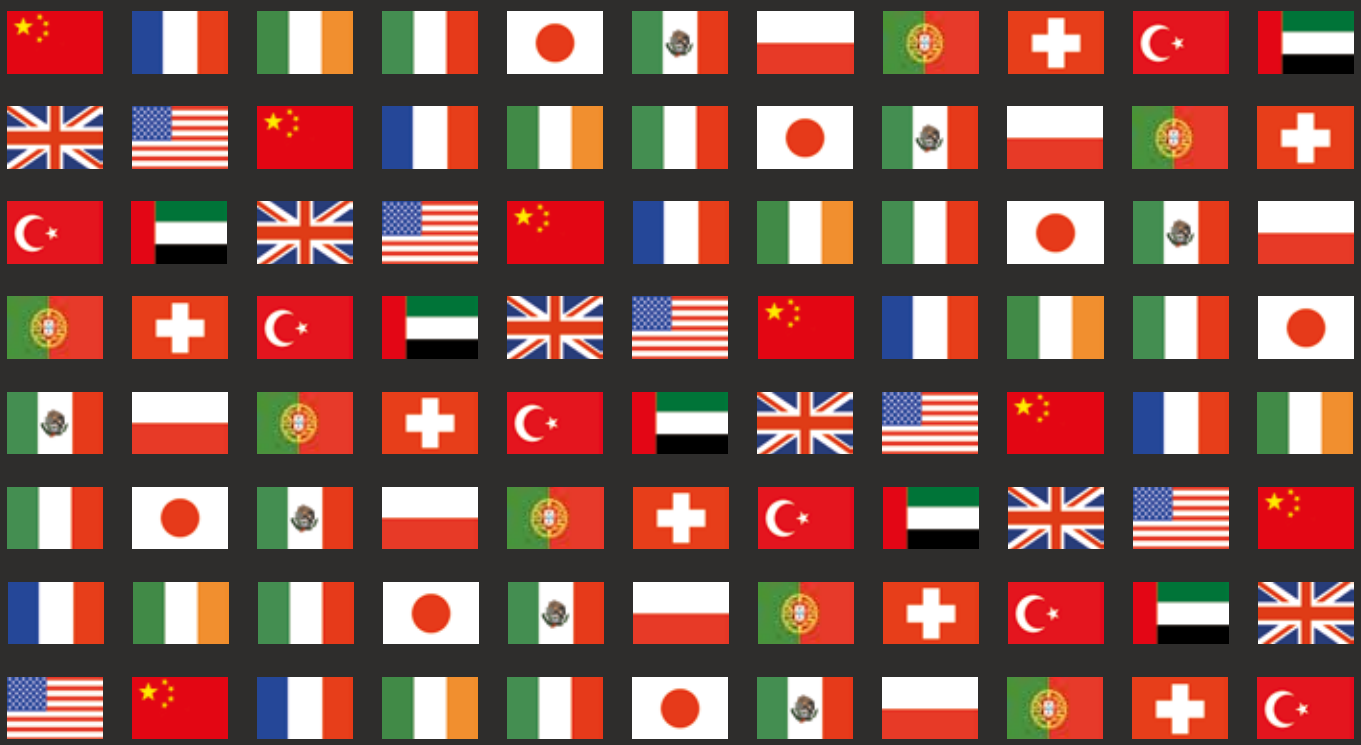
Healthcare Enforcement & Litigation 2019

Contributing editors
Michael K Loucks, Jennifer L Bragg and Alexandra M Gorman



2019

GETTING THE DEAL THROUGH

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Skadden, Arps, Slate, Meagher & Flom LLP

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Healthcare Enforcement & Litigation 2019

Fourth edition

Getting the Deal Through is delighted to publish the 2019 edition of *Healthcare Enforcement & Litigation*, which is available in print, as an e-book and online at www.gettingthedealthrough.com.

Getting the Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique **Getting the Deal Through** format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes new chapters on France, Italy, Japan and United Arab Emirates.

Getting the Deal Through titles are published annually in print. Please ensure you are referring to the latest edition or to the online version at www.gettingthedealthrough.com.

Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

Getting the Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to Michael K Loucks, Jennifer L Bragg and Alexandra M Gorman of Skadden, Arps, Slate, Meagher & Flom LLP, the contributing editors, for their continued assistance with this volume.

GETTING THE DEAL THROUGH

London
September 2018

Mexico

Alejandro Luna, Armando Arenas and Karla Overa

Olivares

Overview

1 In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

The Mexican healthcare system comprises of public (social security institutions) and private institutions, insurers and independent professionals.

Individuals and private insurers fund the private sector. 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 six years. 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, insurance and drug acquisitions.

The public sector comprises of:

- social security institutions exclusively directed to formal workers, in which the funding comes from contributions by the federal government, the employer and the employee; and
- public institutions exclusively directed to attend people not covered by social security, in which the funding comes from the federal government, states and patients.

The public health sector normally faces financial problems and implements measures to limit costs by, for example, pressing for price reductions in consolidated public tenders (involving the most important health institutions) and encouraging competition.

In the public sector, social security and public institutions provide medicines. However, if the medicine is not available when required, it can be dispensed in a private registered drugstore.

2 In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

The public sector comprises of:

- social security institutions exclusively directed to formal workers such as the:
  - Mexican Institute of Social Security (IMSS);
  - Institute of Social Security for State Workers (ISSSTE);
  - specialised public institutions for members of the military and navy force (SEMAR);
  - PEMEX Medical Services, for Mexican petroleum workers; and
- public institutions exclusively directed to attend people not covered by social security, such as the People's Health Insurance and state health institutions.

The private sector comprises of private institutions, insurers and independent professionals, the users of which are not restricted.

3 Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

Key legislation includes the following:

- the General Health Law;
- the General Health Law Regulations;
- the Health Supplies Regulation;
- the Official Mexican Standards (NOMs); and
- the Mexican Pharmacopoeia.

4 Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

The Federal Commission for Protection against Sanitary Risks (COFEPRIS), is an administrative agency of the Ministry of Health that is funded by the federal government.

The General Health Law entitles COFEPRIS to recover income derived from insurance rescue and other exceptional incomes.

5 What is the scope of their enforcement and regulatory responsibilities?

In accordance with the General Health Law, COFEPRIS is in charge of the following:

- the sanitary regulation, surveillance and control of public social security institutions and private institutions;
- the sanitary control of products and services, and their importation and exportation;
- the sanitary control of the processing, use, maintenance, import, export and disposal of medical equipment, prosthetics, orthotics, functional aids, diagnostic agents, dental supplies, surgical materials, healing and hygienic products;
- preparing and issuing NOMs relating to health facilities, products and services;
- evaluating, issuing or revoking sanitary authorisations;
- exercising control and sanitary surveillance of drugs and other health supplies;
- disposal of organs, tissues, human cells and their components, toxic or dangerous substances, biotechnological products and raw materials;
- exercising control and surveillance of the advertising of sanitary activities, products and services; and
- imposing sanctions and implementing security measures.

6 Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

The General Health Council is an agency controlled by the Executive and funded by the federal government.

COFEPRIS is an administrative agency controlled by the Ministry of Health and funded by the federal government. (For more information about COFEPRIS, see question 5.)

7 What is the scope of their enforcement and regulatory responsibilities?

The General Health Council is in charge of the following:

- preparing, updating and circulating the National Formulary of Basic Drugs;
- preparing and updating the Guidelines for the Evaluation of Health Supplies; and
- preparing the Guidelines for Interchangeability Tests of medicines that will be submitted before COFEPRIS for the granting of marketing authorisation as generics.

8 Which other agencies have jurisdiction over healthcare, pharmaceutical and medical device cases?

The following agencies have jurisdiction over healthcare, pharmaceutical and medical device cases:

- the Mexican Institute of Industrial Property (IMPI);
- the Office of the Federal Prosecutor for the Consumer (PROFECO);
- the Antitrust Commission (COFECE); and
- the Federal District Attorney's office (PGR).

9 Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

Multiple government agencies can simultaneously conduct investigations on the same subject, provided that the corresponding actions are independent from each other and intended for different purposes.

Regulation of pharmaceutical products and medical devices

10 What powers do the authorities have to monitor compliance with the rules on drugs and devices?

Pharmaceutical products

Pharmaceutical products are subject to the following provisions.

New molecules

Essentially, applicants for marketing authorisations must prove the 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 also have to request approval of their products as new molecules from the New Molecules Committee of COFEPRIS. According to the Health Law Regulations article 2 section XV, a new molecule is:

- an active ingredient or drug not approved worldwide (a new molecular entity);
- an active ingredient or drug already available in other countries but with limited clinical experience or disputed information, that has not be approved in Mexico;
- a drug which is a non-marketed combination of two or more active ingredients; or
- an active ingredient or drug already available on the market, but to be marketed for a new therapeutic indication.

R&D companies benefit from a special procedure for drugs that have been previously approved by a regulatory authority abroad to be approved for the first time in Mexico.

Generics

Applicants for marketing authorisations have to prove 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 reference list of 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 IMPI, which aims to prevent the granting of marketing authorisations in violation of patent rights. According to the Intellectual Properties 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). On 31 July 2012, for the first time the IMPI included formulation patents in the Linkage Gazette, in accordance with a 2010 ruling of the Mexican Supreme Court (Jurisprudence No. 2a/J7/2010, Federal Judicial Gazette, No. XXXI, page 135).

Use patents are included in the Linkage Gazette by a court order, since 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 he or she is the owner or licensee of the patent of the active ingredient of the product (recorded before 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

Amendments to the legal framework to regulate the approval of biologics are recent and being tested. Under the General Health Law, applicants have to prove the quality, safety and efficacy of their products, and that they meet their regulations and applicable NOMs, particularly those for good manufacturing practices for medicinal products (NOM-059-SSA1-2015) and for active ingredients (NOM-164-SSA1-2015).

In accordance with NOM-257-SS1-2014, all biological drugs that were authorised before the legal reform and that are still on the market must enter a regularisation process in order to comply with the latest standards for biologics. NOM 257 emphasises that key points to ensure the safety, efficacy and quality of biologics are already regulated in other NOMs currently in effect, such as those for clinical trials and pharmacovigilance. NOM 257 empowers the Assessment Subcommittee 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 to issue opinions to characterise biologics as innovators, reference products or biocomparables.

NOM 257 provides transitional provisions for the renewal of 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 assessment by the SEPB; and
- renewal applications for biocomparables will require prior assessment by SEPB to identify the product of reference in order for applicants to submit the corresponding tests.

These provisions will be applicable only for those renewal applications submitted before 31 December 2015. COFEPRIS, however, missed an opportunity to address the current 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 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 physicochemical studies. For this, the applicant must submit:

- in vitro studies;
- the report of a comparative pharmacokinetic test, 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 the similarity between both the follow-on and the reference biologic.

Although industry participants have welcomed amendments to the approval of biologics, specific rules to approve follow-ons have caused debate. There is currently no indication of a data protection period for biologics. Currently, recognition of data package exclusivity rights for biologics can only be achieved through litigation. Accordingly, there are also concerns regarding the accurate application by COFEPRIS of 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 of an NOM compiling requirements for granting marketing authorisations includes orphan drugs.

Medical devices

The primary legislation for medical devices and diagnostics are the General Health Law, its regulations and the NOM for good manufacturing practices regarding medical devices (NOM-241-SSA1-2012). In general, it would be fair to say that regulation regarding medical devices is lighter than that for drugs and other substances. According to their use, the General Health Law classifies medical devices into:

- medical equipment;
- prosthetics, orthotics and functional supports;
- diagnostic agents;
- dental supplies;
- surgical and healing materials; and
- hygiene products.

Marketing authorisation requirements for these devices depends on the level of risk involved in their use, according to a threefold classification:

- Class I: products that are well known in medical practice and for which safety and efficacy have been proven. They are not usually introduced into a patient's body;
- Class II: products that are well known in medical practice, but may have material or strength modifications. If introduced, they remain in a patient's body for less than 30 days; and
- Class III: products either recently accepted in medical practice or that remain in a patient's body for more than 30 days.

COFEPRIS analyses both medical devices and, if applicable, software that enables them to work. Conversely, mobile medical applications are a new area that COFEPRIS may address in future with particular regulations, especially if they represent health risks. As an incentive, applicants can benefit from a special procedure for certain devices that have been previously approved by the US Drug and Food Administration and Health Canada to be approved in Mexico. This procedure is essentially based on a dossier filed with the foreign regulatory agency, to reduce approval time frames by up to 30 working days. Industry participants have welcomed these new rules, but they are still being tested.

Powers to monitor compliance

COFEPRIS can request reports from marketing authorisation holders, and make on-site inspection visits in the manufacturing, distribution or storage facilities, essentially to verify that their products meet the approved specifications and do not represent a risk for the public health and to ensure that good manufacturing practices, stability, pharmacovigilance and labelling standards are complied with. COFEPRIS can initiate ex officio legal proceedings to sanction non-compliance. Ultimately, these legal proceedings can result in the revocation of the marketing authorisation.

COFEPRIS is also 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 adverts.

Under certain conditions, COFEPRIS has statutory authority to revoke any manufacturing approval or impose sanctions, ranging from a fine of up to 16,000 times the minimum wage to closure of the establishment. The imposition of administrative sanctions does not exclude civil and criminal liability. Administrative infringements can incur penalties ranging from a fine up to 20,000 times the minimum wage to final closure of the establishment. Repeated infringement is also considered a criminal offence.

COFEPRIS has broad jurisdiction to seize counterfeit or illegal medicines. The General Health Law classifies the manufacturing and sale of counterfeit or falsified medicine as a crime. In addition, COFEPRIS commonly enters into collaboration agreements with the PGR and the Customs Office in order to investigate and prevent counterfeit and illegal medicines.

11 How long do investigations typically take from initiation to completion? How are investigations started?

Investigations conducted by COFEPRIS can be initiated either by the complaint of an individual or by COFEPRIS itself. However, the duration of the investigation varies depending on the complexity of the case. Certain investigations related to counterfeit and commercialisation of illegal medicines are generally conducted in a matter of a few days.

12 What rights or access does the subject of an investigation have to the government investigation files and materials?

Third parties are usually restricted from accessing files and materials submitted before COFEPRIS by companies or individuals during the prosecution of administrative proceedings. However, in most contentious administrative and judicial proceedings the subject of an investigation has full access to the files and materials, except for the information expressly classified as confidential upon request of an authority or another individual.

13 If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

No, but to hold a marketing authorisation foreign applicants must have either:

- an approval from COFEPRIS for a manufacturing facility or laboratory for medicines or biologic products for human use in Mexico; or
- an equivalent approval (eg, a licence, certificate or other permit document) for any of these facilities abroad from the competent authority in the country of origin.

14 Through what proceedings do agencies enforce the rules?

Most agencies hold their own administrative proceedings, and the possibility of applying later to a court remains available. COFEPRIS is entitled to revoke sanitary authorisations in the following cases:

- when the corresponding products or activities constitute a risk of harm to human health;
- when exercising an authorised activity exceeds the limits set in the respective authorisation;
- when the authorisation is used for different purposes;
- for non-compliance with the Health Law or Regulations;
- when the product covered by the authorisation does not meet or no longer meets specifications or requirements established by the Health Law, NOMs and other general provisions;
- when information or documents provided by the applicant is false;
- when the reports provided by authorised third parties are false; and
- when the products no longer possess the attributes or characteristics under which they were authorised or lose their preventive or therapeutic properties.

There is also an available action called *accion popular*, whereby any individual with or without proper legal standing can file a complaint before COFEPRIS, arguing and proving that there are certain health risks associated with a product in the market. However, the claimant's procedural rights are very limited, and these actions are intended to end a health risk and not to obtain compensation. For additional information regarding COFEPRIS, see question 10.

In coordination with COFEPRIS, the PGR is entitled to investigate and prevent the commercialisation of illegal medicines and also to implement measures on behalf of public health, such as the seizure of products.

PROFECO can initiate infringement proceedings in relation to violations of the NOMs. Individuals are entitled to file complaints against the providers of a service or manufacturers of a product. PROFECO, non-profit associations and a common representative of a group of at least 30 members can now pursue class actions. The federal procedural laws have been amended to allow class actions before the federal courts.

COFECE or individuals can request investigations and inspection visits. Once the investigation stage has been concluded, the authority will determine whether the case is closed or if it is appropriate to initiate an administrative trial. In both cases, COFECE is entitled to impose preliminary injunctions. The affected party can claim damages before a court. Follow-on private litigation against manufacturers is possible, but has not been as widely spread as in other jurisdictions, such as the United States. Additionally, COFECE can file a criminal complaint.

Individuals can file patent infringement and unfair competition claims before IMPI, which is entitled to implement preliminary measures while investigating the infringement, which includes:

- the recall of infringing goods, or preventing their circulation;
- infringing articles to be withdrawn from circulation, including tools used in the manufacture, production or obtaining of infringing articles;

- the alleged transgressor or third parties to suspend or cease all acts that violate the law; and
- suspension of services or closure of an establishment, when other measures are insufficient to prevent or avoid a violation of rights protected by law.

Once an infringement has been declared and cannot be appealed, the claimant can bring an additional civil action for damages and lost profits, accruing from the date on which the existence of the infringement can be proved. The civil courts impose a tariff scheme specifying the costs that can be claimed for reasonable attorneys' fees, regardless of whether this reflects the actual fees charged. The imposition of administrative sanctions does not exclude civil and criminal liability.

15 What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

See questions 10 and 14.

16 Can the authorities pursue actions against employees as well as the company itself?

Yes, the General Health Code includes a chapter (VI) of specific offences in which both individuals and the responsible legal entity may be the subject of an enforcement action.

17 What defences and appeals are available to drug and device company defendants in an enforcement action?

Company defendants are entitled to file a nonconformity recourse against the decisions issued by COFEPRIS within 15 working days following the issuance of the decision. Likewise, a decision issued by an administrative authority can be appealed through a review before the corresponding authority, within 15 working days following the issuance of the decision. The decision issued in the review recourse can be challenged by means of a nullity trial before an administrative court (the Federal Court for Administrative Affairs) and lastly before an administrative Federal Circuit Court.

18 What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Companies should focus on the diagnosis of the problem and its resolution through institutional proceedings, appealing adverse decisions when applicable.

19 What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

In past years, COFEPRIS' enforcement activities have been focused on the seizure of illegal medicines, which has resulted in the closure of the establishment and suspension of activities.

20 Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

The National Chamber of the Pharmaceutical Industry (CANIFARMA) exercises institutional representation of the pharmaceutical industry before the Mexican authorities. Affiliate members are required to comply with the codes issued by the organisation.

Relationships between healthcare professionals and suppliers

21 What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

There are several bodies of law that refer in general terms to the relationship between the pharmaceutical industry and healthcare professionals, such as the Health Law and Health Law Regulations (including those that concern the sanitary control of activities, establishments, products and services). Industry Codes of Practice complement this regulation. The Council of Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA) has issued the following self-regulatory instruments:

- 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 CANIFARMA are required to follow these Codes. CETIFARMA supervises members' and adherents' compliance.

22 How are the rules enforced?

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 its main purposes:

- scientific exchange;
- medical education; and
- 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. Also, most importantly, they must be accredited and certified by the corresponding academic authorities. Under no circumstances will support be offered in order to influence 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 and be familiar with the products or in order to initiate a treatment. According to article 49 of the Health Law Regulations concerning advertising, providing free samples of products does not require approval, provided that they meet the requirements of the approved medicinal product. These samples should be contained in a package with a smaller number of units than the approved product.

The Code of GPP establishes guidelines for sampling. It prohibits members from offering or supplying 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 that our clients have strict control of product samples as there have been cases of resale 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 or incentives of any kind may be offered to healthcare professionals as an inducement to use, prescribe, purchase or recommend a specific product or influence the results of a clinical study. Similarly, 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.

23 What are the reporting requirements on such financial relationships? Is the reported information publicly available?

The Code of GPP establishes that collaboration between the pharmaceutical industry and patient organisations must have a written agreement in place that includes:

- 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 must follow their applicable guidelines and codes of ethics and conduct, have transparent practices and use 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.

Regulation of healthcare delivery

24 What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

In coordination with the educational authorities, the Ministry of Health and the governments of the states are in charge of monitoring health professionals when providing the following services:

- conducting sanitary evaluations and verification visits and, as a result, issuing an official report which states whether the subject of the investigation complied with laws, regulations and NOMs. In case of non-compliance, the health authority in charge of the investigation will initiate the corresponding administrative proceeding; and
- applying sanctions and safety measures when appropriate, and verifying compliance.

25 How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

The duration of the investigation varies depending on the complexity of the case. The establishment or site requiring an evaluation or verification visit is determined by any of the following:

- random selection;
- a previous contingency or health emergency;
- programmes determined by the health authority;
- a claim by a third party;
- the request of the owner; and
- a follow-up to an administrative procedure initiated by the health authority.

26 What rights or access does the subject of an investigation have to the government investigation files and materials?

The subject of an investigation has full access to the files and materials, except for information that is expressly classified as confidential upon request of the authority or another individual.

27 Through what proceedings do agencies enforce the rules?

Most agencies hold their own administrative proceedings, while applying to a court later remains available. The Ministry of Health and the governments of the states are in charge of performing regular sanitary evaluations and verification visits to public and private institutions that, depending on the results, can lead to the application of sanctions and safety measures. The imposition of administrative sanctions does not exclude civil and criminal liability.

28 What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

If the sanitary conditions of the establishment, raw materials, process, procedures or products present a significant risk to health or lack the essential requirements of the law and other applicable provisions, verifiers should take immediate security measures with the approval or consent of the health authority on which they depend. The competent health authorities may order the application of the following security measures:

- isolation;
- quarantine;
- personal observation;
- vaccination of persons;
- vaccination of animals;
- destroying or controlling of insects or other vermin;
- the suspension of work or services;
- the suspension of advertising in health;
- the issue of advertising messages that warn of potential damage to health;
- the seizure and destruction of objects, products or substances;
- eviction from houses, buildings, facilities and any property in general; and
- other health measures as determined by the competent health authorities.

The sanitary authority has statutory powers to impose sanctions, ranging from a fine of up to 16,000 times the minimum wage to closure of the establishment. The imposition of administrative sanctions does not exclude civil and criminal liability.

29 What defences and appeals are available to healthcare providers in an enforcement action?

Healthcare providers are entitled to file administrative, civil and criminal complaints against sanctions or adverse decisions. The National Commission of Medical Arbitration (CONAMED) provides guidance and assistance to healthcare providers during the process of a complaint filed against them for medical negligence and during the medical arbitration proceeding.

30 What strategies should healthcare providers adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

See question 19.

31 What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

Enforcement activity has been focused on the inspection of private clinics. This has resulted in the closure of establishments and suspension of activities due to a significant risk to health, the lack of essential requirements for the establishments' operation and uncertified medical personnel.

32 Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

Healthcare providers in Mexico are grouped and represented by different private associations depending on their specialisation and field of work.

33 What remedies for poor performance does the government typically include in its contracts with healthcare providers?

Contracts for the acquisition of health supplies and health services provisions usually include the following sanctions:

- Penalties for delays in compliance with agreed dates of delivery or service provision, which shall not exceed the amount of the guarantee of compliance of the contract, and will be determined according to the goods or services not delivered or rendered on time.
- When a supplier totally or partially breaches any of the obligations expressly established in a contract, government entities can terminate the contract in advance without liability and without any judicial resolution.

Contracts for the acquisition of medicines or health supplies provide that the government institution may request that the supplier exchange goods with defects or the total devolution of the goods, where, after delivering the new batches, the same defect is detected.

The supplier of the goods is obliged to respond at its own risk regarding claims that failure or negligence on its part have caused problems for government institutions or third parties.

Private enforcement

34 What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

Besides civil and criminal actions, in order to enforce a healthcare regulation or law, citizens or other private bodies can file an innovative constitutional action against a particular act or omission of the authority, grounding their legal standing in article 4 of the Mexican Constitution, which provides the human right of due access to health.

35 What is the framework for claims of clinical negligence against healthcare providers?

Patients or relatives of patients who have received medical, public or private care that potentially caused them harm because of malpractice are entitled to file complaints against healthcare providers. CONAMED provides guidance and expert advice to patients and healthcare providers about their rights and obligations. It also receives and investigates cases related to irregularity or denial in providing justified or urgent medical services by public institutions.

Patients are entitled to file a complaint before CONAMED, in which case such authority will be a mediator between the patient and the healthcare provider with the purpose of achieving a settlement agreement. If this is not the case, the patient can chose between submitting to a medical arbitration proceeding before CONAMED or filing a civil action. Decisions issued by CONAMED can have the following effects:

- order the provision of adequate medical care; and
- order reimbursement, compensation or both to the patient.

36 How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

Individuals are entitled to file complaints against the providers of a service or manufacturers of a product before PROFECO, on the grounds that the product of interest does not comply with the essential requirements provided by the applicable regulations and NOMs or the advertised characteristics and functionality.

37 Are there any compensation schemes in place?

The State Liability Law aims to establish the bases and proceedings for recognising the right to compensation of those who, without any legal judicial obligation, suffer damages to their property and rights as result of irregular administrative activity of the state.

38 Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

The federal procedural laws have been amended to allow class actions before the federal courts. PROFECO, the Attorney General's Office, non-profit associations and a common representative of a group of at least 30 members can now pursue class actions. These amendments are subject to testing in the courts, and apparently there are no precedents of class actions for product liability.

In addition, there is an action available called *accion popular*, whereby any individual with or without proper legal standing can file a complaint before COFEPRIS, arguing and proving that there are certain health risks in a product in the market. However, the claimant's procedural rights are very limited, and these actions are intended to stop health risks and not to obtain compensation.

39 Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

Yes. Acts, omissions and decisions of both public and private institutions are the subject of administrative, civil and criminal complaints from interested parties before courts. Actions should be filed as soon as possible in order to duly attend and repair the claimed act or omission. In these type of cases the legal standing of the complainant is grounded in the human right of due access to health. In relevant cases it has been decided that the state will always be responsible for appropriate health attention, even if the claimed act or omission derives from a private institution.

Update and trends

As a result of the change of government that will take place in December 2018, considerable changes are expected in the structure of the Ministry of Health and its regulatory agency COFEPRIS, which will be aimed primarily at limiting the powers of COFEPRIS in sanitary regulation and enforcement.

Pending international treaties will certainly impact healthcare related matters. In May 2016, the European Union and Mexico concluded negotiations to modernise their free trade agreement, the release of the final wording of which is still pending, and the Comprehensive and Progressive Agreement for Trans-Pacific Partnership is still waiting to be ratified by the Senate. On the other hand, Mexico is currently renegotiating the North American Free Trade Agreement, which is likewise expected to include favourable amendments related to pharmaceuticals and regulatory matters.

As of 2017, the Superior Chamber of the Federal Court of Administrative Justice has issued several judgments through which it has determined that the Specialised Court on Intellectual Property Matters is not competent to resolve appeals that are filed against acts issued by COFEPRIS, even when these are related to the protection of intellectual property rights, specifically in cases related to marketing authorisations for pharmaceutical products, stating that such matters should be turned over to the Specialised Court on Environmental Matters and Regulation for that resolution.

40 Are there any legal protections for whistleblowers?

No, in Mexico we do not have a figure equivalent to a whistleblower. The Federal Law on the Administrative Responsibilities of Public Servants provides that public servants must inform their superiors in writing about any conclusive doubts that arise from the origin of the orders they receive that could constitute an infringement of any legal or administrative provision. However, the law fails to consider the protection that should be granted to the public servant, or the process that should be implemented in order to preserve the confidentiality of the denouncement.

41 Does the country have a reward mechanism for whistleblowers?

No.

42 Are mechanisms allowing whistleblowers to report infringements required?

Yes. The Ministry of Public Administration is the authority in charge of verifying that public servants act in accordance with the applicable laws during the exercise of their functions, and is the authority in charge of implementing the corresponding sanctions.

Cross-border enforcement and extraterritoriality

43 Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

Yes. In accordance with the Health Law, its Regulations and the international treaties subscribed by Mexico, the Ministry of Health is in charge of institutional relationships with the health dependencies of other governments and international organisations in order to facilitate the provision of technical advice, information and assistance in everything related to sanitary regulation, control and health promotion.

Additionally, the Ministry of Health notifies the World Health Organization of all the measures it has taken, temporarily or permanently, in international health, as well as of any case that is of interest in the surveillance of the diseases listed in the International Health Regulations.

44 In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

When the Ministry of Health receives an international communication, alert or requirement on health matters, in coordination with the corresponding administrative entities (Ministry of Foreign Affairs and Ministry of the Interior) it will conduct inspection visits in order to verify compliance or non-compliance with international sanitation rules,

which could lead to an administrative procedure in accordance with the applicable laws.

45 In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

Mexican healthcare laws, regulations and official standards are equally enforceable against foreign companies and nationals.

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