



GETTING THE  
DEAL THROUGH 

# Life Sciences 2015

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# Mexico

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Olivares

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## Organisation and financing of health care

### 1 How is health care in your jurisdiction organised?

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

The major public segments of the Mexican health-care system are as follows:

- the Mexican Institute of Social Security (IMSS) provides social security for the self-employed and employees in private companies;
- the Institute of Social Security for State Workers (ISSSTE);
- the 'Seguro Popular' programme, which was created in 2004 as part of a strategic reform to the General Health Law (HL). It provides a public insurance scheme for those not covered by social security and other formal arrangements. Seguro Popular was created to cover people with lower incomes. The federal government pays 70 per cent of the annual family premium, states provide 20 per cent and patients provide 10 per cent; and
- other social security institutes for particular sectors, for example, for members of the military and for Mexican petroleum workers (PEMEX medical services).

Private health insurance generally covers professionals, executives and people in the higher levels of the private sector. Enrolment in private health insurance has increased considerably over the past five years.

The public health sector is generally subject to financial problems. Measures to limit costs are implemented, for example, by pressing for price reductions in public bids and encouraging competition.

### 2 How is the health-care system financed in the outpatient and in-patient sectors?

The manner in which health-care institutions are financed is based on whether they lie within the public or private sector, rather than on whether they relate to the outpatient or in-patient sector.

#### Public segments of the Mexican health-care system

The public segments of the Mexican health-care system are mostly financed through contributions from public and private sector workers. Employers and employees both pay a tax solely used to provide health-care services. There are special rules for those who are incapable of paying but are still eligible to benefit from the health-care system. In the case of the Seguro Popular programme, as mentioned above, the federal government pays 70 per cent of the annual family premium, while states provide 20 per cent and patients 10 per cent.

#### Private segments of the Mexican health-care system

According to official figures, up to 50 per cent of annual health spending in Mexico comes from out-of-pocket expenses related to private doctors and insurance, as well as drug acquisitions.

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## Compliance – pharmaceutical manufacturers

### 3 Which legislation governs advertising of medicinal products to the general public and health-care professionals?

The primary legislation regarding the advertising of medicinal products is the HL and its Regulations concerning advertising (HLR). These norms are supplemented by guidelines published by the regulatory agency, the

Federal Commission for Protection against Sanitary Risks (COFEPRIS) ([www.cofepris.gob.mx](http://www.cofepris.gob.mx)), which is part of the Ministry of Health and controls the advertising of medicinal products.

Several Industry Codes of Practices supplement the above-mentioned legislation. The Council of Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA) has issued the following self-regulatory instruments (Codes):

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

The latest versions of the Codes have been in force since 1 April 2013. Affiliate members of the National Chamber of the Pharmaceutical Industry (CANIFARMA) are required to follow the Codes. CETIFARMA supervises the compliance of members and adherents.

The Advertising Council, which includes representatives from the Ministry of Health, the academic and scientific communities, the business sector, and media and consumer groups, also issues opinions.

Additionally, other general legislation may be relevant for the advertising of medicinal products, particularly the Federal Law for the Protection of Consumers and the Industrial Property Law.

### 4 What are the main rules and principles applying to advertising aimed at health-care professionals?

According to article 42 of the HLR, advertisements directed to health-care professionals can only be published in specialised media, and must be based on the recommended information for the corresponding medicinal product, which must contain the following data:

- the distinctive denomination, if any;
- the generic denomination;
- the pharmaceutical form and formulation;
- any therapeutic indications;
- the pharmacokinetics and pharmacodynamics;
- any side-effects;
- general precautions;
- the restrictions of use during pregnancy and breast feeding;
- any secondary and adverse reactions;
- any medical interactions;
- any alterations in results from laboratory tests;
- any precautions related to carcinogenic, mutagenic, teratogenic and fertility effects;
- the dose and tract of administration;
- any manifestations and the handling of overdose or accidental ingestion;
- a presentation or presentations;
- storage recommendations;
- protection notices;
- the name and domicile of the laboratory; and
- the marketing authorisation number.

Article 42 also mentions that in cases where some of the above-mentioned data do not exist, such circumstance must be expressly mentioned.

The Code of GPP states that relationships between pharmaceutical industry personnel and health-care professionals should encourage the development of medical practices that are committed to the well-being of

patients; and that such medical practices are based on truthful and accurate information, and are tested and up-to-date in terms of scientific evidence, in order to contribute to the appropriate use of approved medicines.

### **5 What are the main rules and principles applying to advertising aimed at the general public?**

Pursuant to article 310 of the HL, only non-prescription medicines can be advertised to the general public, and the objective of the advertisements must be to inform the public about the characteristics of the products, its therapeutic properties and the form of use. Advertising is subject to approval by COFEPRIS.

Pursuant to article 43 of the HLR, any visual or audio advertisement must contain the following message: 'Consult your physician'. Advertisements should mention applicable precautions, and indicate when the use of a medicine represents any danger in the event of an existing pathology.

The Code of GPP requires that promotional activities of CANIFARMA members directed towards consumers must be undertaken with the aim of generating a new culture regarding the rational and appropriate consumption of medicines, and encouraging guidance of health-care professionals who are authorised to prescribe.

In February 2014, COFEPRIS issued detailed guidelines regarding the approval of advertisements for non-prescription medicinal products.

### **6 What are the most common infringements committed by manufacturers with regard to the advertising rules?**

The most well known recent infringements have probably been committed by manufacturers of health or dietary supplements and so-called 'miracle' products, which are launched via aggressive infomercial campaigns containing exaggerated claims about the benefits of such products. Fairly recently, the HLR were reformed to allow COFEPRIS to order both manufacturers and media outlets to cease advertising activities. Infringements can lead to high fines and closure of business.

### **7 Under what circumstances is the provision of information regarding off-label use to health-care professionals allowed?**

According to article 42 of the HLR, prescribing information about products to health-care professionals is subject to approval before publication. This information is approved while granting the marketing authorisation for the corresponding product. Any publication should contain the marketing authorisation number of the product.

The Code of GPP sets forth that information on medicinal products must be grounded on scientific evaluation and related empirical evidence, which must be kept at the disposal of health-care professionals, if required. It must not induce confusion by means of distortion, unjustified pressure, omission or any other means.

The Code of GPP also states that when scientific information is provided and is not part of the prescribing information duly approved or authorised in a product's marketing authorisation, it should be strictly limited to a scientific audience, and should avoid the promotion (directly, indirectly or through a third party) of any unauthorised directions of use.

### **8 Which legislation governs the collaboration of the pharmaceutical industry with health-care professionals? Do different rules apply regarding physicians in the outpatient and in-patient sectors?**

There are several bodies of law that refer in general terms to the relationship between the pharmaceutical industry and the health-care professionals, including the HL, the HLR and the HL Regulations concerning sanitary control of activities, establishments, products and services. The Code of GPP sets forth guidelines for promotional activities. Public institutions usually have their own particular guidelines. These regulations apply to physicians in both the outpatient and in-patient sectors.

### **9 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with health-care professionals?**

#### **Scientific and educational events**

The Code of GPP states that congresses, lectures, symposia, meetings and other similar scientific or educational events sponsored, financed or supported by pharmaceutical companies or any other third party must have, as a main purpose, scientific exchange, medical education or information about medicines.

Whenever support for continuing education or independent educational programmes is being provided, the education of health-care professionals should be encouraged, primarily, to improve their knowledge of patient care. In each case, programmes must comply with the guidelines of the applicable laws; they must have strict scientific content that is sustained, if required, by clinical evidence. Most importantly, the programmes must be accredited and certified by the corresponding academic authorities.

Support in general must not be offered, under any circumstance, in order to exert any kind of influence on the decision-making process involved in prescribing medicines, or in buying, including, excluding or modifying official product catalogues.

#### **Samples**

According to the Code of GPP, samples are provided directly, in fair amounts and without cost to health-care professionals, so that they may get to know and become familiar with the products, or in order for them to initiate a treatment, or both.

According to article 49 of the HLR, providing samples of products for free does not require approval, provided the samples meet the requirements of the approved medicinal product. The samples should be in a package that contains fewer units than are contained in the approved product.

The Code of GPP establishes guidelines regarding sampling: it prohibits CANIFARMA members offering or supplying samples with the aim of seeking or rewarding prescription practices, and also forbids any trade of samples.

CANIFARMA members are required to have full and up-to-date control of their samples, including their manufacture, storage, delivery to regional coordinators or others, and provision to medical representatives and physicians.

It is always recommended that CANIFARMA members maintain strict control over their product samples, since there have been cases of the resale of samples in the past.

#### **Gifts and donations**

The Code of GPP essentially states that companies must act responsibly regarding sponsorships and donations. No gifts of significant commercial value may be offered to health-care professionals, or incentives of any kind, as an inducement to use, prescribe, purchase or recommend a specific product, or influence the results of a clinical study.

No gifts, bonuses, pecuniary advantages, benefits in kind or any sort of incentive may be offered or promised to health-care professionals, administrative staff or government employees involved in the cycle of prescription, purchase, distribution, dispensing and administration of medicines, except in the case of inexpensive promotional aids related to the practice of medicinal or pharmaceutical activities.

The Code delineates an inexpensive promotional aid as one that does not exceed the equivalent of 10 times the minimum wage (around US\$50).

Regarding health-care professionals based in government institutions, article 47 of the Federal Law of Responsibilities for Government Officers expressly forbids such officers from requesting, accepting or receiving any gifts or donations from persons whose commercial or industrial activities are directly linked, regulated or supervised by government officers.

### **10 What are the most common infringements committed by manufacturers with regard to collaboration with health-care professionals?**

According to CETIFARMA's 2013 Annual Report, seven complaints were received during 2013. CETIFARMA issued decisions in four of those complaints. Of the remaining three complaints, one was withdrawn, another was terminated through mediation, and the final complaint was sent to the health authorities. However, CETIFARMA does not provide any details of the complaints in the Annual Report, such as the grounds for the complaints, the parties involved or the content of the decisions. According to CETIFARMA, the number of complaints in 2013 represented a reduction of 80 per cent in comparison with 2012, when there were 32 complaints.

### **11 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations?**

The Code of GPP establishes that any collaboration between the pharmaceutical industry and patient organisations must be accompanied by a

written agreement that will include, at the very least, the activities to be undertaken, and the cost, source and destination of their funding; and details of any direct and indirect support, as well as any other relevant non-financial aid.

Under these agreements, CANIFARMA members have to follow any applicable guidelines and codes of ethics and conduct, as well as the transparent practices and deontological instruments approved by CETIFARMA and CANIFARMA.

The Code of GPP requires CANIFARMA members to set forth criteria and procedures for the approval and implementation of these kinds of collaborations.

Any other kind of sponsorship provided by social, governmental or private sector organisations should not be excluded from the above-mentioned rules.

## 12 Are manufacturers' infringements of competition law pursued by national authorities?

While Mexico does have a Federal Antitrust Law and an active antitrust commission (ECCF) ([www.cfc.gob.mx](http://www.cfc.gob.mx)), few investigations have been initiated against manufacturers of pharmaceutical products.

A notable exception is a 2011 investigation that reviewed public tender proceedings before IMSS after evidence was found of collusion between manufacturers to set prices. A fine was imposed, and the case is still under appeal. ECCF has broad jurisdiction to investigate future cases of infringements of the Federal Antitrust Law.

## 13 Is follow-on private antitrust litigation against manufacturers possible?

The Federal Antitrust Law enables private entities to request investigations, as well as to provide all kinds of elements and evidence related to an investigation that is in process.

Further, once the preliminary determination of antitrust practices has been declared and published in the Mexican Government Official Gazette, anyone related to or affected by the decision has the opportunity to provide arguments and evidence.

Follow-on private litigation against manufacturers is possible, but has not been as widely pursued as it has in other jurisdictions, such as the United States.

## Compliance - medical device manufacturers

### 14 Is the advertising of medical devices and the collaboration of manufacturers of medical devices with health-care professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

Generally speaking, it would be fair to say that the regulation of medical devices is lighter than the regulation of drugs and other substances. Advertising concerning medical devices is regulated in articles 52 to 56 of the HLR. Standards contained in the Code of GPP that apply to medicines also apply to medical devices.

## Pharmaceuticals regulation

### 15 Which legislation sets out the regulatory framework for granting marketing authorisations and placing medicines on the market?

The primary legislation for medical products is as follows:

- the HL;
- the Health Law Regulations;
- the Official Mexican Norms (NOMs); and
- the Mexican Pharmacopoeia.

### 16 Which authorities may grant marketing authorisation in your jurisdiction?

The regulatory authority in charge of granting marketing authorisations is COFEPRIS. The granting of authorisations for innovator drugs is also reviewed by the New Molecules Committee of COFEPRIS, which includes physicians from the National Academy of Medicine.

## 17 What are the relevant procedures?

The relevant procedures are as follows:

### New molecules

Essentially, marketing authorisation applicants must prove the safety and efficacy of their products through standard clinical trials run according to the rules set out by the HL, its regulations and the NOMs of good manufacturing of medicines and active ingredients.

Concurrently, applicants must request the approval of their products as new molecules by the New Molecules Committee of COFEPRIS. A new molecule is, according to article 2, section XV of the Health Law Regulations):

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

Research and development companies can benefit from a special shortened procedure for drugs to be approved for the first time in Mexico if such drugs have been previously approved by one of the following organisations:

- the European Medicines Agency;
- the US Drug and Food Administration;
- Health Canada;
- Swissmedic (the Swiss Agency for Therapeutic Products); or
- the Therapeutic Goods Administration in Australia.

In 2012, COFEPRIS published new rules setting out this procedure, which is essentially based on the dossier filed with the foreign regulatory agency to reduce approval time frames by up to 60 working days. Industry participants have welcomed these new rules, but they are still being tested.

### Generics

Applicants for marketing authorisations have to prove basically 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 authorisations 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 authorisations in violation of exclusive rights. According to Mexico's intellectual property (IP) Regulations, every six months IMPI must publish 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). However, on 31 July 2012, the IMPI for the first time included formulation patents in the Linkage Gazette in accordance with a 2010 ruling of the Mexican Supreme Court. (Jurisprudence No. 2a./J.7/2010, Federal Judicial Gazette, No. XXXI, p. 135).

Under the linkage regulations, at the time of filing 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 IMPI), or state under oath that its application does not violate the list of products published in the Linkage Gazette and observes patent law.

### Biologics

Amendments to the legal framework to regulate the approval of biologics are recent and being tested. Applicants have to prove the quality, safety and efficacy of their products under the HL, its regulations and the applicable NOMs, particularly those for good manufacturing practices for medicinal products (NOM-059-SSA1-2013) and for active ingredients (NOM-164-SSA1-2013).

### Biocomparables (follow-ons)

Applicants must submit clinical tests and, when appropriate, in vitro tests, to prove that the safety, efficacy and quality of their product are comparable (similar) with those of 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 physico-chemical studies. For this, the applicant must submit the following:

- evidence from any in vitro studies;
- a report on the comparative testing of the pharmacokinetic, if determined to be necessary by the Ministry of Health to show the pharmacokinetic comparability of key parameters between both the follow-on and the reference biologic;
- any pharmacodynamics test reports; and
- the results of any comparative efficacy and safety clinical tests to show the similarity between the follow-on and the reference biologic.

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

Based on the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS) and the North America Free Trade Agreement (NAFTA), and also the hierarchy of international treaties contained within the Mexican legal system, it is possible to obtain recognition of data package exclusivity for products that deserve this protection, and to obtain court precedents recognising and ordering COFEPRIS to observe data package exclusivity.

### Orphan drugs

Orphan drugs were recently introduced into the HL and the Mexican Pharmacopeia. Specific rules regarding orphan drugs are still pending. In practice, they are currently approved under a procedure that follows the rules for new molecules when applicable and appropriate. The draft of the NOM compiling requirements for granting marketing authorisations includes orphan drugs.

### 18 Will licences become invalid if medicinal products are not marketed within a certain time? Are there any exceptions?

Prior to 2010, all marketing authorisations were issued without any sort of time limit, and therefore were not subject to expiration.

Since 2010, a reform to the law and regulations has established a five-year term for marketing authorisations. Even though proof of use is not a requirement for renewal, technical reports on pharmacovigilance are. Therefore, renewal of an authorisation for a drug that is not on the market would be denied.

### 19 Which medicines may be marketed without authorisation?

According to article 376 of the HL, all medicines require a marketing authorisation. Health supplements and herbal remedies are excluded.

### 20 Are any kinds of named patient programmes in place? If so, what are the requirements for pre-launch access?

Yes. Article 102 of the HL establishes that COFEPRIS can authorise the use of drugs or materials that have not been previously authorised for clinical trial purposes.

In addition, according to article 103 of the HL, a physician can authorise therapeutic or diagnostic resources that are still in the research phase when the potential to save lives, restore health or diminish suffering exists, as long as there is written consent and an authorisation is provided by the Ministry of Health.

A special marketing authorisation for the distribution of an unauthorised medicinal product may also be granted if a medicine meets most of the criteria, but the requirements on effectiveness and the risk-benefit ratio are merely suspected and cannot be confirmed because the number of patients involved in the clinical trial of the product is insufficient due to the rarity of the disease.

Compliance with the requirements is assessed at least once a year. At the manufacturer's request, the time limit of such provisional marketing authorisation may be extended by a maximum of one year.

### Pricing and reimbursement of medicinal products

#### 21 To what extent is the market price of a medicinal product governed by law or regulation?

Mexican law does not establish specific provisions concerning medicinal product pricing for either the outpatient or in-patient sectors. However, several mechanisms are in place that lead to a certain degree of control of such prices in practice.

Price control in the private sector is based on a scheme of self-regulated maximum retail price (MRP), only 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.

Concerning the public acquisition of innovator drugs covered by patent rights, their price is negotiated in bulk between the patent or licence holder and a government commission for price negotiation. The negotiation proceedings end with a single yearly price for all public sales.

Off-patent drugs are purchased through public tender proceedings, under which a reference price is set based on previous purchasing experiences (ie, a maximum amount that can be paid for a specific drug) and the lowest bidder is assigned the tender.

Since the government is the main purchaser of drugs, pricing for publicly acquired drugs helps regulate prices in the private sector.

#### 22 Must pharmaceutical manufacturers negotiate the prices of their products with the public health-care providers?

Yes. As mentioned above, prices for patented drugs are negotiated with a government commission and set for every public acquisition. When patent rights have expired (or in some cases when there is more than one participant in the market), drugs are acquired through public tender proceedings based on previous purchasing prices.

#### 23 In which circumstances will the national health insurance system reimburse the cost of medicines?

Commonly, public insurers dispense to patients medicinal products prescribed by their health-care professionals. Products are prescribed and dispensed from a basic medicinal products list, which public insurers essentially base on the National Formulary issued by the Ministry of Health. Public insurers acquire those listed products mostly by public tender processes.

Public health-care Institutions, scientific organisations and pharmaceutical providers may request that a drug be listed in the National Formulary. Essentially, the principal conditions for listing eligibility are that the drug has a marketing authorisation, has met all safety and efficacy tests (clinical trials), and is cost-effective (pharmacoeconomic tests).

IMSS is the largest public sector buyer of drugs. Public institutions may also have their own formularies that contain less drugs than the National Formulary.

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

#### 24 If applicable, what is the competent body for decisions regarding the pricing and reimbursability of medicinal products?

While the Ministry of Economy is empowered to issue observations regarding the pricing and reimbursability of medicinal products under the MRP scheme, the Commission for Drug Price Negotiations, which is made up of several public offices, including the Ministries of Economy and Health, negotiates with the patent holder or licensee to establish the single price of a patented drug for all sales to the public sector.

#### 25 Are manufacturers or distributors of medicinal products statutorily obliged to give a discount?

There is no obligation in Mexican law regarding this specific point; however, sales to public institutions are generally done at much lower prices than sales in the private market.

## Update and trends

### Advertising

Several amendments to the Industry Codes of Practices by CETIFARMA were approved in 2013. As a consequence of compliance practices, there is an expectation that the rules governing pharmaceutical advertisements will be strengthened by both industry associations and regulatory authorities.

In February 2014, COFEPRIS issued detailed guidelines regarding the approval of advertisements for non-prescription medicinal products. Most of these guidelines are in line with the Codes. In terms of developments, we would highlight that an advertisement providing information about a disease, if it is immediately followed by another advertisement for a medicinal product related to that disease, will not be approved unless both advertisements are approved jointly.

### Marketing authorisations

A draft NOM compiling the requirements for granting marketing authorisations for medicinal products (PROY-NOM-257-SSA1-2013) was published in 2013 for public comment and review. This draft addresses the linkage between patents and marketing authorisations. However, a uniform text in which the linkage is set for each type of product would be welcome, as the draft contains some differences in the text used according to the type of drug to be authorised. The publication of the last version of this NOM is still pending.

### Trans-Pacific partnership (TPP)

During the November 2011 Asia Pacific Economic Cooperation (APEC) meeting, Mexico outlined its willingness to initiate consultations to participate in the TPP. On 18 June 2012, during the G20 in Los Cabos,

Mexico, the countries currently participating in the TPP made the decision to invite Mexico to participate.

Regarding IP, the TPP partners remain confident that copyrights, patents and trademarks will continue to be enforced. There appears to be general consensus that the standard of protection for IP should go beyond TRIPS.

The terms, conditions and wording of the TPP regarding IP rights remain confidential. However, it has been made public that the main topics regarding IP include effective customs measures, pharmaceutical patents and agrochemical patents. In the case of pharmaceutical patents and regulation, the main topics appear to be that the countries involved commit to implementing additional mechanisms for IP protection, such as patent linkage; extensions of or compensation for the life term of patents due to regulatory delays; and data package exclusivity for new chemical compounds and formulations and second uses.

Mexico has implemented the first steps towards integrating the TPP with the WIPO Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks 1989 (Madrid Protocol), which entered into force in Mexico at the start of 2013. The rushed approval of this without a full review of the trademark system (and assuming IMPI is prepared to properly adopt the Madrid Protocol system) is a good indication that the Mexican government is willing to fulfil the standards of the TPP, and replicate the enactment of the IP Law 1991, when NAFTA began to be discussed.

Due to the negotiations and eventual integration of Mexico into the TPP, the country has a new and valuable opportunity to review and change its entire IP system, and to adopt higher and, more importantly, more efficient standards of IP protection.

## Medicine quality and access to information

### 26 What rules are in place to counter the counterfeiting and illegal distribution of medicines?

COFEPRIS has broad jurisdiction to seize counterfeit or illegal medicines. The manufacturing and sale of counterfeit or falsified medicines is classified as a crime under the HL. In addition, COFEPRIS commonly enters into collaboration agreements with the Federal District Attorney's Office and the Customs Office in order to investigate and prevent counterfeit and illegal medicines.

Private companies have also run successful collaboration campaigns with COFEPRIS to counter these actions, including through funding investigations and providing full packages of information to the authority.

### 27 What recent measures have been taken to facilitate the general public's access to information about prescription-only medicines?

As a general rule, laboratories are forbidden from any form of advertisement to the general public concerning prescription-only medicines. The public policy in place in this regard is that the public's access to information on these medicines must be limited to avoid self-prescription (since sales of drugs without a prescription is a common practice in Mexican pharmacies).

Concerning information about prescription-only medicines that is published online and addressed to health-care professionals, the Code of GPP states that this practice must be duly approved by the corresponding authorities. Such information must clearly identify the sponsoring pharmaceutical company and be disclosed on scientific websites. Companies must adopt the proper measures to ensure that the promotion of prescription-only medicines on their websites will only be accessible to health-care professionals.

### 28 Outline major developments to the regime relating to safety monitoring of medicines.

The NOM for pharmacovigilance (NOM-220-SSA1-2012) has been recently updated, establishing that marketing authorisation holders basically must:

- report to the health authorities any adverse event or suspected adverse reaction that they are aware of and that may have been caused by any their products that are 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;



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- 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); and
- ensure the confidentiality of the identity of patients and reporters.

Holders of marketing authorisations must submit reports periodically.

The NOM for good manufacturing practices of medicinal products (NOM-059-SSA1-2013) has been also recently updated, and now requires that a programme to recall products that do not meet quality standards is implemented in an appropriate and efficient manner. Such programme should essentially include measures for recalling products in a rapid and effective manner, their storage, and a list of authorities to be notified according to the distribution of the product. Marketing authorisation holders must report to COFEPRIS any product recall decision, and provide details of such products, any causes and a store centre.

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## Vaccination

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### 29 Outline your jurisdiction's vaccination regime for humans.

The Ministry of Health's National Committee for Vaccination implements and elaborates the public policies for vaccination and the prevention of diseases in Mexico. There is no obligation for an individual to be vaccinated unless an emergency situation occurs requiring vaccination. The obligation to vaccinate the population lies with the government and occurs through different federal, local and municipal health entities, which should provide the population with the required vaccines free of charge in order to achieve universal coverage.

Official Norm NOM-036-SSA2-2012 establishes the standards and goals for vaccination of the population, listing the required vaccines and identifying the characteristics of the subjects of vaccination. Control of vaccination through the National Health Card scheme, and the safety, efficacy and quality of vaccines and biologics, are also warranted under this official regulation. A principle of free and universal coverage exists for the listed vaccines in this Official Regulation.

## Getting the Deal Through

|                            |                                   |                              |                             |
|----------------------------|-----------------------------------|------------------------------|-----------------------------|
| Acquisition Finance        | Dispute Resolution                | Licensing                    | Public-Private Partnerships |
| Advertising & Marketing    | Domains and Domain Names          | Life Sciences                | Public Procurement          |
| Air Transport              | Dominance                         | Mediation                    | Real Estate                 |
| Anti-Corruption Regulation | e-Commerce                        | Merger Control               | Restructuring & Insolvency  |
| Anti-Money Laundering      | Electricity Regulation            | Mergers & Acquisitions       | Right of Publicity          |
| Arbitration                | Enforcement of Foreign Judgments  | Mining                       | Securities Finance          |
| Asset Recovery             | Environment                       | Oil Regulation               | Ship Finance                |
| Aviation Finance & Leasing | Foreign Investment Review         | Outsourcing                  | Shipbuilding                |
| Banking Regulation         | Franchise                         | Patents                      | Shipping                    |
| Cartel Regulation          | Gas Regulation                    | Pensions & Retirement Plans  | State Aid                   |
| Climate Regulation         | Government Investigations         | Pharmaceutical Antitrust     | Tax Controversy             |
| Construction               | Insurance & Reinsurance           | Private Antitrust Litigation | Tax on Inbound Investment   |
| Copyright                  | Insurance Litigation              | Private Client               | Telecoms and Media          |
| Corporate Governance       | Intellectual Property & Antitrust | Private Equity               | Trade & Customs             |
| Corporate Immigration      | Investment Treaty Arbitration     | Product Liability            | Trademarks                  |
| Data Protection & Privacy  | Islamic Finance & Markets         | Product Recall               | Transfer Pricing            |
| Debt Capital Markets       | Labour & Employment               | Project Finance              | Vertical Agreements         |

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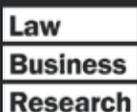
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