Mexico

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OLIVARES

ORGANISATION AND FINANCING OF HEALTHCARE

Organisation

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:

social security institutions exclusively directed to formal workers, in which the funding comes from contributions by the federal government, the employer and the employee, such as the:

- Mexican Social Security Institute (IMSS);
- Civil Service Social Security and Services Institute (ISSSTE);
- Social Security Institute for the Mexican Armed Forces (ISSFAM); or
- PEMEX Medical Services, for Mexican petroleum workers; 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, such as the:
- Wellness and Health Institute (INSABI); and
- States Health Institutions.

In the public sector, social security and public institutions provide medicines. However, if the medicine is not available when required, some public insurers allow private registered drugstores to supply prescribed medicines and to request their refund.

The private sector comprises private institutions, insurers and independent professionals, the users of which are not restricted. Individuals and private insurers fund this 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 years. According to official figures, up to 50 per cent of annual health spending in Mexico comes from out-of-pocket payments related to private doctors, insurance and drug acquisitions.

Financing

2 | How is the healthcare system financed in the outpatient and inpatient sectors?

The manner in which healthcare institutions are financed relies on whether they belong to the public or private sectors rather than whether they belong to outpatient or inpatient sectors.

Public sector

Public-sector healthcare institutions are mostly financed through contributions from public and private sector workers. Employers and employees both pay a tax solely for the purpose of providing healthcare services. There are special rules for those who are unable to pay but are still eligible to benefit from the healthcare system.

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, insurance and drug acquisitions.

Basic structures

3 | What are the basic structures of the provision of care to patients in statutory and private care?

According to Health Law and its regulations, depending on the type of healthcare services, these services should be provided by physicians licensed in Mexico and through licensed healthcare centres. Enrolment of patients in social security healthcare centres derives from their social security rights. Enrolment of patients in public healthcare centres derives from national policies to provide healthcare to citizens. Enrolment of patients in private healthcare centres is an individual decision.

In the public sector (social security and public institutions), healthcare centres dispense medicinal products prescribed by their healthcare professionals from a medicinal products' list, which is a National Formulary issued by the MoH. Public insurers acquire those listed products mostly by public tender processes. The IMSS is the largest public-sector buyer of drugs.

HEALTHCARE SERVICES

Authorisation

4 | What steps are necessary to authorise the provision of health services, and what law governs this?

The Health Law and its Regulations for Health Services, and the Mexican Official Norm for Hospitals (NOM-016-SSA3-2012) are the main laws that govern the provision of health services in Mexico. Prior to opening, hospitals and specialist healthcare centres require a licence granted by the Mexican Healthcare Regulatory Agency (COFEPRIS). The main requirement for getting a licence is by providing a description of the internal organisation and human and financial resources, internal rules of the establishment, description of healthcare facilities and services and a designated qualified person. For high-risk healthcare services, such as radiotherapy and haemodialysis, an additional licence is required. Conversely, low-risk healthcare services that do not involve surgeries or obstetric services may require to give only notice of operation to COFEPRIS rather than getting a licence.

COFEPRIS is an agency in charge of the control and surveillance in all aspects related to sanitary regulation (in connection to drugs, medical devices, health services, food supplements, food and beverages, cosmetics, pesticides and clinical studies).

In August 2020, COFEPRIS was incorporated into the Undersecretary for Prevention and Promotion of Health of the Ministry of Health. COFEPRIS' faculties depend directly on the Undersecretary.

Structure

5 | Which types of legal entities can offer healthcare services?

The Health Law regulations do not clearly specify that certain types of healthcare services can only be provided by specified types of entities. Therefore, associations, corporations and limited liability companies can provide healthcare services, if they get a licence, or a notice of operation given to COFEPRIS.

Services of foreign companies

6 | What further steps are necessary for foreign companies to offer health services?

Pursuant to current COFEPRIS criteria, companies constituted in Mexico hold a licence. Thus, foreign companies might either constitute a company in Mexico or have a holding agreement with a local partner.

ADVERTISING

Legislation

7 | Which legislation governs advertising of medicinal products to healthcare professionals?

The primary legislation for the advertising of medicinal products is the General Health Law (HL), and its Regulations concerning advertising (HLR). These norms are supplemented by guidelines published by Mexican Healthcare Regulatory Agency (COFEPRIS). This agency is part of the Undersecretary for Prevention and Promotion of Health of the Ministry of Health and controls the advertising of medicinal products.

The Council of Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA) has issued the Integrity, Ethics and Transparency of Health Supplies Companies Code (CIETEMIS), which complements the legislation for the advertising of medicinal products.

Affiliate members of the National Chamber of the Pharmaceutical Industry (CANIFARMA) are required to follow this code. CETIFARMA supervises members' and adherents' compliance. Although these provisions are not mandatory, failure to comply can result in a suspension of rights as a member of the chamber or exclusion from it.

There are also opinions issued by the Advertising Council, which include representatives from the Ministry of Health (MoH), the academic and scientific communities, the business sector, and 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 Federal Law for the Protection of Industrial Property.

Main principles

8 | What are the main rules and principles applying to advertising of medicinal products aimed at healthcare professionals?

According to article 42 of the HLR concerning advertising, advertisements directed at healthcare professionals can only be published in specialist 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 if some of the above-mentioned data does not exist, the circumstance must be expressly mentioned.

Moreover, article 88 of the HLR concerning advertising, establish that advertising of medicinal products addressed to health professionals must be carried out by means of a notice of operation filed before COFEPRIS.

Article 12, subsection 12.2 of the Integrity, Ethics and Transparency of Health Supplies Companies Code 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, revealing up-to-date scientific evidence to contribute to the appropriate use of approved medicines.

Conversely, in December 2017, COFEPRIS issued new guidelines regarding the advertising of prescription-only medicinal products. According to these guidelines, prescription-only medicinal products that can be purchased as many times as prescribed, and can now be advertised in the mass media, provided that these advertisements are transmitted within specialist programmes, informative segments or advertising breaks, which should be targeted at professionals, technicians and volunteers of health disciplines, or in another type of programme or means of communication, provided it complies with the following characteristics:

that within the advertising message there is a strong message warning of the consequences of self-prescription and microbial resistance, which should have an approximate duration of 10 to 20 per cent of the entire advertising message;

knowledge of innovative or generic medicines should be promoted;

a caption should be included stating: 'Exclusive information for health professionals, avoid self-medication' in accordance with the provisions of article 10 of the Health Law Regulations;

advertising on television or in electronic media must contain the following caption: 'The use of this medicine requires a prescription' and must include at least one of the following disclaimers:

- The improper and excessive use of antibiotics generates resistance and puts your health at risk';
- Only use antibiotics when a health professional prescribes it';
- Never use antibiotics that you have left over and do not share them with others';
- 'Always take the complete prescription, even when you feel better'; or
- 'Doctor: prescribe and dispense antibiotics only when needed'; and
- the advertising notice must be made five days prior to its dissemination in any means of communication for the purpose that during that period COFEPRIS will give its approval.

CETIFARMA issued a paper position in this regard in 2018, stating a deep legal, regulatory and ethical analysis of this advertising allowance before pharmaceutical companies release them.

We also suggest that in-depth analysis of this situation is needed on a case-by-case basis in view of the potential impact on patients' health, and potential contingencies to pharmaceutical companies advertising in such a way. Moreover, the legal strength of COFEPRIS' guidelines is

questionable, since they were published on COFEPRIS' website instead of an official gazette to have legal worth. Because of this reason, on 25 June 2019, COFEPRIS revoked other guidelines relating to product advertising.

Advertising of medical devices

9 Is the advertising of medical devices to healthcare professionals regulated as rigorously as advertising in the pharmaceuticals sector? What are the main differences?

Generally speaking, it would be fair to say thatregulations regarding medical devices are lighter than those for medicinal products. The HLR regarding advertising provides minimum requirements for advertising aimed at healthcare professionals, such as messages to prevent auto treatment. Integrity, Ethics and Transparency of Health Supplies Companies Code standards for medicines apply to medical devices.

DATA PROTECTION, PRIVACY AND DIGITISATION IN HEALTHCARE

Digitisation

10 What are the legal developments regarding digitisation in the healthcare sector and industrial networks or sales channels?

The most relevant regulatory step by the Mexican Healthcare Regulatory Agency (COFEPRIS) in digitisation related to the healthcare sector was the publication of their Guidelines for Digital Advertisement (Official Communication No. CAS/1/OR/22/2014) by 2014. These guidelines provided some basic concepts and proceedings related to digital advertisements. However, COFEPRIS revoked the Guidelines on 25 June 2019 because they were published on the COFEPRIS website instead ofin the Official Gazette.

Moreover, on 21 December 2015, was published in the Federal Official Gazette the draft of the Mexican Official Standard 'NOM-036-SSA3-2015, For the regulation of remote medical care', which contemplated digital health services such as telemedicine, however, the draft of this Mexican Official Standard was rejected on 27 April 2018.

Although there is a global trend to quickly invest in digital transformation that connects and enables analysis of every piece of data across the supply chain, channels, operation and patient outreach, health legislation and regulatory bodies are slow to follow suit. Moreover, the prohibition on advertising prescription medicines and the requirement to provide prescription medicines using bricks-and-mortar pharmacies are important obstacles for business models based on digital tools. Therefore, we expect some push on regulators to facilitate new business models in the near future.

Provision of digital health services

11 Which law regulates the provision of digital health services, and to what extent can such services be provided?

The General Health Law regulates the provision of health services by physicians licensed in Mexico. This law does not specifically establish digital health services yet, which is why new types of services such as telemedicine remain unusual in Mexico.

Authorities

12 Which authorities are responsible for compliance with data protection and privacy, and what is the applicable legislation? Have the authorities issued specific guidance or rules for data protection and privacy in the healthcare sector?

The applicable legislation is the Federal Law on Transparency and Access to Public Government Information and the responsible authority for its compliance is the National Institute for Transparency, Access to Information and Personal Data Protection (INAI). This authority is responsible for overseeing the Regulations for the Protection of Personal Data. Its main purpose is the disclosure of governmental activities, budgets and overall public information, as well as the protection of personal data and the individuals' right to privacy. The INAI has the authority to:

- conduct investigations;
- review and sanction data protection controllers; and
- authorise, oversee and revoke certifying entities.

The Ministry of Economy is responsible for informing and educating on the obligations regarding the protection of personal data between national and international corporations with commercial activities on Mexican territory. Among other responsibilities, it must issue the relevant guidelines for the content and scope of the privacy notice in cooperation with the INAI.

The INAI has not issued specific guidelines or rules for data protection and privacy in the healthcare sector yet, but it has issued some decisions advising how to protect or disclose information related to the healthcare sector in cases where freedom of information request refusals were contested.

Requirements

13 What basic requirements are placed on healthcare providers when it comes to data protection and privacy? Is there a regular need for qualified personnel?

The main and mandatory requirement is the appointment of a data protection officer (person or department) as a controller by the healthcare provider. There are no statutory requirements for qualifications of such officer, but it is advisable to appoint a person or department with at least with the following qualifications:

- data privacy expertise; and
- enough authority and resources to implement measures in order to protect the personal data.

Common infringements

14 What are the most common data protection and privacy infringements committed by healthcare providers?

The establishment and development of the legal framework for data protection in Mexico is quite recent in comparison with other areas such as healthcare products and services. Thus, there are no enforcement trends that have emerged during the previous 12 months. However, as a result of an investigation process started by the Mexican DPA (INAI) in February 2019 related to a data breach at KPMG Mexico, the INAI is calling for the need to modify Mexican data protection law to include an obligation to notify the DPA in case of a data breach.

COLLABORATION

Legislation

15 Which legislation governs the collaboration of the pharmaceutical industry with healthcare professionals? Do different rules apply regarding physicians in the outpatient and inpatient 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 General Health Law (HL), and its Regulations concerning advertising (HLR) concerning advertising and the HL Regulations concerning sanitary control of activities, establishments, products and services. The Code of Good Practices of Promotion

(GPP) sets forth guidelines for promotional activities. Public institutions usually have their own particular guidelines. These regulations apply to both physicians in the inpatient and outpatient sectors.

Collaboration with healthcare professionals

16 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with healthcare professionals?

Scientific and educational events

The GPP Code included in the Integrity, Ethics and Transparency of Health Supplies Companies Code 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 GPP Code included in the Integrity, Ethics and Transparency of Health Supplies Companies Code, samples are provided directly, in fair amounts and without cost to healthcare professionals, so that they may get to know the products or to initiate a treatment.

According to article 49 of the HLR concerning 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 fewer units than the approved product.

The GPP Code included in the Integrity, Ethics and Transparency of Health Supplies Companies Code 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 GPP Code included in the Integrity, Ethics and Transparency of Health Supplies Companies Code 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 GPP Code included in the Integrity, Ethics and Transparency of Health Supplies Companies Code delineates an inexpensive promotional aid as one that does not exceed the equivalent of 10 units of measure (UMA) (around US$50).

Regarding healthcare professionals in government institutions, article 52 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.

Collaboration with patient organisations

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

The GPP Code Integrity, Ethics and Transparency of Health Supplies Companies 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 must follow their applicable guidelines, codes of ethics and conduct, their transparent practices and the deontological instruments approved by the Council of Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA) and the National Chamber of the Pharmaceutical Industry, CANIFARMA.

The GPP 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.

Common infringements

18 What are the most common infringements committed by pharmaceutical manufacturers regarding collaboration with healthcare professionals?

CETIFARMA publishes an updated report over complaints on an annual basis. According to the last report, despite receiving 139 complains in total from 2005 to 2020, they received a mere seven complaints in 2020. From that complaints' total, the most common alleged infringements were non-supported or imprecise medical information (20 per cent), unauthorised incentives (17 per cent), undue sales practices to the government (14 per cent) and unfair promotion (14 per cent).

Collaboration on medical devices

19 Is the collaboration of manufacturers of medical devices with healthcare professionals and patient organisations regulated as rigorously as collaboration in the pharmaceuticals sector? What are the main differences?

Generally speaking, regulation regarding medical devices appears lighter than that for medicinal products; however, the standards of the Integrity, Ethics and Transparency of Health Supplies Companies Code in the collaboration between manufacturers of medical devices with healthcare professionals and patient organisations should apply.

COMPETITION LAW

Authority enforcement

20 Are infringements of competition law by healthcare providers pursued by national authorities?

The Federal Economic Competition Commission (COFECE) has powers to pursue any infringement of competition law by healthcare providers. In 2016, COFECE launched an antitrust analysis on a pharmaceutical market in Mexico for the first time, which was justified by the market's numerous flaws and the confusion surrounding its multiple concepts.

On 9 August 2017, the COFECE published a study concluding there are some competition anomalies in these markets, which are essentially derived from a lack of development in regulations and public policies. The COFECE considers, among other issues, that these anomalies arose from:

- the linkage system between patents and approvals of generics is non-transparent;
- data of approved healthcare products is not up-to-date and remains incomplete;
- incomplete use of the *Bolar* exemption delays generics' approvals;
- several patents are granted for the same active substance; and
- disputes over patent infringements.

Thus, COFECE recommends public policies that practically eliminate obstacles to generics entry and promotes the demand for generics. Some recommendations are proper, such as improving quality, access and transparency of public data of approved healthcare products, but others are worrying, such as establishing restrictions on granting some types of patents.

The authors believe that the COFECE study has several flaws in its contents and methodology. We consider that COFECE applied concepts, provisions and practices of the international and national patent system, linkage system, Bolar exemption and patent infringement in an inexact manner. For example, it is inconceivable that any country would specify a pharmaceutical active ingredient claimed by several patents.

Fortunately, the COFECE recommendations are not binding and may be taken as 'a first approximation' by such agency. Olivares has monitored COFECE studies as well as learning the intersection of regulations over healthcare products, patent rights and competition, which is required to encourage appropriate competition.

Private enforcement

21 Is follow-on private antitrust litigation against healthcare providers possible?

The Federal Antitrust Law allows for private entities to request investigations, as well as providing numerous examples and evidence related to a given investigation in progress.

COFECE proceedings have three central features: the secrecy of investigations, discretion surrounding dawn raids, and the linkage that has come about between dawn raids and its own immunity programme.

Further, once the preliminary determination of antitrust practices is declared and published in the Mexican government's Official Gazette, anyone related or affected by the decision has the opportunity to appeal and submit evidence.

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

Anti-corruption and transparency

22 What are the main anti-corruption and transparency rules applicable to healthcare providers?

The main mandatory anti-corruption rules and provisions currently in place that are applicable to private parties, whether individuals or corporations (including healthcare providers), are contained in:

- the Mexican Federal Constitution;
- the Federal Anticorruption Law for Government Procurement;
- the Federal Criminal Code; and
- the international anti-corruption conventions to which Mexico is a party, namely:
  - 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.

Since 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.

PRICING AND REIMBURSEMENT

Price regulation

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

Mexican laws do not establish specific provisions concerning medicinal product pricing for either the outpatient or inpatient sectors. However, several mechanisms are in place, enabling a certain degree of control of such prices in practice.

Private-sector price control is based on a scheme of self-regulated maximum retail price (MRP) covering patented products only and is overseen by the Ministry of Economy. Pharmaceutical company 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, and a market factor. There are no established sanctions for MRP violations.

In 2008, the government created the Committee for the Negotiation of Drug Prices (CNDP). Until 2018, recommended prices for patented and unique drugs (or those with exclusive distributors) for all public institutions were formerly negotiated with the CNDP under the supervision of the Ministry of Public Function and the Mexican Antitrust Authority (COFECE).

Under that scheme, the price review and eventual changes are done annually. This new administration is implementing modifications frequently, so it can impact the frequency of price change. Please anticipate that the austerity measures that have been taken by the government recently will continue and may drive a more frequent price review.

Regarding the public acquisition of innovator drugs covered by patent rights, the 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 drugs purchaser, pricing for publicly acquired drugs helps regulate prices in the private sector.

Negotiations between manufacturers and providers

24 | Must pharmaceutical and medical device manufacturers negotiate the prices of their products with public healthcare providers?

Yes, 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.

Reimbursement

25 | In which circumstances will the national health insurance system reimburse the cost of medicines?

Typically, public insurers dispense medicinal products prescribed by their healthcare professionals to patients. Products are prescribed and dispensed from a basic medicinal products list, which public insurers essentially based on the National Formulary issued by the Ministry of Health (MoH). Public insurers acquire those listed products mostly through public tender processes.

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

The Mexican Social Security Institute (IMSS) is the largest public-sector drugs purchaser. 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 Civil Service Social Security and Services Institute (ISSSTE), a prescribed medicinal product can be dispensed in a private pharmacy registered with this public insurer, provided that it is not available within ISSSTE facilities and under certain conditions. The ISSSTE reimburses the cost of that product to the pharmacy 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 MoH evaluate the inclusion of orphan drugs in the National Formulary before considering its purchasing.

There have been more and more legal precedents by the Federal Court ordering the national health insurance institutions to provide a patient with a drug that was not listed in any formulary or available. These precedents are not binding for other cases; however, they provide a basis for further debate in this regard.

Price adjudication

26 | 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. Likewise, as commented above, public insurers that acquire products through direct acquisition or public tender are the ones that decide on the corresponding reimbursement.

Discount

27 | Are manufacturers or distributors of medicinal products statutorily obliged to give a discount to health insurance schemes or third parties?

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

UPDATE AND TRENDS

Key developments of the past year

28 | Is there any legislation expected in the near future that will have a major impact on the current legal environment for medicines or medical devices?

Amendments to the equivalence Decree to import health supplies without a marketing authorisation

On 22 June 2021, it was published in the Federal Official Gazette a new decree, establishing some amending to the equivalence decree published back on 28 January 2020, in the Federal Official Gazette by the Ministry of Health.

This Decree as the one issued in January 2020 aims to expedite the granting of marketing authorisations for foreign health supplies (ie, medicines, vaccines) in Mexico, by establishing that if the particular products had met the requirements and procedures before a foreign regulatory agency, would be considered as equivalent to those in the Mexican legislation. Moreover, this last Decree reduces requirements and timelines in connection to the prosecution of sanitary approvals.

General Health Law Regulations for Healthcare Products

On 31 May 2021, on the Federal Official Gazette a decree was published that amends, adds and repeals various provisions of the General Health Law Regulations for Healthcare Products. These amendments to the Health Law Regulations, in general, are focused on improving the analysis and resolution of various processes before the Sanitary Authority.

Guidelines for temporary authorisations for health supplies that contribute to the eradication and mitigation of the SARS virus CoV2 (COVID-19) in Mexico

These guidelines were published in March 2021 in the Official Gazette. The Federal Commission for the Protection against Sanitary Risks (COFEPRIS) will follow the extraordinary measures in the processes of submission, evaluation and authorisation of health supplies and health care establishments, including the temporary certification of good manufacturing practices for establishments that contribute to the eradication and mitigation of covid-19.

Regulations of the General Health Law on Sanitary Control for the Production, Research and Medicinal Use of Cannabis and its Pharmacological Derivatives

On 12 January 2021, the Regulations of the General Health Law on Sanitary Control for the Production, Research and Medicinal Use of Cannabis and its Pharmacological Derivatives were published in the Federal Official Gazette as ordered by the Supreme Court. This regulation aims to address the regulation, control, promotion and sanitary surveillance of raw materials, molecular complexes, pharmacological derivatives and medicines for the production, research and medicinal

use of cannabis and its pharmacological derivatives, and includes provisions regarding the import, export, advertising and marketing of cannabis and its pharmacological derivatives.

Federal Law for the Protection of Industrial Property Regulations

The entry into force of the Federal Law for the Protection of Industrial Property on 5 November 2020, to comply with the areas relating to intellectual property, including pharmaceutical patents.

Currently, the Federal Law for the Protection of Industrial Property Regulations is being drafted.

Other legislation includes:

- Health emergency decrees issued as a result of the outbreak of covid-19.
- Decree establishing the preventive measures that must be implemented to mitigate and control the health risks posed by the disease caused by the SARS-CoV2 virus (covid-19), DOF-24-03-2020.
- Decree establishing extraordinary actions to address the health emergency generated by the SARS-CoV2 virus, DOF-31-03-2020.
- Decree declaring extraordinary actions in the affected regions of the entire national territory in matters of general health to address the serious disease of priority attention generated by the SARS-CoV2 virus (COVID-19), DOF-27-03-2020.
- Decree establishing extraordinary actions that must be carried out for the acquisition and importation of goods and services to combat the serious disease of priority attention generated by the SARS-CoV2 virus, published 27 March 2020).
- Decree by which the suspension of legal terms and diligences in the administrative procedures that are developed before the Ministry of Health, its administrative units and decentralised administrative bodies is lifted.
- Federal Commission for Prevention and Protection Against Sanitary Risks.

Recently, the Draft Decree Issuing the Law of the Federal Commission for Prevention and Protection Against Sanitary Risks was presented to the Senate.

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