the Industrial Property Law. The IMPI grants patents protecting compounds, formulations, uses and manufacturing processes for medicines.

Article 19 of the Industrial Property Law excludes medical procedures from being the subject matter of an invention. However, a patent can be obtained for a therapeutic method by drafting the claims in the Swiss-style format, that is, claiming the medical use of the compound for the treatment of a specified illness.

How is a patent obtained?

Application and guidance

Applications must be filed with IMPI. Details of government fees are available in Spanish only at the IMPI website (*www.impi.gob.mx*).

Process and timing

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

A patent application includes a narrative statement that sets out:

- A description of the invention that is sufficiently clear and complete to allow it to be fully understood, and to guide any person knowledgeable in the invention's field.

- The best method known by the applicant of putting the invention into practice.

- Drawings required for an understanding of the description, when necessary.

- A claims chapter, which must be clear and concise, and must describe the invention's concept without overlapping with the description.

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

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

The IMPI conducts a formal examination of the documentation and can order clarifications or further details, or that an omission be remedied. An official communication is issued to request any outstanding documents, usually four to six months after filing. The IMPI grants the applicant a term of two months, and two additional months on payment of extra fees, to comply with these requirements. If the applicant fails to comply, the application is deemed abandoned.

After all the formal documents have been filed, an official communication is issued that notes the priority claimed, when applicable. An abstract of the application is published in the *Official Gazette*. This step normally occurs 18 months after filing of the priority claim, or if no priority is claimed, 18 months from the filing date.

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

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

IMPI has implemented Patent Prosecution Highway (PPH) pilot programmes to accept examinations by the United States Patent and Trademark Office (USPTO), the Japanese Patent Office (JPO), the Spanish Patent and Trade mark Office (SPTO), the Korean Intellectual Property Office (KIPO) and the State Intellectual Property Office of China (SIPO). These programmes are an attempt to accelerate pending applications.

How long does patent protection typically last? Can monopoly rights be extended by other means?

Duration and renewal

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

Extending protection

There are no provisions for exclusivity term extensions or supplementary protection certificates in Mexican law.

In theory, the life term of a patent can be extended under certain international treaties (for example, the North America Free Trade Association (NAFTA)), where the health authority has delayed the process to obtain a marketing authorisation for a patented product. However, in practice no-one has yet

attempted this. We would suggest that anyone seeking to extend the life term of a patent on these grounds would need to argue that the international law has supremacy over Mexico's domestic legislation. In relation to data package exclusivity, COFEPRIS has recently provided some recognition of data package exclusivity according to international treaties.

In addition, Mexico is participating in the Trans-Pacific Partnership (TPP) which has not yet entered into force in Mexico. The TPP contemplates patent term adjustments due to unreasonable delays in patent prosecution and unreasonable curtailment of patent protection due to the regulatory processes. Taking into consideration that the current law expressly limits the life term of a patent to 20 years as from the filing date, in this case Mexican IP law and the Health Law should be amended. There are transitional periods for some countries to be obligated to comply with the TPP. In the case of Mexico this is five years for any case of RDP and four and a half years for unreasonable curtailment of the life term of a patent due to regulatory delays.

How can a patent be revoked?

The validity of a patent can be challenged through a nullity action before the IMPI. A patent can be established as invalid by proving one of the following:

- The patent covers subject matter that cannot be regarded as an invention, product or process.

- The subject matter qualifies as an invention but the patent does not meet one or more of the patentability standards or conditions (novelty, inventive activity or step and industrial application).

- The patent was granted in contravention of the law and does not comply with formal or technical legal provisions.

- The patent was granted due to an error or serious oversight, or was granted to someone not entitled to obtain it.

In the first three situations the nullity action can be exercised at any time. In the fourth situation the nullity action must be exercised within five years from the date on which publication of the patent in the *Official Gazette* occurred or when registration becomes effective.

How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

Conditions for infringement

The Industrial Property Law grants patentees the right to the exclusive exploitation of the patented invention and to exclude others from making, using, offering for sale or importing the covered invention. In a patent infringement action, the claimant must prove either of the following, without authorisation:

- Production, offering to sell or importing of the patented invention. A manufacturer can infringe directly, while infringement by sellers requires prior notice of the infringement. If a claimant claims infringement of a patented process, the defendant must prove use of a process other than the patented process. There are no grounds in the Industrial Property Law to apply the contributory infringement doctrine.

- Use of the patented invention. The Industrial Property Law only recognises literal infringement, and there is no doctrine of equivalence. The claimant must prove that the wording of the patent's claim or claims

cover the alleged infringing product or process. The Industrial Property Law provides that the scope of the claims is determined by their wording, aided by the description and drawings.

The burden of proving authorised use is on the defendant. The doctrine of implied licence has not been tested before the Mexican courts.

Claim and remedies

Proving patent infringement in Mexico is difficult, since Mexico follows a strict civil law system which has formalistic rules for both evidence and proceedings. A patent infringement claim must be submitted to the IMPI. The claim is served on the alleged infringer, who then has ten working days to respond and, if applicable, bring a counterclaim. That response is then served on the claimant for the claimant to refute it. The evidence is then analysed and a decision is issued. That decision can be challenged before the federal courts. The IMPI is an administrative authority. There is no judge or jury participation in patent infringement actions.

The IMPI can take certain preliminary measures while investigating the infringement (*Article 199 bis, Industrial Property Law*). They include ordering:

- 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.

- Suspension of services or closure of an establishment, when other measures are insufficient to prevent or avoid a violation of rights protected by law.

Administrative infringements can incur penalties ranging from a fine up to 20,000 times the minimum wage (about US$76,190) to final closure of the establishment (*Article 214, Industrial Property Law*). Repeated infringement is also considered a criminal offence (*Article 223, Industrial Property Law*).

Once an infringement has been declared and cannot be appealed, the claimant can bring an additional civil action for damages and lost profit, accruing from the date on which the existence of the infringement can be proved (*see Article 221 bis, Industrial Property Law*). The civil courts impose a tariff scheme specifying the costs that can be claimed for reasonable attorneys' fees, regardless of whether this reflects the actual fees charged.

Are there non-patent barriers to competition to protect medicinal products?

Mexican domestic law is silent about data package exclusivity. However, on 19 June 2012 COFEPRIS published an internal decree on its website, providing some recognition of data package exclusivity according to international treaties. The primary features of the guidelines issued by COFEPRIS are that:

- Information submitted in a process of regulatory approval is protected against unfair commercial use and disclosure.

- Five years maximum protection. During this period of time, no one can use information provided by the innovator for the commercialisation of the drug.

- COFEPRIS will grant approvals for generics once the five years of protection lapses, unless the generic drug proves safety and efficacy independently.

Conversely, there are some pending issues, such as that COFEPRIS has stated that the guidelines do not apply to biological products. The internal decree is also silent about the proceedings and measures to enforce and observe the right, which would provide certainty to all the involved parties. The main question and test will be the weight and strength of these guidelines as an internal decree against the lack of domestic statutory law recognising DPE.

The Trans-Pacific Partnership (TPP), which has not yet entered into force in Mexico states that protection would be at least three years for new formulations, new indications or new methods of administration, or at least five years for new chemicals. Parties may limit the period of protection for three and five years respectively. Currently, Mexico is granting “de facto” five years for chemicals. The TPP establishes at least eight years or five years plus for biologics. “Other” measures, recognising market circumstances, also contribute to effective market protection, to deliver a comparable outcome in the market.

Trade marks

What are the legal conditions to obtain a trade mark and which legislation applies? What cannot be registered as a trade mark and can a medicinal brand be registered as a trade mark?

Conditions and legislation

All visible signs can be protected as a trade mark if they are sufficiently distinctive and able to identify the products or services to which they apply or are intended to apply against others in the same class (*Article 89, Industrial*

Property Law).

Scope of protection

Brands for medicinal products can be registered as trade marks.

Trade marks in Mexico are regulated under the Industrial Property Law. Article 90 provides a long list of prohibitions against registration of certain signs as trade marks. In addition, Article 4 prohibits registration of marks whose content or form is contrary to public order, morals and decency, or that contravene any legal provision.

Sounds and smells cannot be protected as trade marks. Three-dimensional forms can be protected as trade marks, as they are visible signs, if they comply with the principle of distinctiveness. However, the Industrial Property Law establishes certain limitations on three-dimensional marks.

On granting marketing authorisations, COFERPRIS must ensure that when the proposed trade mark of a drug is orthographic or phonetically similar to another previously approved, this must differ at least by three letters in each word (*Article 23, RIS*). Such provisions are known in Mexico as the three letters rule, and although it is established in a Regulation of the Health Law, it has the rationale of avoiding the granting of a marketing authorisation with a distinctive denomination (trade mark) similar to a distinctive denomination of a prior marketing authorisation, but taking into consideration the number of different letter of the denomination. The regulation only binds the health authorities in charge of processing a marketing authorisation application. It has not been applied by IMPI when studying conflicts of trade marks applied to pharmaceutical products, as IMPI sustains that the rule is not contemplated in the IPL or its regulation, and that it limits the likelihood analysis to a number of letters of the conflicting trade marks.

International non-proprietary names (INNs) cannot be registered as trade marks. Article 225 of the General Health Law expressly forbids the use of pharmaceutical trade marks that clearly or even slightly resemble an INN.

How is a trade mark registered?

Application and guidance

Applications have to be submitted to the IMPI (*www.impi.gob.mx*).

Process and timing

An application for a new trade mark follows the following process:

- A formal examination, which checks compliance with the formal legal requirements (for example, the official application form must be duly completed and the government fees paid).

- A second examination of the inherent registrability of the mark (without evidence of use), that is, whether it complies with the legal conditions for registration.

On April 28, 2016, the Mexican Congress approved a long-awaited Decree, whereby some articles of the IP Law were amended and new articles also introduced, pertaining to the implementation of a trademark opposition proceeding in Mexico (hereinafter "the Reform"). The Reform came into force August 30th of 2016.

According to the Reform, all new applications filed in Mexico will be published for opposition purposes within the next 10 working days of the filing date to allow any third party who deems that a published application falls within the absolute or relative grounds of refusal as provided in Articles 4 and 90 of the IP

Law to submit a brief of opposition, within a non-extendable one month term of publication of the application. The brief shall be accompanied by all documentation supporting the opposition.

Once the one month term for opposition expires, IMPI will publish within the next 10 working days all oppositions filed. Owners of opposed applications will have a one month term to raise arguments against the alleged grounds of opposition.

It is important to note that the opposition will not suspend prosecution of the applications, as IMPI will continue to conduct its official examination of trademark applications on both absolute and relative grounds in parallel to the opposition proceeding.

It will be optional for IMPI to consider the arguments submitted by the opponent in an opposition, as well as the defensive arguments raised by the applicant. Thus, if the application is refused, IMPI will serve the opponent with a writ informing of such refusal. In turn, if the application matures into registration, IMPI shall serve the opponent with a writ informing of the granted registration.

Finally, despite the outcome of an opposition proceeding, the post-registration grounds for invalidation currently established by the IP Law will remain available.

If the trade mark registration for a word mark does not face any objection as to its inherent registrability, and there is no known similar or identical prior registered mark, completing registration can take three to four months. For a design trade mark, it can take at least six months because searches for prior registrations relating to designs are mostly conducted manually by the IMPI.

How long does trade mark protection typically last?

Trade mark registrations are valid for ten years from the filing date and can be renewed for any number of further ten-year periods.

Renewal of trade mark registration can be requested by the holder from six

months before its renewal date. However, the IMPI will accept and process renewal petitions filed within a six-month grace period after the renewal date, on payment of an additional government fee.

How can a trade mark be revoked?

If a trade mark is not used for three consecutive years in relation to the goods or services for which it is registered, the registration is subject to cancellation for non-use, unless either (*Articles 130 and 152(II), Industrial Property Law*):

- A duly licensed holder or user has used the mark for three consecutive years immediately before the filing date of the cancellation action.

- There are legitimate reasons for the non-use that are beyond the control of the trade mark owner (for example, import restrictions or other government requirements).

Trade marks can also be cancelled if (*Article 151, Industrial Property Law*):

- The registration was granted in breach of the law, although the invalidity action cannot be based on a challenge to the applicant's legal representation. An action on these grounds can be made at any time.

- The trade mark is identical or confusingly similar to another that has been continuously used in Mexico or abroad before the application for registration, and is applied to the same or similar products or services. An action on these grounds must be made within three years of the trade mark's registration.

- The registration was granted on the basis of false information in the application. An action on these grounds must be initiated within five years of the trade mark's registration.

- The registration was granted by mistake. An action on these grounds must be initiated within five years of the trade mark's registration.

- The agent, representative, user or distributor of a trade mark registered abroad requests and obtains registration in his name of the trade mark or another confusingly similar one, without the express consent of the holder of the foreign trade mark. In this situation, the registration is deemed to have been obtained in bad faith. An action on these grounds can be initiated at any time.

How is a registered trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?

Conditions

For administrative infringements, the claimant must prove use of a confusingly similar/identical trade mark by a third party without authorisation, to distinguish identical or similar goods or services to those covered by the registration.

Criminal proceedings can be brought against counterfeit goods with a trade mark identical to the one held by the claimant (counterfeiting).

A claimant can also bring an action for unfair competition. In this case, the claimant must prove that use of the trade mark by the infringer makes some

form of false representation, that tends to cause consumers to believe that the defendant's goods or services come from the claimant.

Claim and remedies

Administrative actions for trade mark infringement can be brought before the IMPI. IMPI can impose a fine and order an immediate halt to the infringing activities. A civil action to claim damages in a civil court is possible once an IMPI resolution declaring infringement is final and cannot be appealed.

A criminal action against counterfeiting can be brought by filing a complaint with the attorney general's office. On receiving the complaint, the attorney general's office will conduct an inquiry, to determine whether a crime has been committed. If so, the district attorney submits the matter to a federal district judge. Criminal penalties range from between two and ten years' imprisonment, to about US$100,000 in fines. Imprisonment and fines can be imposed simultaneously.

Outline the regulatory powers and enforcement action against counterfeiting in the pharmaceutical sector.

COFEPRIS has statutory authority to:

- Seize any drug held for sale that is adulterated, misbranded, mislabelled, and/or lapsed.

- Inspect at reasonable times, subject to reasonable limits and in a reasonable manner any place where health products are manufactured, packed and/or held for marketing.

Right holders can enforce border measures and the remedies provided by the IP Law (*see Question 11*), if applicable.

The fight against counterfeit medicines in Mexico has increased in different aspects, including customs protection. Customs and IMPI are analysing whether the customs database of registered trade marks may be extended to patents.

For information on pharmaceutical pricing and state funding, manufacturing, marketing, clinical trials, advertising, labelling, and product recall and liability, visit *Medicinal product regulation and product liability in Mexico: overview.*

IP and competition law issues

Briefly outline the competition law framework in your jurisdiction and how it impacts on the pharmaceutical sector. In particular, the competition authorities and their regulatory powers, key legislation, whether pharmaceutical investigations are common, key recent activity and case law.

The Economic Competition Federal Commission (ECCF) (*www.cfc.gob.mx*) enforces the competition legal framework in Mexico. This regulatory authority is an administrative agency with technical and operational autonomy, not governed by but related to the Ministry of Economy. The primary legislation is:

- The Economic Competition Federal Law (*Ley Federal de Competencia Económica*) (ECL).

- The LEC Regulations (*Reglamento de la Ley Federal de Competencia Económica*) (ECR).

- Administrative Rules (*Disposiciones administrativas de carácter general reglamentarias*).

The ECFC has statutory authority to review practices by pharmaceutical companies. In 2010, the ECFC published the imposition of a fine on six pharmaceutical companies for anti-competitive practices in public tender proceedings by IMSS. This decision is final and may be the cause of consolidated public bids.

Briefly outline the competition issues that can arise on the licensing of technology and patents in a pharmaceutical context

Patent licensing and anti-trust law

In theory, an action could be brought against activities falling outside the scope of a patent, such as:

- Non-competition agreements for products that are not covered by the claims.

- Product-tying within that scope.

- Unfair competition activities, such as advertising that a product is better than an alternative for the sole reason of it having a patent.

Actions could also be brought before the ECFC for other forms of abuse of

patent rights, such as clearly unfounded attempts to enforce a patent.

Compulsory licensing

After three years starting from the date of grant of the patent or four years from the filing date, whichever is later, any person can request from the IMPI the grant of a compulsory licence when the patent has not been used, except if there are justified reasons for the non-use (*Article 70, IP Law*).

A compulsory licence will not be granted when the patent holder or a licensee has been importing the patented product or the product obtained by the patented process (*Article 70, IP Law*). Further, the working of a patent by a licensee will be deemed to be worked by its holder, provided that the licence has been recorded with the IMPI (*Article 69, IP Law*).

A party applying for a compulsory licence must have the technical and economical capacity to efficiently work the patented invention (*Article 71, IP Law*).

Before the grant of the first compulsory licence, the IMPI will provide the patentee with the opportunity to begin working the patent, within one year from the date of personal notification given to him (*Article 72, IP Law*). Following a hearing with the parties, the IMPI will decide on the grant of a compulsory licence. If the IMPI decides to grant it, it will set out its duration, conditions, field of application and amount of royalties to be paid to the patent holder. The royalties are established by the IMPI after a hearing with the parties and they should be fair and reasonable.

We are not aware of any compulsory licences being granted in recent years.

Are there competition issues associated with the generic entry of pharmaceuticals in your jurisdiction?

The IP Law grants patent holders capacity to oppose exploitation of patented goods, such as importation (*see Question 5*). The linkage regulation prevents

violation of patents by preventing approval of marketing authorisations for patented products.

The linkage system contain a Bolar-type exemption. This allows generic companies to apply for marketing authorisations and use patented materials to meet the regulatory requirements, three years before the expiry of a patent covering chemicals and eight years before for biologics.

Problems arise because the law and regulation of import permits for raw materials is silent about IP related controls and does not provide a reference to the *Linkage Gazette*. Basically, there are no guidelines or standards to bind COFEPRIS to review and take into consideration the amount of raw materials (active pharmaceutical ingredients) (APIs) that are authorised to be imported. The main concern is that recently, there have been an increasing number of permits to import patented compounds in bulk, that clearly exceed the justified amounts for clinical trials or experimental use.

As a result, patent holders have had to attempt different strategies to attack these violations of their IP rights, including patent infringement actions, where co-ordination between the patent and customs offices is not always ideal, and challenges against import permits issued by COFEPRIS. Measures by the authorities would be welcome to prevent the entry of infringing pharmaceutical substances into Mexico. Examples are:

- COFEPRIS using and observing the patent *Linkage Gazette* for the approval or rejection of import permits.

- COFEPRIS establishing the amount of APIs sufficient to comply with regulatory tests for marketing authorisation for follow-on products, denying imports of non-adequate amounts.

- COFEPRIS requiring importers to declare the destination of the imported products.

- IMPI clearly establishing through case law the differences between the sole experimental use and the Roche-Bolar exception.

- IMPI being careful when, on a case by case basis, it reviews what is an adequate amount to be imported for tests regarding a generic marketing authorisation application. In certain cases, a small amount of an API can represent the manufacturing of thousands of infringing products, which may end up in the grey and black market.

- Customs to take advantage of the information in the patent *Linkage Gazette*, to detect and stop eventual substances entering Mexico in violation of valid patents.

Have abuse of dominance issues arisen in the pharmaceutical sector in your jurisdiction?

The ECFC published in 2010 the imposition of a fine on six pharmaceutical companies for anti-competitive practices in public tender proceedings by IMSS. This case is final (*see Question 13*).

Have parallel imports of pharmaceuticals raised IP and competition law issues in your jurisdiction?

Although the Intellectual Property Law does not specifically address patents in this context, it is likely that the principle of exhaustion of rights also applies to them. The Mexican government has entered into two main treaties on the subject of international trade and intellectual property rights: the North American Free Trade Agreement (NAFTA) and the Trade Related Aspects of

Intellectual Property Rights (TRIPS).TRIPS allows countries to engage in parallel importation by adopting international doctrines of patent exhaustion, that is, once products are placed on the international market, patent holders' exclusive rights are exhausted. NAFTA expressly provides for the protection of IP rights as long as such protection does not constitute a bar on the free circulation of goods and services. Similarly, Article 1 of TRIPS can be interpreted as providing for a balanced system of rights between traders and IP owners.

Does a patent or trade mark licence and payment of royalties under it to a foreign licensor have to be approved or accepted by a government or regulatory body? How is such a licence made enforceable?

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

Recording a patent or a trade mark licence is not mandatory and the agreement is enforceable between the parties regardless of whether or not it is recorded. However, to be effective against any third party, and to ensure the title holder has the use of the trade mark or patent, the licence must be recorded with IMPI (*Industrial Property Law*).

For information on pharmaceutical pricing and state funding, manufacturing, marketing, clinical trials, advertising, labelling, and product recall and liability, visit *Medicinal product regulation and product liability in Mexico: overview*.

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

Recent transactions

- Participated in cases against the unconstitutionality and inefficiency of certain amendments to the Federal Law of Administrative Proceedings in Mexico, which have affected the venues for challenging resolutions by the Mexican Institute of Industrial Property.

- Sponsor of a proposal to modify the litigation system of industrial property, limiting the Mexican Institute of Industrial Property to an exclusive registration authority, 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, published by the IP Media Group*.

- *Maximising IP rights in the life sciences industry, 2012, Intellectual Asset Management magazine issue 54, published by the IP Media Group*.

- *New Regulations Pending, 2011 edition of Life Sciences, Mexico Chapter: Biologic Drugs; published by 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. Mexico, Bachelor Degree by National Autonomous University of Mexico (UNAM), 1995.

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

Recent transactions

- First case in México in which a Circuit Court recognizes the application of the Linkage System in relation to use patent.

- First case in Mexico where a marketing authorisation of a pharmaceutical product was revoked for being in violation of a formulation patent listed in the Linkage Gazette.

- First case in Mexico of a use patent being effectively enforced in México relating to a public tender.

- The unconstitutionality of Article 167bis of the Health Supplies Regulation, as it does not provide the right of the titleholder of a patent to be heard during the prosecution of the marketing authorisation.

Languages. English, Spanish

Professional associations/memberships. Mexican Association for IP Protection (AMPPI). Mexican Bar (BMA), member of Inter- American Association of Intelectual Property (ASIPI)

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*