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Life sciences in Mexico: overview

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REGULATORY OVERVIEW

1. What is the regulatory framework for the authorisation, pricing and reimbursement of drugs, biologicals and devices (as they are termed in your jurisdiction)?

Legislation

The main regulatory framework in relation to medicine, biological products for human use and medical devices is set out in the following federal laws:

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

Regulatory authorities

The authority responsible for enforcing the regulatory framework in relation to these products is the Federal Commission for Protection against Sanitary Risk (*Comisión Federal para la Protección contra Riesgos Sanitarios*) (COFEPRIS) (*see box, Regulator details*), which is part of the Ministry of Health (*Secretaria de Salud*).

Biotechnology and combination products

On October 2011, the Health Law Regulations were amended to establish the requirements to approve biologics and biocomparables, an area which was previously poorly regulated (*see Question 8*).

PRICING AND STATE FUNDING

2. 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.

The Mexican healthcare system comprises public and private insurers, out-of-pocket payments and informal arrangements.

The major public segments of the Mexican healthcare system are:

- Social Security (*Instituto Mexicano del Seguro Social*) (IMSS) (for the self-employed and employees in private companies).
- Social Security for State Workers (*Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado*) (ISSSTE).
- *Seguro Popular* (SP). This is a programme for the state workforce, created in 2004 as part of a strategic reform to the General Health Law, providing 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 participants provide 10%.

The Department of Defence provides health coverage for members of the military.

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 contain costs by using price reductions and encouraging competition.

3. 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 negotiation transparency between public insurers and pharmaceutical companies.
- Determine the cost-benefits ratio of new medicines and therapies in relation to their prices and those of other products in the market.

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

The IMSS is the largest public sector buyer of drugs. Public sector purchases are made through public tender processes. The CNDP analyses the effectiveness of drugs and relevant therapeutic alternatives, and the feasibility and implications of an eventual substitution with equivalent medicines.

The CNDP also conducts an economic evaluation of the cost-effectiveness of patented medicines compared with potential substitutes. Drug payments by the government (mainly in the IMSS) derive from compulsory fees paid by both employees and employers. However, federal government subsidies are necessary in all segments of the public health system at the federal and state levels.

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 in the last six years.

MANUFACTURING

5. What is the authorisation process for manufacturing medicinal products?

Application

Companies manufacturing medicines and/or medical products in Mexico must be approved by COFEPRIS through a manufacturing licence/authorisation (*licencia sanitaria*).

Conditions

There are two main NOMs that oversee good manufacturing practice in the industry. These are reviewed every five years and regulate and provide guidelines and standards for:

- Workforce conditions in the plant (including responsibilities, uniforms, medical examinations and so on).
- Legal and technical documentation.
- Facilities requirements.
- Manufacturing control and protocols.
- Packaging.
- Equipment.
- Destruction and elimination of waste.

Restrictions on foreign applicants

To hold a marketing authorisation, the applicant must have a license/authorisation for a manufacturing facility or laboratory for medicines or biologic products for human use (*Article 168, Health Law Regulations*). For foreign manufacturers, a licence, certificate or document proving that the company has a permit to manufacture medicines, issued by the competent authority in the country of origin, is required.

Key stages and timing

The timeframe for reviewing an application for a manufacturing licence/authorisation is 60 working days (*Health Law Regulations*). This timeframe will be reduced by up to ten working days if the application has been reviewed by one of the Third Health Institutions (private/public companies authorised by COFEPRIS to review regulatory submissions).

COFEPRIS ensures the NOMs are enforced when a facility begins production and thereafter at least every two years.

Fee

The fee is about US$6,000.

Period of authorisation and renewals

Manufacturing licences/authorisations 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.

6. What powers does the regulator have in relation to manufacturing authorisations?

Monitoring compliance

COFEPRIS has a permanent pharmacovigilance programme. This is based on information on possible adverse effects of the drugs given, among others, by:

- Doctors and physicians, on a voluntary basis.
- The pharmaceutical companies that manufactured the products and those who conduct clinical trials, who must both report any health risks.

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

- Ensuring compliance with good manufacturing practices and standard operating procedures.
- Ensuring the activities do not exceed the limits set by the authorisation and do not differ from those activities which were authorised.
- Ensuring the performance of validation analysis of the manufacturing processes and systems involved.

Imposing penalties

COFEPRIS is entitled to implement measures on behalf of public health, for example:

- The seizure of products.
- Ordering the partial or total suspension of activities, services or advertisements.

An *ex officio* proceeding can be initiated to review a suspected health risk concerning an authorised product, and the marketing authorisation holder must then in turn file their response to the initial request for review.

COFEPRIS can revoke licences/authorisations and/or impose sanctions, ranging from a fine of up to 16,000 times the minimum wage (about US$83,000) to closure of the establishment.

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

CLINICAL TRIALS

7. Outline the regulation of clinical trials.

Legislation and regulatory authorities

Clinical trials are regulated by the Health Law Regulations for Health Research (*Reglamento de la Ley General de Salud en Materia de Investigación para la Salud*) (RLGSMIS), which are enforced by the Ministry of Health and COFEPRIS.

Authorisations

Clinical trials require:

- Authorisation from the head of the health institution where the clinical trials will take place.
- Supervision by the Ministry of Health.
- A favourable opinion from a committee of research, ethics and biosafety.

Consent

The subject's consent to the clinical trial must be established in a formal written document, witnessed before two witnesses. That written document must also show that the subject:

- Has been provided with full information about the nature and risks of the clinical trial.
- Is exercising free will in taking part in the clinical trial.

The information provided to the subject must be detailed and accurate.

Trial pre-conditions

There is no express obligation that the subjects of clinical trials must be insured.

The institution running the clinical trial must provide medical assistance and financial indemnification for damages caused by the clinical trial.

Under Article 63 of the RLGMIS, when there is sponsorship or other forms of remuneration for the clinical trial, measures must be put in place to ensure that there is no conflict of interest between the principal researcher's duties to:

- Protect the rights of the subjects of the trial.
- Maintain accurate results.
- Allocate resources.

Procedural requirements

The RLGMIS also provides the guidelines and standards for the trial protocol, including rules concerning documentation, compilation, confidentiality and reports.

Under the NOM for Clinical Trials any clinical trial must be conducted following ethical guidelines and must always respect the dignity, rights and welfare of the human being.

Clinical trials can specify certain steps or goals to be achieved. The principal researcher must compile a final technical report for the clinical trial, and where the clinical trial lasts longer than one year, annual technical reports for the Health Authorities must be compiled.

The final technical report must contain, among other things, the following:

- **Summary.** A general overview of the work performed, outcomes, relevant conclusions and possible applications.
- **Preamble.** Theoretical overview of the research, providing general background information and highlighting any relevant problems identified. Hypothesis, justifications and objectives should also be included here.
- **Materials and methods.** A detailed description of the research, including the apparatus and instruments used, together with the validity and quality controls used.
- **Relevant outcomes.** A summary of the actual outcomes of the clinical trial.
- **Analysis and interpretation of the research outcomes.** This should compare them with the studies that support or contradict the research.
- **Conclusions.** Proposals and possible applications.

MARKETING

Authorisation and abridged procedure

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

Application

Manufacturers must obtain a marketing authorisation by COFEPRIS to sell any medicine or certain medical devices. There is a list of authorised health institutions to pre-examine applications to be submitted to COFEPRIS, in order to reduce approval timeframes (*see Question 9*).

There is a linkage system between COFEPRIS and the Mexican Institute of Industrial Property (IMPI). This is to prevent the granting of marketing authorisations in violation of exclusive 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.

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.

Authorisation conditions

Chemical drugs. To obtain marketing authorisation, the safety and efficacy of drugs must be proved, through standard clinical trials, according to the rules in the General Health Law and its regulations. A committee studies applications for new drugs (defined as new molecules), which include:

- Medicines to be approved for the first time in Mexico.
- Medicines with a new combination of two compounds that do not exist in Mexico.
- Drugs or medications on the market but with a different therapeutic indication.

Applicants for marketing authorisation for a generic drug are not required to prove safety or efficacy of their products. They only have to provide information concerning dissolution profiles or bioavailability studies regarding the innovator product (*see Question 9*).

Biologics and biocomparables. The General Health Law and its regulations have been reformed to establish rules for the approval of biologics and biocomparables. Although industry participants welcomed these amendments, specific rules to approve biocomparables 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.

Other conditions

Manufacturers must comply with good manufacturing practices, stability, pharmacovigilance and labelling standards and all other applicable provisions.

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 prohibit bad practices. Ultimately, these legal proceedings can result in the revocation of the marketing authorisation.

Medicines must only be available in authorised drug stores and can only be sold to patients with a physician's prescription, especially antibiotics (unless they are over-the-counter products) (*Health Law Regulations*).

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).

These timeframes can be reduced by half if the application has been pre-examined by an authorised health institution/laboratory.

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

In practice, these timeframes may vary.

Fee

Fees are about the following:

- New molecules/biologics: US$8,600.
- Generics/biocomparables: US$4,810.
- Herbals: US$1,150.

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 for renewal to be approved.

Post-marketing commitments and pharmacovigilance obligations

The Health Law Regulations and the Official Mexican Standard for pharmacovigilance establish, broadly, 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.
- 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.

9. 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

Generic companies can obtain marketing authorisation for a generic product by providing dissolution profiles or bioavailability studies relating to the innovator product.

Therefore, the General Health Law and its regulations allows 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 TRIPS and 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 the only two 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. 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 35*).

Expedited procedues

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.

On 5 October 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.

A pre-examination of formal and substantive requirements of applications for marketing authorisations by an authorised health institution reduces approval timeframes by up to half. A pre-examination does not bind COFEPRIS, but it should indicate the outcome of an application. General results from introducing this option into the Mexican legal framework are still pending.

Orphan drugs have been recently defined by the General Health Law and the Mexican Pharmacopeia, and in practice are approved by a particular procedure. Specific rules are still pending.

10. Are foreign marketing authorisations recognised in your jurisdiction?

In general, Mexico does not recognise foreign marketing authorisations. However, COFEPRIS has recently set an abridged procedure for drugs to be approved for the first time in Mexico, where they have been previously approved by foreign regulatory agencies, and the requirements for approval of these agencies are recognised as equivalent to those in Mexico (*see Question 9*).

11. What powers does the regulator have in relation to marketing authorisations?

Monitoring compliance

COFEPRIS can request reports from, and make on-site inspection visits in the manufacturing, distribution or storage facilities of marketing authorisation holders to both:

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

Imposing penalties

COFEPRIS can impose strong administrative sanctions for breaches of the legal health framework (*see Question 6*).

Parallel imports

12. 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.

Restrictions

13. 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.

14. What are the restrictions on marketing medicinal products on the internet, by e-mail and by mail order?

Medicines must only be made available in authorised drug stores, and can only be sold to patients with a physician's prescription, especially antibiotics (unless they are over-the-counter products) (*Health Law Regulations*).

For advertising on the internet, see *Question 15*.

ADVERTISING

15. What are the restrictions on advertising medicinal products?

Legislation and regulatory authority

Advertising of medicinal products in Mexico is governed by the Regulation of the General Law of Health regarding Advertising (*Reglamento de la Ley General de Salud en Materia de Publicidad*) (RLGSMP), and opinions issued by the Advertising Council. COFEPRIS enforces the provisions on advertising.

The Industrial Property Law and the Federal Law for Protection of Consumers both have provisions on advertising. 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 the 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$83,000).

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.

PACKAGING AND LABELLING

16. 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 must include the following information (*NOM 072-SSA1-2012 and Health Law Regulations*):

- 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.

Country Q&A

- Batch number.
- Expiration date.
- Manufacturer's and, if applicable, distributor's information, including address.
- Content.
- 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.

TRADITIONAL MEDICINES

17. Outline the regulation of the manufacture and marketing of alternative or complementary medicinal products.

Traditional herbal medicinal products are regulated by the General Health Law and the Health Law Regulations.

Traditional herbal medicinal products can contain excipients and additives besides vegetable materials (*Health Law Regulations*).

Traditional herbal medicinal products must not:

- Be isolated or chemically defined active ingredients.
- Be injectable.
- Include psychotropic or narcotic substances.
- Be mixed with conventional medicines or other substances that represent a health risk.

Traditional herbal medicinal products can be advertised to the general public. Any visual or audio advert must bear the message "Consult your physician" (*Article 310, General Health Law*).

Adverts must limit themselves to indicating the general characteristics of the product, its therapeutic properties and use (*see Question 15*).

PATENTS

18. 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.

19. How is a patent obtained?

Application and guidance

Applications must be filed with IMPI. Details of government fees are available 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) and the Korean Intellectual Property Office (KIPO). These programmes are an attempt to accelerate pending applications, and their implementation is still being tested.

20. 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.

Patents cannot be extended.

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, 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 (*see Question 9*). In addition, Mexico is participating in the Transpacific Partnership (*see Question 35*).

21. 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.

22. 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$105,000) 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.

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

Mexican domestic law is silent about data package exclusivity. However, COFEPRIS has recently provided some recognition of data package exclusivity according to international treaties (*see Question 9*).

TRADE MARKS

24. 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*). This is known as the three-letter rule.

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.

25. How is a trade mark registered?

Application and guidance

The application is made to the IMPI. The government fees for filing a trade mark application are around US$270. If objections are faced, further fees can be incurred, in the region of US$125.

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 (*see Question 24*).

The examiners then search the IMPI's database to check if there is a trade mark (on record or at the registration stage) that is similar or confusingly similar to the proposed mark. If a similar trade mark is revealed in the search, it is analysed to determine whether the confusion is triggered by graphic, phonetic or conceptual aspects, considering the similarities between the relevant products or services.

If the examiners find that a prior mark is a barrier to registration, or that the application does not comply with all the formal requirements, an official notice of this is issued, detailing these reasons and granting the applicant a two-month term (automatically extendable for a further two months) to comply or provide legal arguments. IMPI then grants or refuses the registration. On the applicant's request, the IMPI will suspend the trade mark application if legal action against prior registration begins.

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.

There is no opposition system in Mexico. The IMPI's current approach is to not recognise consent letters or co-existence agreements for identical or confusingly similar trade marks owned by different parties. The Protocol relating to the Madrid Agreement concerning the International Registration of Trademarks 1989 (Madrid Protocol) entered into full force and effect in Mexico on 19 February 2013. However, full implementation by IMPI is still pending (*see Question 35*).

26. 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.

27. 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.

28. 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 agains 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. For more information on claims and remedies, see *Question 22*.

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.

Patent and trade mark licensing

29. Does a patent or trade mark licence agreement and payment of royalties under it to a foreign licensor have to be approved or accepted by a government or regulatory body?

There is no requirement for a patent or trade mark licence agreement 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 agreement 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 agreement must be recorded before IMPI (*Industrial Property Law*).

Patent and trade mark conventions

30. Is your jurisdiction party to international conventions on patent and trade mark protection?

Mexico, currently participating in the Transpacific Partnership (*see Question 35*), is a signatory to a number of international conventions related to intellectual property protection, including the:

- Paris Convention.
- Patent Cooperation Treaty.
- Madrid Protocol.
- WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS).
- WIPO Vienna Agreement Establishing an International Classification of the Figurative Elements of Marks 1973.
- Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure 1977.

- WIPO Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of Registration of Marks 1957.
- WIPO Strasbourg Agreement Concerning the International Patent Classification 1971.

Mexico is also party to various bilateral treaties regarding free trade and intellectual property.

PRODUCT LIABILITY

31. Outline the scope of medicinal product liability 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. Recently, the Federal Consumer Protection Law has been amended to allow class actions (*see Question 32*).

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.

Liability

Individuals can be liable if they manufacture, distribute, store or transport products that have been falsified, altered or contaminated.

32. 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 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.

REGULATOR DETAILS

Federal Commission for Protection against Sanitary Risk (COFEPRIS)

W *www.cofepris.gob.mx*

Main areas of responsibility. Main areas of responsibility. Part of the Ministry of Health, COFEPRIS is responsible for enforcing the regulatory framework in relation to medicines.

33. What defences are available to product liability claims?

Equitable defences are available. Available defences include statutes of limitations (which ranges from two to ten years), assumption of the risk and contributory negligence. Under the Civil Code, liability for any illicit action (excluding criminal offences) expires after two years.

34. 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

35. 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

In June 2012, the countries participating in the Transpacific Partnership invited Mexico to participate. In relation to pharmaceutical patents and regulation, the main topics appear to be countries committing to have additional protection, such as:

- Patent linkage, extensions or compensation, due to regulatory delays.
- Data package exclusivity for new chemical compounds and formulation and second uses.

Bill to reduce patent terms for medicines

On 23 January 2013, the senate published a bill adding Article 23 bis to the Industrial Property Law. This intends to establish a special term for patents claiming a substance or a mix of substances regulated by Article 221, sections I to III, of the Health Law (that is, drugs, active ingredients and raw materials related to drugs).

According to this bill, the 20 year term for patents claiming such subject matter would start from the date of filing of the first patent application abroad (priority date), instead of the filing date in Mexico, as currently set out by law. This could reduce the term by up to one year. The authors consider this bill to breach international IP treaties adopted by Mexico, mainly through an arbitrary shortening of a patent term (which is privative and would be declared unconstitutional), and intend to follow up and oppose it.

ONLINE RESOURCES

The COFEPRIS website (*see box, Regulator details*) and the IMPI website (*see Question 19*) contain official updated 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.

Madrid Protocol

The authors' firm is preparing proposals to amend the Industrial Property Law, including the introduction of a trade mark opposition system. These will be presented to the legislative and administrative authorities in due course, and to the Mexican Association for the Protection of Intellectual Property (AMPPI) (the Mexican Chapter of the AIPPI).

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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 in infringement cases, and cases related to the annulment of trade mark registrations or patents to administrative courts.

Languages. English, Spanish

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

Publications

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

Recent transactions

- Invalidity of a marketing authorisation for a blockbuster product unduly granted to a non-authorised third party.
- Microsoft Corporation: several cases of computer implemented inventions.
- Patent infringement/invalidity of a blockbuster product.
- McDonald's International Property Company Ltd. Several litigation proceedings against formative trade marks.

Languages. English, Spanish

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

Publications

- *New rules to speed up administrative appeals. Managing Intellectual Property, September 2011.*
- *Scope of new specialised courts widened. Managing Intellectual Property, February 2011.*
- *IP Law amended. Managing Intellectual Property, June 2010.*
- *Make your case online. Managing Intellectual Property, IP Focus, 2009.*