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SOCIO

REGULATORY OVERVIEW

1. Please give a brief overview of the regulatory framework for medicinal products/pharmaceutical products/drugs (as they are called in your jurisdiction), including the key legislation and regulatory authorities. If biotechnology products are treated differently, please specify the differences.

The main regulatory framework in relation to medical products is mainly set out in the following federal laws:

- General Health Law (*Ley General de Salud*) (LGS).
- Health Supplies Regulation (*Reglamento de Insumos para la Salud*) (RIS).
- Official Mexican Standards (*Norma Oficial Mexicana*) (NOMs).

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

See *Question 37*.

PRICING AND STATE FUNDING

2. Please give a brief overview of the structure and funding of the national healthcare system.

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 is composed of 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 LGS, 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 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 currently faces its worst ever financial crisis and has implemented measures to contain costs through reductions in prices and encouraging competition (*see Question 37*).

3. In what circumstances 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 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 or reimbursed by the state? Please briefly outline the procedure and pricing for state funding or reimbursement (for example, is the reimbursement paid to the producer, pharmacist or end-user)?

The IMSS is the largest public sector purchaser 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 the obligatory 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, the majority of 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 five years.

MANUFACTURING

5. Please give an overview of the authorisation process to manufacture medicinal products. In particular:

- To which authority must the application be made?
- What conditions must be met to obtain authorisation?
- Are there specific restrictions on foreign applicants?
- What are the key stages and timing?
- What fee must be paid?
- How long does authorization last and what is the renewal procedure?

Application
COFEPRIS grants medical licences.
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.

Historically COFEPRIS only granted medical licences to manufacturers in Mexico, due to a lack of resources to inspect production processes abroad. However, in 2008 the Mexican government eliminated the plant inspection requirement, which was replaced by a certificate of good manufacturing practice issued by the authority of the country of origin, with inspection visits only in high-risk cases.

Key stages and timing

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

Fee

The fee is approximately US$6,000 (as at 1 November 2010, US$1 was about EUR0.7).

Period of authorisation and renewals

Drug manufacturers must renew their licence every five years, subject to the relevant tests, including the presentation of a certificate of good manufacturing practice.

6. What powers does the regulator have to:
· Monitor compliance with manufacturing authorisations?
· Impose penalties for a breach of a manufacturing authorisation?

COFEPRIS has a Permanent Pharmacovigilance Programme. This is based on the information on possible adverse effects of the drugs given 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.

CLINICAL TRIALS

7. Please give an overview of the regulation of clinical trials. In particular:
· Which legislation and regulatory authorities regulate clinical trials?
· What authorisations are required and how is authorisation obtained?
· What consent is required from trial subjects and how must it be obtained?

· What other conditions must be met before the trial can start (for example, the requirement for a sponsor and insurance cover)?
· What are the procedural requirements for the conduct of the trial (for example, using certain medical practices and reporting requirements)?
Clinical trials are regulated by the Regulation for Health Investigation (RHI), which is enforced by the Ministry of Health and COFEPRIS.
Clinical trials require:
· Authorisation from the head of the health institution where the proceeding will take place.
· Ministry of Health supervision.
· A favourable opinion from the Committee of Investigation, Ethics and Biosafety.
A clinical trial requires the subject's consent with:
· A written formality before two witnesses.
· Full information about the nature and risks of the proceedings.
· Free will.
The information provided to the subject of the clinical trial should be detailed and accurate.
There is no express obligation for subjects of clinical trials to be insured. However, the institution running the clinical trial must provide medical assistance and financial indemnification for damages caused.
The RHI also provides the guidelines and standards for the trial protocol, including rules on the documentation, compilation, confidentiality and reports.

MARKETING

8. Please give an overview of the authorisation process to market medicinal products. In particular:
· To which authority must the application be made?
· What conditions must be met to obtain authorisation?
· What are the key stages and timing?
· What fee must be paid?
· How long does authorisation last and what is the renewal procedure?
Application
COFEPRIS grants marketing authorisations for medicines and other goods.

Conditions

The LGS and its regulations have been reformed to establish clear rules to improve the safety and efficacy of approved medicines thorough standard clinical trials. 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 does not exist in the national market.
- Drugs or medications on the market but with a different therapeutic indication.

Amendments were made to the RIS in 2008 to assure safety and efficacy by eliminating the concept of similar products and including a requirement for an interchangability test for the approval of generics. Although this reform eradicated the concept of similar products and assures the quality of generic medicines, this modification now contradicts the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS) and North America Free Trade Agreement (NAFTA) because it disregards data package exclusivity. Generic applications now benefit indirectly by proving safety and efficacy through interchengability tests with the product of reference, with no minimum five-year period of no-reliance as required by NAFTA. Actions are being tested before the courts to recognise data package exclusivity rights.

Key stages and timing

The average time to obtain a marketing authorisation in Mexico is between 12 and 18 months.

Fee

Fees are approximately:

- New molecules: US$9,000.
- Generics: US$5,000.
- Herbals: US$1,000.

Period of authorisation and renewals

The period before renewing a marketing authorisation is five years. As the renewal requirement derives from recent modification to the regulations, its application and interpretation has recently caused several problems for the pharmaceutical industry.

9. Please briefly outline the abridged procedure for obtaining marketing authorisations for medicinal products. In particular:

· Which medicinal products can benefit from the abridged procedure (for example, generics)?
· What conditions must be met?
· What procedure applies and what information can the applicant rely on?

Generic companies obtain marketing authorisation for a generic product by providing dissolution profiles or bioavilability studies for the innovator's product. A generic applicant therefore benefits indirectly from the safety and efficacy studies contained in the innovator's dossier. This is a violation of the international treaties such as NAFTA and TRIPS, which give a minimum term of five years indirect reliance on data exclusivity to avoid unfair commercial use of the undisclosed information provided by the innovators to the regulatory agencies. Actions are being tested before the courts to recognise data package exclusivity rights.

10. Are foreign marketing authorisations recognised in your jurisdiction? If so, please briefly outline the recognition procedure.

In general, Mexico does not recognise foreign marketing authorisations. However, some licences and authorisations can be recognised or granted in Mexico based on co-operation agreements signed by Mexico and other countries.

11. What powers does the regulator have to:
· Monitor compliance with marketing authorisations?
· Impose penalties for a breach of a marketing authorisation?

COFEPRIS can impose strong administrative and criminal sanctions for breaches and violations of rights and obligations under marketing authorisations.

12. Are parallel imports of medicinal products into your jurisdiction allowed? If so, please briefly outline what conditions must be met by the parallel importer. Can intellectual property rights be used to oppose parallel imports?

Parallel imports are allowed in Mexico for trade marks where both the:
· Product was legally introduced in the country of origin.
· Trade mark is owned by the same company or a related company in Mexico.

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

13. Please briefly outline the restrictions on marketing practices such as gifts 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 therefore are 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 LGS 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.
14. Please briefly outline the restrictions on marketing medicinal products on the internet, by e-mail and by mail order.
Electronic advertisement falls under the general rules for advertising in Article 2 of the Regulation of the General Law of Health regarding Advertising (*Reglamento de la Ley General de Salud en Materia de Publicidad*) (RGLHRA). There are no specific rules on internet advertisement.

ADVERTISING

15. Please briefly outline the restrictions on advertising medicinal products. In particular:

- Which legislation applies and which regulatory authority enforces it?
- What types of medicinal product cannot be advertised?
- What restrictions apply to advertising that is allowed?
- If advertising over the internet is treated differently, please identify the differences.

Advertising of medicinal products in Mexico is governed by the RGLHRA and

opinions issued by the Advertising Council. COFEPRIS enforces the provisions on advertising.

The IPL and the Federal Law for Protection of Consumers both have provisions on advertising, and 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.

Only non-prescription medicines can be advertised to the general public and it is not possible to advertise prescription medicines to the general public (*Article 310, LGS*). Any visual or audio advertisement for non-prescription medicines must bear the message "Consult your physician" and must mention any required precautions when the use of the medicine represents any danger in the case of an existing pathology (*Article 43, RGLHRA*).

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

Electronic advertisement falls under the general rules for advertising in Article 2 of the RGLHRA and there are no specific rules for internet advertisement. However, the health authorities monitor internet advertisements less stringently that television or radio advertisements and there are few cases of actions by COFEPRIS related to internet advertisements.

PACKAGING AND LABELLING

16. Please briefly outline the regulation of packaging and labelling of medicinal products. In particular:

- Which legislation applies and which regulatory authority enforces it?
- What information must the packaging and/or labelling contain?
- What other conditions must be met (for example, information being stated in the language of your jurisdiction)?

Packaging and labelling of medicinal products is regulated by the:

- LGS.
- RIS.
- NOM 072-SSA1-1993 relating to the labelling of medicinal products.

COFEPRIS is responsible for enforcing the provisions relating to the packaging and labelling of medicinal products.
The labelling of medicinal products must include the following information (*NOM 072-SSA1-1993 and RIS*):

- 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.
- Sanitary registration code.
- Batch number.
- Expiration date.
- Manufacturer's and, if applicable, distributor's information, including address.
- Content.
- Maximum price to the public.
- Active ingredients description.
- In cases of drugs with 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.

The information can be stated in another language, although the information must also be stated in Spanish in the same font and at least in the same size.

TRADITIONAL HERBAL MEDICINES

17. Please briefly outline the regulation of the manufacture and marketing of traditional herbal medicinal products in your jurisdiction.
Traditional herbal medicinal products can contain excipients and additives besides vegetable materials (*Health Products Regulation*).

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 advertisement must bear the message "Consult your physician" (*Article 310, LGS*).

Advertisements must limit themselves to indicating the general characteristics of the product, its therapeutic properties and use.

18. What types of medicinal products and related substances and processes can be protected by patents and what types cannot be patent protected? If process patents only are available for these products and substances, please give details including whether the situation is likely to change. What are the legal criteria to obtain a patent? Which legislation applies?

Patent applications are regulated by the IPL and its regulations.

Products and processes can be subject of a patent protection under the IPL.

In 1991 the IPL was reformed, removing the prohibition on patenting medicinal products and pharma-chemicals. The Mexican Institute of Industrial Property (IMPI) now grants patents protecting the compounds, formulations, uses and manufacturing processes of medicines.

Article 19 of the IPL 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.

Patentable inventions must (*Article 16, IPL*):

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

19. How is a patent obtained? In particular:

- To which authority must the application be made?
- What fee must be paid?
- What are the key stages and timing?
- Does the patent office operate a deposit system or are applications subject to some form of scrutiny before acceptance?

The authority

Applications must be made to the IMPI.

Fee

The government fees are:

- Filling a patent application: about US$720.
- Issuing the patent title: about US$300.
- Annual payments:
  - years one to five: US$100.
  - years six to ten: US$120.
  - years 11 to 20: US$150.

Process and timing

The average time for obtaining a Mexican patent varies depending on the field of technology. Generally, it takes from four to six years to obtain a patent.

A patent is obtained by filing a patent application with the IMPI.

The key stages are:

- Filing a patent application with the IMPI. The patent application consists of a narrative statement about the invention that includes:
  - 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, the corresponding Spanish translation must be filed within two months commencing from the filing date.

A filing date is received by filling a request form, delivering the narrative statement and submitting the application to the IMPI at its central or regional offices.

- The certified copy of the priority right document (only applicable to Paris Convention for the Protection of Industrial Applications 1976 [Paris Convention]) must be filed within three months from the filling date.
- The IMPI conducts a formal examination of the documentation and may order clarifications or further details, or that omissions be remedied. If so, an official communication requests the outstanding documents (that is, a power of

attorney and an assignment of rights). This communication is usually issued 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 with these requirements in the four-month total term, the application is deemed to be abandoned.

· After all the formal documents have been filed an official communication is issued that all the formal requirements are complied with and taking note of the priority claimed, when applicable.

· The abstract is published in the *Official Gazette*. This step normally occurs 18 months after the 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 concurrently with filing the application.

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

· Maintenance fees are due every five years until the life of the patent is terminated.

20. How long does patent protection last? How is a patent renewed or patent protection extended? If the patent itself cannot be extended, can the organisation's monopoly rights be extended by other means, such as supplementary protection certificates or (regulatory) data exclusivity periods?

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

The patent cannot be renewed.

In general, Mexican law does not allow patent term extensions. However, there are two specific situations where there may be an exception:

· In 1991 the IPL was amended to allow patenting of pharmaceutical compounds. These patents were subject to a pipeline regime in which the life term of the mexican patent was tied to the life term of a patent application or

patent granted abroad. This caused several patent terms to be modified either directly by IMPI or through litigation, when proven that the patent application had a different life term. All of these patents will expire no later than June 2012.

· NAFTA establishes in Article 1709 section 12 the possibility of patent correction cases due to delay in regulatory proceedings. However, Mexican domestic law has not adopted this provision and therefore, the direct enforcement of NAFTA would be very difficult to obtain in Mexico.

21. In what circumstances can a patent be revoked?

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

· 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 the publication of the patent in the *Official Gazette* occurred or when registration becomes effective.

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

The IPL 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:

· Ownership or recorded licence over a granted, valid and fully in force patent. Generally, a certified copy of the “Me wrapper” of the patent prosecution is enough to prove these requirements. Validity of the patent may be challenged by the defendant.

· The 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. When a plaintiff claims infringement of a patented

process, the defendant has the burden of proving the use of a process other than the patented process. There are no grounds in the IPL to apply the contributory infringement doctrine.

· Use of the patented invention. The IPL only recognizes 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. First, the claimant must define the scope of the approved claims. The IPL provides that the span of the claims is determined by the wording of the claims, aided by the description and drawings. The interpretation of the claims and the use of the patented invention of the infringing product or process are technical issues. Therefore, infringement actions may require expert evidence even though the technical department of the Patent Office will provide a report to its legal team.

· Non-authorised use. The burden of proving authorisation is on the defendant. The doctrine of implied licence has never been tested before the Mexican courts.

TRADE MARKS

23. Can a medicinal product brand be registered as a trade mark? What are the legal criteria to obtain a trade mark? Which legislation applies?

Brands for medicinal products can be registered as trade marks. Trade marks in Mexico are regulated under the IPL. 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, IPL*).

Three-dimensional forms can be protected as trade marks, as these are visible signs, if they comply with the principle of distinctiveness.

However, the IPL establishes the following limitations for three-dimensional marks:

· They are not in the public domain.

· They have not fallen into common use.

· They are sufficiently original to be easily distinguished.

· The shape does not represent the product and is not imposed by the product's function.

The IMPI holds that the slightest indication of a product shape can trigger an objection or rejection based on the mark being merely descriptive and not sufficiently descriptive. This is problematic for pharmaceutical products where the trade mark application purports to protect the shape, combination of colours and/or designs in the pills and tablets. Fortunately, case law shows that in reviewing the IMPI's rejections, the Mexican courts have taken a trade mark fashion interpretation of prohibitions that were focused on distinctive and non-functional elements, and some of the rejections by the IMPI have been reversed.

New marketing authorisations granted by COFERPRIS for two or more provisions that are orthographic or phonetically similar must differ at least by three letters of each word (*Article 23, Regulation of the LGS*). This is known as the three letters rule.

The IMPI studies and grants trade mark registrations, but also reviews in the first stage of any administrative litigation, in which IMPI has been reluctant to apply the three letters rule. The IMPI's interpretation of the IPL and the Regulation of the LGS is controversial and may lead to undesirable scenarios, such as contrary decisions by the IMPI and COFERPRIS on the likelihood of confusion over the same trade mark. However, some courts have determined that the three letters rule must be taken into consideration by the IMPI when deciding the likelihood of confusion between trade mark registrations applied for by pharmaceutical products. As there is legal uncertainty, an analysis is required on a case-by-case basis.

24. How is a trade mark registered? In particular:

- To which authority must the application be made?
- What fee is payable?
- What are the key stages and timing**?**

The authority

The application is made to the IMPI.

Fee

The government fees for filing a trade mark application are around US$25. If objections are faced, further fees may be accrued in the region of US$125.

Process and timing

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 regarding designs are mainly conducted manually by the IMPI.
All new trade mark applications are subject to a dual examination by the IMPI. The first formal examination is focused on checking compliance with all formal legal requirements (the official application form must be duly completed and the government fees paid, and so on). After this the second examination takes place. The inherent registrability (without evidence of use) is determined at this second stage, that is, whether the proposed trade mark has any negative linguistic (or other) connotations that would make it unacceptable in the local language, and so on. The examiners then conduct an online search of the IMPI's database to determine whether there is already a trade mark (on record or at the registration stage) that could be considered 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 between them is triggered by their graphic, phonetic or conceptual aspects, and considering the similarities between the products or services of interest.
If the examiners find that a prior mark is a barrier to registration of the proposed mark or that the application does not comply with all the formal requirements, an official action is issued detailing these reasons and granting the trade mark applicant a two-month term (automatically extendable for a further two months) to comply with the formal requirements or to provide legal arguments. The IMPI then grants or refuses the registration. On request of the applicant, the IMPI holds the trade mark application while a legal action against the prior registrations takes place.
There is no opposition system in Mexico and currently the approach of the IMPI is to not recognise consent letters or co-existence agreements for identical or confusingly similar trade marks owned by different parties.
25. How long does trade mark protection last? How is a trade mark renewed?
Trade mark registration 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 may 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, through the payment of an additional government fee.
If the registration is not used and not contested by any third party, it remains in full force until its renewal.

A trade mark registration can only be renewed if the interested party presents proof of payment of the fee and presents an affidavit to the effect that it uses the trade mark on at least one of the products or services and that it has not interrupted this use for at least three consecutive years, otherwise the renewal is not allowed and the registration lapses.

The government fees for renewing a trade mark are around US$269. IMPI charges US$7 extra for each month of late filing after the renewal date during the grace period.

The estimated time frame for a trade mark renewal is approximately two months from application.

26. In what circumstances 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), IPL*):

· 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 (such as import restrictions or other government requirements).

Trade marks can be cancelled if (*Article 151, LIP*):

· The registration was granted in contravention of the provisions of this law or of the law that was in effect at the time of its registration, although the nullity 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 used in the country or abroad before the application for the registered trade mark 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 made within five years of the trade mark's registration.

· The registration was granted in error. An action on these grounds must be made within five years of the trade mark's registration.

· The agent, representative, user or distributor of a trade mark registered abroad request 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 made at any time.

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

A trade mark registration can be enforced against alleged infringers in two different venues:

· The IMPI, if the infringer is using a confusingly similar trade mark distinguishing identical or similar goods or services to the one covered by registration. The IMPI can impose a fine and order an immediate halt to the infringing activities. A civil action to claim damages before a civil court is possible once the IMPI's resolution declaring the infringement of a trade mark registration is final and beyond the possibility of appeal. When an infringement case has come to a conclusion, a successful claimant is entitled to claim no less than 40% of the entire sales of the infringing product at the sale price before a civil court.

· The Federal Prosecutor's Office, if the infringer is using a trade mark identical to the one registered to distinguish the same goods or services (falsification or counterfeiting). There are no other criminal provisions on trade mark enforcement.

28. Is there a requirement for a patent or trade mark licence agreement to be approved by any government or regulatory body? If so, please provide details including anticipated timelines and cost.

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 with the IMPI (*IPL*).

COFEPRIS can request applicants to prove whether they are the owner or licensees of the patents in the*Linkage Gazette*. A similar situation may occur for trade marks under the three letters rule (*see Question 23*).

The government fees to record a patent licence agreement before the IMPI are around US$316. The government fees to record a trade mark licence agreement before the IMPI are around US$39. Completing the licence agreement can take two to three months.

29. Is there a requirement for remittance of royalties payable under a patent or trade mark licence agreement to a foreign licensor to be approved by any

government or regulatory body? If so, please provide details including anticipated timelines and cost.

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

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

Mexico is a signatory to the following international trade mark treaties:

- NAFTA (Sixth Part, Chapter XVII-Intellectual Property).
- TRIPS.
- Paris Convention.
- The Mexico-France Convention for the Mutual Protection of Industrial Property (1900).
- The Mexico-EU Free Trade Agreement (Chapter VI- Intellectual Property).
- The Mexico-Uruguay Free Trade Agreement (Chapter XV-Intellectual Property).
- The Mexico-Salvador-Guatemala-Honduras Free Trade Agreement (Chapter XVI- Intellectual Property).
- The Mexico-Chile Free Trade Agreement (Chapter XV-Intellectual Property).
- The Mexico-Nicaragua Free Trade Agreement (Chapter XVIII- Intellectual Property).
- The Mexico-Colombia-Venezuela Free Trade Agreement (Chapter XVIII-Intellectual Property).
- The Mexico-Costa Rica Free Trade Agreement (Chapter XIV-Intellectual Property).
- Patent Cooperation Treaty

PRODUCT LIABILITY

31. Please give an overview of medicinal product liability law, in particular:

- Under what laws can liability arise (for example, contract, tort or statute)?
- What is the substantive test for liability?
- Who is potentially liable for a defective product?

Legal provisions

In general terms, liability arises from provisions in federal or local Civil Codes in Mexico. Liability can also arise from statutory terms.

Substantive test

Liability claims are mainly regulated by statutes and not by court precedents. Therefore, there is no clear substantive test.

Liability

Individuals who are guilty of the manufacturing, distributing, storage and transportation in case of falsification, alteration and contamination of products can be liable.

32. What are the limitation periods for bringing product liability claims?

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

33. What defences are available to product liability claims?

Equity defences are available.

34. What remedies are available to the claimant?

Preliminary injunctions can be ordered to stop the commercialisation and distribution of a product. Monetary compensation is the most common but equitable remedies would also be available.

35. Are class actions allowed for product liability claims? If so, are they common?

Class actions are not allowed under Mexican Law. However, there is a current proposal to pass a law to allow for class actions. Currently, the *accion popular* is available in which 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.

36. Are punitive damages allowed for product liability claims? If so, are they common? What comment can you make about likely quantum?

Punitive damages are not subject to regulation and there are no public precedents to make estimations.

REFORM

37. Please summarise any proposals for reform and state whether they are likely

to come into force and, if so, when.

The general legal definition of biotech drugs and biocomparable medicines in Article 222 of the LGS was adapted in June 2009.

However, the tests necessary to establish therapeutic equivalence or biocomparability, and how to identify these products in the market, remain to be decided by the Regulation for Biological Products, which is still under discussion. The draft regulation:

- Defines tests for comparability between an innovator and a biocomparable drug.
- Requires biocomparable drugs to use the same name for the active ingredient as the innovator.
- Eliminates the three-year research exemption for submitting an application for marketing authorisation before patent expiration, with the intent of launching after the date of expiry (which was similar to the US Roche-Bolar safe harbour exemption). Under the draft regulation the submission can be made at any time. This will also be applicable to chemical drugs.
- Establishes the periods that COFEPRIS has for approval of both innovator and biocomparable drugs.

The Federal Commission for Improvement of the Mexican Regulation (COFEMER) is currently reviewing submissions by different sectors of the pharmaceutical industry, for and against the new regulation. A decision by COFEMER authorising or modifying the new regulation is expected in the first quarter of 2011.