by Alejandro Luna, Alejandro Torres, Ingrid Ortíz and Laura Medina

Trends and developments

Legal developments

Are there any notable trends or recent legal developments in your jurisdiction's pharmaceutical industry?

It is expected that the North American Free Trade Agreement will be soon reviewed, renegotiated or terminated. However, there is a degree of uncertainty about the issue.

Legal framework

Legislation

What is the primary legislation governing medicinal products in your jurisdiction?

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

- the General Health Law;
- the Health Supplies Regulation;
- the Official Mexican Standards; and
- the Mexican Pharmacopoeia.

Are any legislative changes proposed or expected in the near future?

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

There is a multiparty scheme in place for th

e TPP to enter into force. However, considering that the United States has recently withdrawn from the ratification process, there is a degree of uncertainty about the issue.

In this regard, it is possible that Mexico will execute bilateral agreements with some of the 12 Pacific Rim countries. It is expected that the eventual bilateral free trade agreements will have a TPP standard.

Regulation

Which bodies regulate medicinal products in your jurisdiction and what is the scope of their powers?

The authority responsible for enforcing the regulatory framework in relation to medicines is the Federal Commission for Protection Against Sanitary Risk, which is part of the Ministry of Health.

Are any other legal regimes applicable to the trade of medicinal products (eg, competition, international trade, data protection, consumer protection)?

Other legal regimes applicable to the trade of medicinal products include:

- competition;

- antitrust;
- transparency;
- data protection regarding clinical trials and other activities involving patents or clinical data;
- consumer protection; and
- industrial property.

Are any medicinal products exempt from regulation (eg, complementary and alternative medicines)?

No medicinal products are exempt from regulation.

Supply

Manufacture

What is the authorisation procedure for the manufacture of medicinal products in your jurisdiction?

Companies manufacturing medicines and medical products in Mexico must be approved by the Federal Commission for Protection Against Sanitary Risk (COFEPRIS) through a manufacturing licence or authorisation.

What is the fee for obtaining authorisation?

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

What is the validity period for authorisation?

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

How robust are the standard good manufacturing practices followed in your jurisdiction?

Good manufacturing practices are well adhered to in Mexico.

COFEPRIS can make onsite visits at any time to inspect premises and verify compliance, and can initiate *ex officio* legal proceedings to penalise non-compliance. Ultimately, these legal proceedings can result in the revocation of marketing authorisation.

Good manufacturing practices, stability, labelling standards and all other applicable provisions must be complied with. A programme to recall and destroy products that do not meet quality standards must be in place.

What are the consequences of failure to obtain manufacturing authorisation and/or follow good manufacturing practices?

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

- the seizure of products; and

- ordering partial or total suspension of activities, services or advertisements.

Under certain conditions, COFEPRIS has statutory authority to revoke any manufacturing approval and impose penalties, ranging from a fine of up to 16,000 times the minimum wage (approximately $3,523) to closure of the establishment.

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

Distribution

How are the distribution and storage of medicinal products regulated?

The Official Mexican Standard (NOM) for the good manufacturing practice of medicinal products (NOM-059-SSA1-2015) requires a programme to recall products that do not meet quality standards in an appropriate and efficient manner. This programme must include:

- activities planned for recalling products in a rapid and effective manner;
- storage; and
- a list of authorities to be notified according to the product distribution.

Marketing authorisation holders must report any product recall decision to COFEPRIS, providing details of the products and the causes leading to the recall.

Import and export

How are the import and export of medicinal products regulated?

A marketing authorisation granted by COFEPRIS is required when importing medicinal products.

Foreign marketing authorisations are not valid in Mexico. However, COFEPRIS has set a special procedure for drugs requiring first-time approval in Mexico, but that have been approved by equivalent regulatory authorities abroad. In this procedure, the approval requirements of the foreign agencies are recognised as equivalent to those in Mexico.

Are parallel imports permitted in your jurisdiction?

Any import of drugs, health products or raw materials for drugs must be approved by COFEPRIS. Marketing authorisations are required. The import of a minimum quantity of products without a marketing authorisation can be approved in certain circumstances (eg, clinical trials and orphan drugs).

Regarding IP rights, parallel imports are allowed in Mexico in relation to trademarks where:

- the product was legally introduced in the country of origin; and
- the trademark is owned by the same company or a related company in Mexico.

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

Sale and purchase

What rules govern the dispensing, sale and purchase of medicinal products?

Price control in the private sector is based on a self-regulated maximum retail price (MRP) scheme covering patented products, which is overseen by the Ministry of Economy. The participation of pharmaceutical companies 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 penalties for MRP violations.

In 2008 the government created the Committee for the Negotiation of Drug Prices to:

- support public acquisitions through a process of transparent negotiation between public insurers and pharmaceutical companies; and

- evaluate cost benefits of new medicines and therapies in view of prices and other comparable products in the market.

Are there any restrictions on the online sale and purchase of medicinal products?

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

Named patient supply

What rules govern named patient supply of pre-launch medicinal products?

The following rules govern named patient supply of pre-launch medicinal products:

- the Code of Good Practices of Advertising of the National Chamber of the Pharmaceutical Industry (CANIFARMA);

- the CANIFARMA Code of Ethics;

- the Health Law Regulations; and

- the NOM-072- SSA1-2012 for medicinal products labelling.

Clinical trials

Authorisation

What is the authorisation procedure for conducting clinical trials in your jurisdiction?

Any research on human beings must be approved by the Federal Commission for Protection Against Sanitary Risk (COFEPRIS). Research can include testing new medicinal products and new uses, as well as dosages and administration routes for already approved medicinal products. Essentially, the main requirements for an application for authorisation from COFEPRIS include:

- approval by an independent ethics committee registered with the Ministry of Health;

- approval by the medical institution or institutions where the clinical trials will be conducted;

- COFEPRIS approval for institutions to conduct clinical trials;

- clinical trial protocol (including a schedule and the approximate amount of medicinal products to be imported);

- written informed consent templates;

- pre-clinical and clinical data that justifies conducting the research;

- a description of available resources to conduct the research and to address emergencies (including a statement of sponsorship); and

- a written letter by the qualified investigator acknowledging his or her responsibilities, and data from the qualified investigator and his or her staff.

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

Clinical practices

How robust are the standard good clinical practices followed in your jurisdiction?

Good clinical practice in Mexico is well regulated. However, although the regulation is robust, there is scope for improvement. Currently, efforts are in place to reach international standards.

Reporting, disclosure and consent

What are the reporting and disclosure requirements for the results of clinical trials?

The Health Law Regulations for Health Research and the Official Mexican Standard (NOM) for health research in human beings provide the guidelines and standards for the clinical trial protocol, including rules concerning documentation, compilation, confidentiality and reports.

Essentially, according to the NOM for health research in human beings, any clinical trial must be conducted following ethical guidelines regarding the dignity, rights and welfare of human beings.

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

- medicinal products labelling (NOM-072- SSA1-2012);

- pharmacovigilance (NOM-220-SSA1-2012);

- interchangeability and bio-comparability tests (NOM-177-SSA1-2013);

- biological products (NOM-257-SSA1-2014);

- good manufacturing practices for medicinal products (NOM-059-SSA1-2015); and

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

What are the informed consent obligations with respect to clinical trial subjects?

Investigators must collect informed consent from research participants in a formal written document signed by two witnesses. A participant must grant consent on a voluntary basis, with sufficient access to information regarding potential risks and benefits. Participants maintain the right to give up the research at any time. Investigators must ensure post-care for patients until it is clear that no damage has occurred as a result of the research.

Insurance

What are the insurance requirements for clinical trials?

According to NOM-012-SSA3-2012, regarding clinical trials in human beings, the clinical trial budget should include compensation to which the subject of investigation will be legally entitled in case of damages directly related to the clinical trial. Where appropriate, this financial fund may be covered under study insurance.

Data protection

What data protection issues should be considered when conducting clinical trials?

The primary legislation is the Personal Data Protection Law. This legal framework requires the person or entity in charge of compliance to observe consent, quality, purpose, loyalty, proportionality, responsibility, security and confidentiality requirements. It relates to the pharmaceutical legal framework (eg, health research, clinical trials and pharmacovigilance).

The NOM for health research in human beings requires protection of access, rectification, cancellation and opposition rights of research participants by deferring to the Personal Data Protection Law. Investigators and committees of the institution where the research is conducted must protect participants' personal data in the research and publishing stages. Investigators must collect informed, valid consent from research participants.

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

Marketing authorisation

Authorisation

What is the marketing authorisation procedure for medicinal products in your jurisdiction?

Manufacturers must obtain marketing authorisation from the Federal Commission for Protection Against Sanitary Risk (COFEPRIS) to sell any medicinal product. Requirements and timeframes vary among new molecules, biologics and follow-on products. An Official Mexican Standard (NOM) compiling the requirements for granting marketing authorisations for medicinal products (NOM-257-SSA1-2013) is in place. In addition, there is a NOM for the specifications of stability tests (NOM-073-SSA1-2015), which was published in

2016. This NOM specifically addresses the test for stability to be carried out on drugs in Mexico (World Health Organisation classification: Climate Zone II, subtropical with possible high humidity). Article 166 of the Health Law Regulations sets out the following approval timeframes:

- 180 calendar days for medicines including an active pharmaceutical ingredient or therapeutic indication already approved in Mexico;

- 240 calendar days for medicines approved abroad but not in Mexico; and

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

The approval timeframe for biologics and bio-comparables is 180 calendar days (Articles 177 and 177*bis* 4 of the Health Law Regulations).

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

What criteria are considered in granting marketing authorisation?

New molecules

Essentially, applicants for marketing authorisations must prove the safety and efficacy of their products through:

- standard clinical trials;

- adherence to General Health Law regulations; and

- adherence to NOMs regarding good manufacturing of medicines and active ingredients.

Applicants must also seek approval of their products as new molecules from the COFEPRIS New Molecules Committee. According to Article 2(15) of the Health Law Regulations, a new molecule is:

- an active ingredient or drug not approved worldwide (new molecular entity);

- an active ingredient or drug without approval in Mexico but already available in other countries, but with limited clinical experience or disputed information;

- a drug which is a non-marketed combination of two or more active ingredients; and

- an active ingredient or drug already available in the market, but to be marketed for a new therapeutic indication.

Research and development companies can benefit from a special procedure for

drugs which have been previously approved by a regulatory authority abroad but require first-time approval in Mexico.

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

Recently, the NOM setting the test to prove that a generic drug is interchangeable with a reference drug was updated (NOM-177-SSA1-2013). Legally, COFEPRIS should not grant marketing authorisation for generics breaching exclusivity rights.

There is a linkage system between COFEPRIS and the Mexican Institute of Industrial Property (IMPI), which aims to prevent the granting of marketing authorisation in violation of patent rights. According to the IP Regulations, every six months the IMPI must publish patents covering allopathic medicines in the *Linkage Gazette*. The initial IMPI position was that only patents relating to a compound were relevant to linkage review (excluding formulation and use patents). On July 31 2012, for the first time, the IMPI included formulation patents in the *Linkage Gazette*, in accordance with a 2010 Supreme Court ruling (2a/J7/2010, *Federal Judicial Gazette,* XXXI, page 135).

Use patents and purpose limited product patents are included in the *Linkage Gazette* by court orders, since the IMPI considers that they should not be included in the linkage system.

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

Biologics Recent amendments to the legal framework to regulate the approval of biologics are being tested. Applicants must prove the quality, safety and efficacy of products under the General Health Law, its regulations and applicable NOMs, particularly those for good manufacturing practices for

medicinal products (NOM-059-SSA1-2015) and active ingredients (NOM-164-SSA1-2015).

According to NOM-257-SS1-2014, all biological drugs authorised before the legal reform and that are still on the market must enter a regularisation process to comply with the new biologics standard. NOM 257 emphasises that key points to ensure the safety, efficacy and quality of biologics are regulated by other Official Standard Rules (eg, regarding clinical trials and pharmacovigilance). NOM 257 empowers the Assessment Sub-committee on Biotech Products (SEPB) to:

- assess technical and scientific data in connection with clinical trials, approval or renewal of innovator biologics or follow-on biologics (biocomparables); and

- issue opinions to characterise biologics as innovators, reference products or biocomparables.

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

- COFEPRIS will assess whether biologics refer to innovators or biocomparables;

- renewal applications for innovators will not require SEPB assessment; and

- renewal applications for biocomparables will require prior SEPB assessment to identify the product of reference in order for applicants to submit the corresponding tests.

These provisions apply only to renewal applications submitted before December 31 2015. However, COFEPRIS missed an opportunity to address the uncertainty in respect of regulatory data protection for biologics, as NOM 257 does not provide for guidelines in this regard.

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

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

- *in vitro* studies;

- a comparative pharmacokinetic test, if determined by the Ministry of Health, to show pharmacokinetic comparability on key parameters between both the follow-on and reference biologic;

- pharmacodynamics test reports; and

- a comparative efficacy and safety clinical test to show similarity between the follow-on and reference biologic.

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

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

What is the fee for obtaining marketing authorisation?

Government fees for analysing marketing authorisation applications are as follows:

- new molecules and biologics – $8,600; and

- generics and biocomparables – $4,800.

What is the validity period for marketing authorisation?

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.

What are the consequences of failure to obtain marketing authorisation?

Manufacturers that do not obtain a marketing authorisation from COFEPRIS cannot sell the applied-for medicinal product.

Pharmacovigilance

Monitoring

What post-market monitoring mechanisms are in place to ensure the ongoing safety and efficacy of medicinal products after marketing authorisation has been granted?

The Federal Commission for Protection Against Sanitary Risk (COFEPRIS) has a permanent pharmacovigilance programme based on information regarding possible adverse effects of drugs issued by:

- doctors and physicians, on a voluntary basis;
- the pharmaceutical companies that manufactures the products; and
- conductors of clinical trials.

Under the Health Law Regulations and Official Mexican Standards (NOMs), COFEPRIS's monitoring is focused, among other things, on:

- ensuring compliance with good manufacturing practices and standard operating procedures;

- ensuring that activities do not exceed the limits set by the authorisation and do not differ from those activities which are authorised; and

- ensuring the performance of validation analysis of the manufacturing processes and systems involved.

Data protection

What data protection issues should be considered when conducting pharmacovigilance activities?

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

The NOM for health research in human beings requires the protection of access, rectification, cancellation and opposition rights of research participants by deferring to the Personal Data Protection Law. Investigators and committees of the institution where the research is conducted must protect the personal data of participants in the research stages and publishing stages. Investigators must collect informed, valid consent from research participants.

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

Pricing and reimbursement

Pricing

Are there rules governing the pricing of medicinal products in your jurisdiction?

Price control in the private sector is based on a scheme of self-regulated maximum retail price (MRP) covering patented products and overseen by the Ministry of Economy. The participation of pharmaceutical companies 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. In 2008 the government created the Committee for the Negotiation of Drug Prices (CNDP) to:

- support public acquisitions through a process of transparent negotiation between public insurers and pharmaceutical companies; and

- evaluate cost benefits of new medicines and therapies in view of prices and other comparable products in the market.

Reimbursement

What is the structure for state reimbursement of medicinal product costs?

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 (IMSS), Social Security for State Workers (ISSSTE) and Seguro Popular. The Seguro Popular was created for people with lower incomes. The federal government pays 70% of the annual family premium, while states provide 20% and participants provide 10%.

Public insurers dispense medicinal products prescribed by their healthcare

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

For direct purchasing of patented products, the CNDP analyses the effectiveness of the 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.

For the ISSSTE, a prescribed medicinal product can be dispensed in a private drug store registered with a public insurer, provided that this is not available within ISSSTE facilities and under certain conditions. The ISSSTE reimburses the cost of that product according to previous agreements.

In the private sector, most payments are made on an out-of-pocket basis. Private insurers are improving the level of pharmaceutical coverage as the private market in medicines has grown considerably.

Advertising and labelling

Advertising

How is the advertising of medicinal products to healthcare professionals and the general public regulated in your jurisdiction?

The primary legislation on advertising of medicinal products is the General Health Law's regulations regarding advertising (RLGSMP) and opinions issued by the Advertising Council. The IP Law and the Federal Consumer Protection Law also have provisions on advertising.

The Federal Commission for Protection Against Sanitary Risk (COFEPRIS – health legal framework) and the Federal Attorney's Office of Consumers (consumer legal framework) are regulatory authorities in this field.

The National Chamber of the Pharmaceutical Industry has a code of ethics that

includes provisions on advertising. Although these provisions are not mandatory, failure to comply can result in a suspension of rights as a member of the chamber or exclusion from it.

Do any special rules apply to online advertising of medicinal products?

Electronic advertising falls under the general rules for advertising in Article 2 of the RLGSMP. COFEPRIS is increasing its monitoring of online advertisements for medicinal products, which to date has been less stringent than advertising on television and radio.

Labelling

What are the packaging and labelling requirements for medicinal products?

Packaging and labelling of medicinal products are regulated by the:

- General Health Law;
- Health Law Regulations; and
- 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.

The labelling of medicinal products should include the following:

- the distinctive brand name;
- the generic name;
- the pharmaceutical form;
- the drug concentration;
- the formulation;
- the formula description;
- the dose;
- the mode of administration;
- the conservation and storage information;
- the precaution and warning legends, including risks in case of pregnancy;
- the marketing authorisation number;

- the batch number;

- the expiration date;

- the manufacturer's and, if applicable, distributor's information, including address;

- the content;

- the maximum price to the public; and

- in cases of drugs with a biological origin, the specifications of the live organism 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.

How is the promotion of off-label use regulated?

Whereas there is no specific provision in the Health Law Regulations concerning advertisements for off-label use, advertisement activities addressed to health professionals do not require a permit from COFEPRIS; a notice of such an advertisement is sufficient. However, off-label advertisements should be avoided.

Relations with healthcare professionals

Gifts and incentives

What rules apply to the provision of gifts, discounts and other incentives to healthcare professionals?

Government officers must not request, accept or receive any gifts or donations from persons with whom they have direct links through commercial or industrial activities, including activities that they regulate or supervise (Article 8 of the Federal Law of Responsibilities for Government Officers).

Doctors working for the Social Security (IMSS) and Social Security for State Workers (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 of IMSS or ISSSTE facilities.

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 of the Code of Good Practices of Advertising of the National Chamber of the Pharmaceutical Industry (CANIFARMA)). The corresponding penalties 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.

Liability

Defect products

How can a liability claim for a defective medicinal product be brought?

Limitation periods

Depending on the conduct and cause of action, limitation periods are:

- two to 10 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, the Attorney General's Office, non-profit associations and a common representative of a group of at least 30 members can now pursue class actions. These amendments are subject to testing in the courts and apparently there are no precedents of class actions for product liability.

In addition, there is an action available whereby any individual with or without proper legal standing can file a complaint before Federal Commission for Protection Against Sanitary Risk (COFEPRIS), arguing and proving that the certain health risks are associated with a product on the market. However, the claimant's procedural rights are limited and these actions are intended to eliminate a health risk, not to obtain compensation.

Which parties can be held liable for a defective medicinal product?

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

Accordingly, the NOM states that when manufacturing through third parties, the marketing authorisation holder must supervise the manufacture of the product and establish in agreements the liabilities and duties of each party involved.

Physicians are also subject to liability for malpractice. In this case, patients can opt between filing a civil action or requiring medical arbitration from the National Commission of Medical Arbitration. The latter is a quick alternative where a non-judicial solution is proposed.

Remedies

What remedies are available to successful claimants?

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.

Exclusion and limitation

On what grounds can liability be excluded?

There are no cases where liability can be excluded.

What preventive steps can be taken to limit liability?

COFEPRIS has a permanent pharmacovigilance programme based on information regarding possible adverse effects of the drugs provided by:

- doctors and physicians on a voluntary basis;

- conductors of clinical trials (periodical reports must be submitted according to the relevant phase); and

- pharmaceutical companies (periodical safety reports must be submitted once every six or 12 months, according to the year after the granting of the marketing authorisation).

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

Compliance and enforcement

Enforcement

What measures are in place to enforce the laws governing medicinal products?

The following measures are in place to enforce the laws governing medicinal products:

- orders to stop the activity;

- fines;

- closure of the facilities where the activities take place; and

- onsite visits at any time to inspect premises.

Dishonest practices

What mechanisms are in place to combat bribery, fraud, collusion, counterfeiting and other dishonest practices in the pharmaceutical sector?

Mexico has no specific anti-bribery law to limit these practices and there is no domestic legislation to regulate such cases beyond Mexico's jurisdiction. However, Mexico has legislation to prevent such practices and has ratified certain international treaties that regulate, and in some cases prohibit, these practices.