Mexico

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Organisation and financing of healthcare

1 How is healthcare in your jurisdiction organised?

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

The major public segments of the Mexican healthcare system are:

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

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 professional, executive and higher levels of the private sector. Enrolment in private health insurance has increased considerably over the past few years.

The public health sector normally faces financial problems and implements measures to limit costs, for example, by pressing for price reductions in public bids and encouraging competition.

2 How is the healthcare system financed in the outpatient and in-patient sectors?

The way of financing healthcare institutions relies on whether they belong to the public or private sectors rather than whether they belong to outpatient or in-patient sectors.

Public sector

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

Private sector

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 and drug acquisitions.

Compliance – pharmaceutical manufacturers

3 Which legislation governs advertising of medicinal products to the general public and healthcare professionals?

The primary legislation for the advertising of medicinal products is the General Health Law (HL), and its Regulations concerning advertising (HLR concerning to advertising). These norms are supplemented by guidelines published by the Regulatory Agency, the Federal Commission for Protection against Sanitary Risks (COFEPRIS). This agency is part of the Ministry of Health and controls the advertising of medicinal products.

Industry Codes of Practices complement this regulation. The Council of Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA) has issued the following self-regulatory instruments (the Codes):

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

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

There are also opinions issued by the Advertising Council, which include representatives from the Ministry of Health, the academic and scientific communities, the business sector, the media and consumer groups.

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 healthcare professionals?

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

- the distinctive denomination, if this is the case;
- the generic denomination;
- pharmaceutical form and formulation;
- therapeutic indications;
- pharmacokinetics and pharmacodynamics;
- side-effects;
- general precautions;
- restrictions of use during pregnancy and breastfeeding;
- secondary and adverse reactions;
- medical interactions;
- alterations in results from lab tests;
- precautions related to carcinogenic, mutagenic, teratogenic and fertility effects;
- the dose and tract of administration;
- manifestations and handling of overdose or accidental ingestion;
- 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 case some of the above-mentioned data does not exist, the circumstance must be expressly mentioned.

The Code of GPP states that the relationships between pharmaceutical industry personnel and healthcare professionals should encourage

the development of a medical practice committed to patients' well-being, based on truthful and accurate information and tested and up-to-date 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 said advertisements is to inform the public about the characteristics of the products, its therapeutic properties and the form of use. The advertising is subject to approval by COFEPRIS.

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

The Code of GPP requires that members' promotional activities directed towards consumers must be undertaken with the aim of generating a new culture in regard to rational and appropriate consumption of medicines, encouraging the guidance of healthcare professionals authorised to prescribe.

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

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

Probably the most renowned recent infringements have been committed by manufacturers of health or dietary supplements and 'miracle' products, which launched aggressive infomercial campaigns with exaggerated claims about the benefits of such products. In this regard, the HLR on advertising allows 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 healthcare professionals allowed?

According to article 42 of the HLR concerning advertising, prescribing information about products to healthcare professionals is subject to approval before publication. This information is approved while granting marketing authorisation for the corresponding product. Any publication should have the marketing authorisation number of this product.

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

This Code also states that, when scientific information is provided and is not part of the prescribing information duly approved or authorised in the marketing authorisation of a product, it should be strictly limited to a scientific audience, avoiding 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 healthcare professionals? Do different rules apply regarding physicians in the in-patient and outpatient sectors?

There are several bodies of law that refer in general terms to the relationship between the pharmaceutical industry and the healthcare professionals, including the HL, the HLR concerning advertising 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 both physicians in the in-patient and outpatient sectors.

9 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with healthcare 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 healthcare 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 a strict scientific content sustained, if required, on clinical evidence; and, most importantly, they must be accredited and certified by the corresponding academic authorities.

Support in general will not be offered, under any circumstance, in order to have any kind of influence on the decision-making process involved in prescribing medicines or 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 healthcare professionals, so that they may get to know the products or in order to initiate a treatment.

According to article 49 of the HLR concerning to advertising, providing samples of products for free does not require approval, provided that they meet the requirements of the approved medicinal product. These samples should be contained in a package with lesser number of units than the approved product.

The Code of GPP establishes guidelines for sampling. It prohibits members to offer or supply samples with the aim of seeking or rewarding prescription practices. The Code also forbids any trade of samples.

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.

We always recommend our clients have strict control on product samples since there have been cases of the re-sale of said samples.

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 healthcare 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 healthcare 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 medicine or pharmaceutical activities.

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

Concerning healthcare professionals in government institutions, article 47 of the Federal Law of Responsibilities for Government Officers expressly forbids these 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 healthcare professionals?

CETIFARMA has not published an updated yearly report over complaints. According to the last report, the 2013/14 annual report of CETIFARMA, in that period they received 10 complaints. CETIFARMA issued decision in six of those complaints. Concerning the remaining four complaints, one was withdrawn and the other three were dismissed. In this report, however, CETIFARMA did not provide any details of the complaints, such as grounds, parties or decisions.

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 collaboration between the pharmaceutical industry and patient organisations must have a written agreement in place that will include, at least:

- the activities to be undertaken, cost, source and destination of funding; and
- direct and indirect support and any other relevant non-financial aid.

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

The Code requires 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.

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

Whereas Mexico does have a Federal Antitrust Law and an active Antitrust Commission (ECCF) (www.cfc.gob.mx), there have been a number of investigations initiated against manufacturers of pharmaceutical products.

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

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

The Federal Antitrust Law allows for private entities to request investigations, as well as to provide all kinds of elements and evidence related to a certain investigation in process.

Further, once the preliminary determination of antitrust practices has been declared and published in the Mexican Government Official Gazette, anyone related 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 widespread as in other jurisdictions, such as the United States.

It is worth mentioning that on 20 July 2016, the ECCF announced that it would conduct a study regarding competition concerns over pharmaceutical products with lapsed patents. This is the first time such a study has been undertaken in Mexico.

The ECCF emphasised that this analysis should not be considered in any way as a prejudgment of potential misconduct. It pointed out that this assessment aims to provide Mexican Regulatory Agencies with recommendations on how to encourage competition and correct inefficiencies.

14 What are the main mandatory anti-corruption and transparency rules applicable to pharmaceutical manufacturers?

On 18 July 2016, several decrees were enacted in accordance with a Constitutional Amendment for Anti-corruption Matters in Mexico. These decrees were aimed at implementing, amending and supplementing various laws and acts, which together comprise the new National Anti-Corruption System.

The main mandatory anti-corruption rules and provisions currently in place applicable to private parties, whether individuals or corporations (including pharmaceutical manufacturers), are contained in: (i) the Mexican Federal Constitution; (ii) the Federal Anticorruption Law for Government Procurement; (iii) the Federal Criminal Code; and (iv) the international anti-corruption conventions to which Mexico is a party (the United Nations Convention Against Corruption, the Inter-American Convention Against Corruption and the Convention on Combating Bribery of Foreign Public Officials in International Business Transactions).

As of 19 July 2017, the General Act of Administrative Responsibilities (GAAR) entered into force in Mexico, repealing the Federal Anticorruption Law for Government Procurement. The GAAR sanctions, among other corrupt activities, the actions of private parties related to administrative liabilities when interacting with public officials, such as bribery, illegal participation on administrative procedures, influence peddling, collusion and undue contracting of former public officials. Some of the main administrative liabilities considered under the GAAR include the disqualification from public acquisitions for no less than three months and no more than 10 years, and the suspension of activities for no less than three months and no more than three years.

Conversely, regarding the mandatory transparency rules, the Code of Ethics and Transparency of the Pharmaceutical Industry issued by CETIFARMA, is a fundamental principle guiding to pharmaceutical manufacturers to prevent unfair competition, greater transparency and an effective accountability, for the purpose of pharmaceutical manufacturers to practise and promote ethical and social responsibility conducts.

The latest version of this Code has been in force since 1 April 2013. Affiliate members of CANIFARMA are required to follow this code, and CETIFARMA supervises members' and adherents' compliance.

Compliance – medical device manufacturers

15 Is the advertising of medical devices and the collaboration of manufacturers of medical devices with healthcare professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

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

Pharmaceuticals regulation

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

The primary legislation for medical products is:

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

17 Which authorities may grant marketing authorisation in your jurisdiction?

The regulatory authority in charge of the granting of marketing authorisations is the Federal Commission for Protection against Sanitary Risk (COFEPRIS) (www.cofepris.gob.mx), which is an administrative agency of the Ministry of Health. 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.

18 What are the relevant procedures?

The relevant procedures are commented as follows.

New molecules

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

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

- an active ingredient or drug not approved worldwide (new molecular entity);
- an active ingredient or drug already available in other countries but with limited clinical experience or disputed information, without approval in Mexico;
- a drug that 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.

R&D companies can benefit from a special procedure for drugs to be approved for the first time in Mexico, if they have been previously approved by:

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

In 2012, COFEPRIS published new rules to set out this procedure. This 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 and used these new rules.

Generics

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

The Mexican Official Norm NOM-177-SSA1-2013 sets standards of tests to prove that a generic drug is interchangeable with a reference drug. Legally speaking, 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 authorisations in violation of exclusive rights. According to the IP Regulations, every six months the 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 of patents). In 2012, for the first time the IMPI included formulation patents in the *Linkage Gazette*, in accordance with a 2010 ruling of the Mexican Supreme Court (Jurisprudence No. 2a./J.7/2010, *Federal Judicial Gazette*, No. XXXI, page 135).

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

Biologics (biotech products)

The Mexican jurisdiction recognises already that biotech products deserve special treatment as a result of their distinct characteristics, such as their complex structures, their size in comparison with chemically synthetised drugs and, particularly, their susceptibility to variation during manufacturing. The regulatory scheme distinguishes from other biologics those products that have been manufactured by molecular biotechnology and provides a robust regulatory process to approve them.

The standards to approve biotech products are essentially the same as for other drugs in Mexico: they must be safe and effective and have appropriate quality. The biotech products, however, must comply with a number of additional dossier requirements, in view of their distinct characteristics. Applicants have to prove quality, safety and efficacy requirements under the General Health Law, its regulations and applicable NOMs, particularly, those for biotech products (NOM-257-SSA1-2014), for good manufacturing practices for medicinal products (NOM-059-SSA1-2015) and for active ingredients (NOM-164-SSA1-2015).

Biocomparables (follow-ons)

Applicants must submit clinical tests and, when appropriate invitro tests, to prove safety, efficacy and quality of this product comparable (similar) to 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 physic-chemical studies. For this, the applicant must have to submit essentially:

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

Although industry participants welcomed amendments to approve biologics, specific rules to approve follow-ons have caused debate. In Mexican domestic law there is currently no indication of a data-protection period for biologics. The recognition of data package exclusivity rights for biologics has been achieved through litigation.

Orphan drugs

They were recently introduced into the General Health Law and the Mexican Pharmacopeia some years ago. In practice, they are approved by a particular procedure, following rules for new molecules when applicable and appropriate.

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

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

Since 2010 a reform to the law and regulations has established a five-year term on 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.

20 Which medicines may be marketed without authorisation?

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

21 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 trials' purposes.

In addition, according to article 103 of the same law, 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 or benefit ratio are merely suspected and cannot be confirmed, since the number of patients involved in the clinical trial of the product is insufficient owing 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

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

Mexican laws do not establish specific provisions concerning medicinal product pricing for either the outpatient or in-patient sectors. However, several mechanisms are in place, which leads 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 to 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, where 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.

23 Must pharmaceutical manufacturers negotiate the prices of their products with the public healthcare 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.

24 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 healthcare 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 through public tender processes.

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

The IMSS is the largest public sector buyer of drugs. Public institutions may have their own formulary, such as in the case of the IMSS, whose formulary contains fewer drugs than the National Formulary.

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

In 2014, the National Formulary has included some orphan drugs and the Mexican Supreme Court ordered the IMSS to request the Ministry of Health to evaluate the inclusion of orphan drugs in the Formulary before considering its purchasing.

In addition, the Seguro Popular manages a National Fund for Natural Disasters, which covers a list of high-cost treatments, including certain orphan drugs. The number of treatments included has increased over time.

In September 2015, a circuit court ordered the IMSS to provide a patient with a drug that was not listed in any formulary. This precedent is not binding for other cases; however, it has provide a basis for a debate in this regard.

25 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 raise observations in the scheme of self-regulated maximum retail price, the Commission for Drug Price Negotiations, which is made up of several public offices, including the Ministries of Economy and Health, negotiate with the patent holder or licensee to establish a single price of a patented drug for all sales to the public sector.

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

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

Medicine quality and access to information

27 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 sales of counterfeiting or falsified medicines is classified as a crime by 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 funding investigations and providing full packages of information to the authority.

28 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 sale of drugs without a prescription is a common practice in Mexican pharmacies).

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

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

The NOM for pharmacovigilance (NOM-220-SSA1-2012) establishes that marketing authorisation holders basically must:

- report to the health authorities any adverse event, or suspected adverse reaction, that they are aware of and which may have been caused by their products manufactured or marketed in Mexico;
- have standard operating procedures;
- receive any report of suspected adverse reactions from any possible source;
- record, validate and identify any reports of misuse or abuse reported by health professionals or patients;
- record and monitor any information related to any product used during lactation and pregnancy;
- investigate serious and unexpected cases;
- estimate the frequency of suspected adverse reactions and investigate the possible risk factors with intensive pharmacovigilance studies (at the request of the health authorities);
- ensure the confidentiality of the identity of patients and reporters; and
- holders of marketing authorisations must submit reports periodically.

The NOM for good manufacturing practices of medicinal products (NOM-059-SSA1-2015) has been fairly recently updated, requiring a programme to recall products that do not meet quality standards to be implemented in an appropriate and efficient manner. This programme should essentially include those activities planned for recalling products in a rapid and effective manner, storage, and a list of authorities to be notified according to the distribution of the product. Marketing authorisation holders must report to COFEPRIS any product recall decision, providing details of these products, causes and a store centre. This NOM is currently under a new updating process in order to adjust this with those standards of the Pharmaceutical Inspection Convention or Pharmaceutical Inspection Co-operation Scheme.

Vaccination

30 Outline your jurisdiction's vaccination regime for humans.

Within the Ministry of Health there is a National Committee for Vaccination, which 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 it is an emergency situation requiring vaccination. The obligation to vaccinate the population is on the government through the different federal, local or municipal health entities, which should provide the population with the required vaccines free of charge in order to obtain universal coverage.

Update and trends

Mexico is participating in the renegotiations of the North America Federal Trade Agreement (NAFTA). Some voices indicates that negotiations Trans-Pacific Partnership would be minimum bar to improve NAFTA and, thus, the main IP issues may include data package exclusivity to biologics, new formulations, second uses, and new methods of administration, linkage system, patent enforcement and non-traditional trademarks. NAFTA is again an opportunity for Mexico to review and improve its IP system.

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 the vaccination. Control of vaccination through the National Health Card and the safety, efficacy and quality of the vaccines and biologics are also warranted in this official regulation. There is a principle of free and universal coverage for the listed vaccines in this Official Regulation.

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