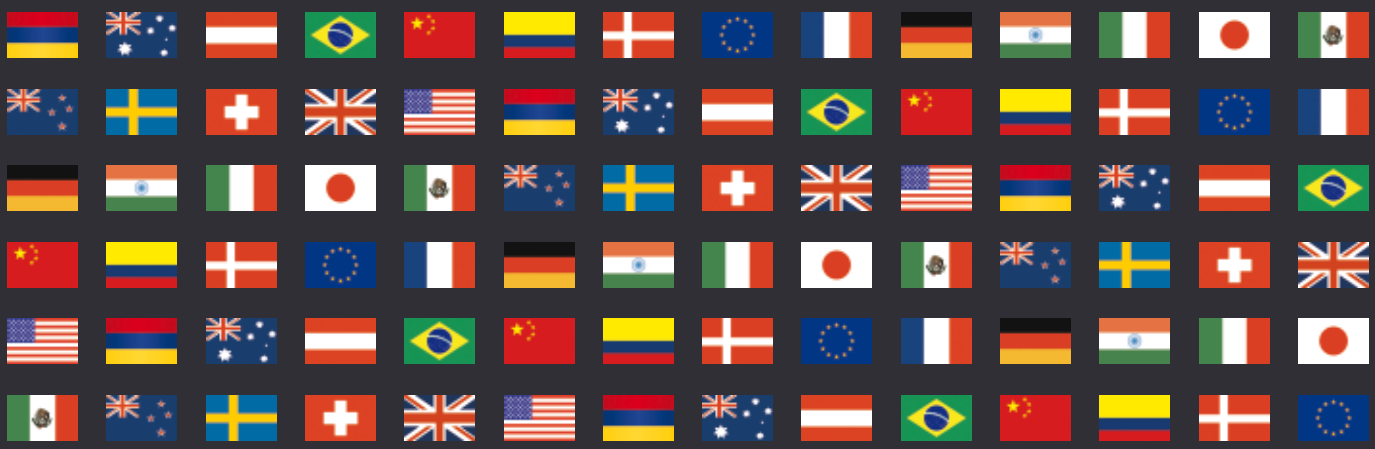
Pharma & Medical Device Regulation 2022

Contributing editors
Alexander Ehlers and Ian Dodds-Smith



LEXOLOGY
Getting The Deal Through

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Lexology Getting The Deal Through is delighted to publish the third edition of *Pharma & Medical Device Regulation*, which is available in print and online at www.lexology.com/gtdt.

Lexology 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 Lexology 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 a new chapter on Armenia.

Lexology 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.lexology.com/gtdt.

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.

Lexology 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 the contributing editors, Alexander Ehlers of Ehlers, Ehlers & Partner and Ian Dodds-Smith of Arnold & Porter, for their continued assistance with this volume.

LEXOLOGY®
Getting The Deal Through

London
October 2021

Contents

Mexico

Ingrid Ortiz and Luz Elena Elías
OLIVARES

HEALTH SERVICES FRAMEWORK AND COMPETENT AUTHORITIES

Healthcare bodies

1 Describe the bodies and their responsibilities (public and private sector) concerned with the delivery of healthcare and appropriate products for treatment.

The Mexican healthcare system comprises public (social security institutions) and private sectors.

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.

The public sector comprises:

- 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 Institute of Social Security;
  - Institute of Social Security for State Workers;
  - specialised public institutions for members of the military and navy force; and
  - 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; and
  - state 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 pharmacies to supply prescribed medicines and to request a refund for these.

Competent authorities for authorisation

2 Identify the competent authorities for approval of the marketing of medicinal products and medical devices. What rules apply to deciding whether a product falls into either category or other regulated categories?

The Mexican authority responsible for enforcing the regulatory framework relating to medical products is the Federal Commission for Protection against Sanitary Risk (COFEPRIS), which is part of the Ministry of Health. Within it is theNew Molecules Committee and the Subcommittee on Biotech Products, which assess biological medicinal products.

The regulatory framework is set out in the following federal laws:

- the General Health Law;
- the General Health Law Regulations for Healthcare Products;
- the Official Mexican Standards (NOMs);
- the Mexican Pharmacopoeia; and
- COFEPRIS's Rules listing healthcare products that do not require a marketing authorisation in view of its low risk to human health.

Products are classified according to the definitions provided in this legal framework.

Approval framework

3 Describe the general legislative and regulatory framework for approval of marketing of medicinal products and medical devices.

Pharmaceutical products

New molecules

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 the NOMs of good manufacturing of medicines and active ingredients, as well as the approval of their products as new molecules from the New Molecules Committee.

Generics

Applicants for marketing authorisations must prove that their products are bioequivalent to the innovator product. The NOM setting the test to prove that a generic drug is interchangeable with a reference drug was updated in recent years (NOM–177–SSA1–2013).

There is a linkage system between COFEPRIS and the Mexican Institute of Industrial Property, which aims to prevent the granting of marketing authorisations in violation of patent rights.

Biologics

Further to legal and administrative information, the essential dossier submission requirements for innovative products manufactured in Mexico are preclinical and clinical trials, certificates of good manufacturing practices (GMP) of the active pharmaceutical ingredient and the medicinal product, analytical methods, summaries, the manufacturing licence, prescription information, the label and a pharmacovigilance programme.

For innovative products manufactured abroad, additional requirements apply, in particular, a certificate for export, a letter of representation with apostille and a legal representative with an address in Mexico. In cases where the GMP certificates are not issued by an agency recognisedby COFEPRIS, such as the US Federal Drug Administration or the European Medicines Agency, an inspection in situ will be required.

On 19 August 2020, COFEPRIS announced new operating rules for the approval of generic drugs in Mexico, yet so far there have been no official or formal amendments.

Biocomparables (follow-ons)

The essential dossier submission requirements for biocomparables are almost the same as those for innovative biotech products, except for the requirements to prove safety, efficacy and quality.

For these purposes, biocomparable applicants must submit:

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

In May 2021, the Health Law Regulations were amended and included changes within the process of approval of biocomparables.

Once approved, close pharmacovigilance should be followed.

Orphan drugs

Orphan drugs were 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; however, specific rules would be welcomed.

Medical devices

Marketing authorisation requirements for medical devices depend 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 all medical devices and, if applicable, the software that enables them to work. Mobile medical applications are a new area that COFEPRIS may address in the future with particular regulations, especially if they present health risks.

CLINICAL PRACTICE

Applicable rules

4 What legislation controls and which rules apply to ethics committee approval and performance of clinical trials in your territory for medicinal products and medical devices?

Further to international guidelines– such as the Nuremberg Code, the Declaration of Helsinki, the World Health Organization guidelines and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use guidelines– the General Health Law and its Regulations for Health Research (RLGSMIS) and the Official Mexican Standard (NOM) for Health Research in Human Beings (NOM-012-SSA3-2012) regulate ethics committee approval and performance of clinical trials in Mexico.

Moreover, Mexican health authorities have issued guidelines for ethics committees (the 'Agreement establishing the general provisions for integration and operation of research ethics committees and hospital units that should have them, in accordance with the criteria established by the National Bioethics Commission'). According to these guidelines, committees must be integrated from different specialties and must include professionals from different areas, such as psychology, nursing, social work, sociology, anthropology, philosophy and law.

The Federal Commission for Protection against Sanitary Risk (COFEPRIS) approves ethics committees pursuant to the regulatory framework.

Reporting requirements

5 What requirements exist for reporting the commencement of a trial and its results to the competent authorities or the public?

Any research on human beings must be approved by COFEPRIS. This research may include testing new medicinal products or new uses, dosages or administration routes for already approved medicinal products. Essentially, the main requirements for an application for authorisation from COFEPRIS are:

- approval by an independent ethics committee registered with the Ministry of Health;
- approval by the medical institution or institutions where the clinical trials will be conducted. These institutions must be approved by COFEPRIS to conduct clinical trials;
- clinical trial protocol (including the schedule and the approximate number of medicinal products to be imported);
- written informed consent templates;
- preclinical and clinical data that justifies conducting the research;
- description of available resources to conduct the research and to address emergencies (including a statement of sponsorship); and
- a written letter by the qualified investigator acknowledging his or her responsibilities, and data from the investigator and his or her staff.

Applications should include details of the time frame of the protocol, indicating the possible dates of commencement and conclusion. The principal researcher must compile a final technical report for the clinical trial. When clinical trials last longer than one year, annual technical reports for the health authorities must be compiled. Medical assistance and financial indemnification for damage caused by the clinical trial must be provided to research participants.

Trial preconditions

Preclinical data must be collected to justify whether clinical trials can be conducted. The RLGSMIS requires measures to ensure that the investigator does not have conflict of interest to:

- protect the rights of research participants;
- maintain accurate results; and
- allocate resources.

The principal researcher must compile a final technical report for the clinical trial. When clinical trials last longer than one year, annual technical reports for the health authorities must be compiled. Accordingly, the following NOMs apply:

- Medicinal Products Labelling (NOM-072-SSA1-2012);
- Pharmacovigilance (NOM-220-SSA1-2016);
- Interchangeability and Biocomparability Tests (NOM-177-SSA1-2013);
- Biological Products (NOM-257-SSA1-2014);
- Good Manufacturing Practices for Medicinal Products (NOM-059-SSA1-2015); and
- Good Manufacturing Practices for Active Ingredients (NOM-164-SSA1-2015).

Consent and insurance

6 Are there mandatory rules for obtaining trial subjects' consent to participate? Must sponsors arrange personal injury insurance to a particular limit?

Investigators must obtain informed consent from the research participants in a formal written document, which must also be signed by two witnesses. In simple terms, the validity requirements for consent are that a participant grants it on a voluntary basis, with capacity to do so and sufficient information (knowing the potential risks and benefits). Participants maintain the right to withdraw from the study at any time. Investigators must ensure post-care for them until it is clarified that no damage arises from the research.

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

MARKETING AUTHORISATION

Time frame

7 How long does it take, in general, to obtain an authorisation from application to grant, what fees are payable and what is the normal period of validity of the authorisation?

Requirements and time frames vary among new molecules, biologicals and follow-on products. Article 166 of the Health Law Regulations sets out the following approval time frames:

- 180 calendar days for medicines that include an active pharmaceutical ingredient or therapeutic indication already approved in Mexico;
- 240 calendar days for medicines approved abroad but not in Mexico; and
- 180 calendar days for new drugs (a meeting with the New Molecules Committee is required).

The approval time frame for biologicals and biosimilars is 180 calendar days (articles 177 and 177-bis(4) of the Health Law Regulations).

These time frames may vary in practice but can be reduced if the application has been pre-examined by a third examiner (private company) approved by the Federal Commission for Protection against Sanitary Risk (COFEPRIS) to do so.

Government fees for analysing marketing authorisation applications are as follows:

- new molecules and biologicals: around US$8,600; and
- generics and biosimilars: around US$4,800.

Drug manufacturers must renew their licence every five years, subject to the relevant tests, including submission of a certificate of good manufacturing practices (GMP) in force.

Protecting research data

8 What protection or exclusivities apply to the data submitted by originators to gain initial approval and, on variation or new application, to add indications or pharmaceutical forms?

There is no specific body of local legislation for data protection exclusivity (RDP) in Mexico. In 2012, COFEPRIS issued internal guidelines to provide a five-year term of protection that only covers new chemical entities. However, the reliability of these guidelines is still uncertain.

Some cases are brought before the federal courts, which decide whether the health authorities have to observe RDP in respect of the product of interest for a five-year period set forth by the North American Free Trade Agreement (NAFTA) and the United States-Mexico-Canada Agreement (USMCA). Within the corresponding cases, preliminary injunctions are requested so that COFEPRIS observes the requested RDP until the merits of the case are decided. The granting of these injunctions is subject to the criterion and discretion of the court handling the case.

Based on the interpretation of international treaties, RPD for at least five years for new chemical entities, formulations, new indications, and orphan drugs has been obtained through litigation.

Concerning biologics, longer periods of RDP have been requested based on NAFTA (which provides that this protection should be at least five years) and international comparative law; however, the analysis in this regard is done on a case-by-case basis.

The new USMCA entered into force on 1 July 2020. This treaty will have an impact on the current situation concerning RDP in Mexico.

The USMCA used to describe the periods of protection more clearly than the current NAFTA; however, the amendments to the USMCA completed on December 2019 eliminated the provisions for new formulations or combinations, and new method of administration: at least three years, at least 10 years for biologics, and at least five years for new chemical molecules, with a transition period of five years.

Without those specific provisions, and with no domestic law, uncertainty among the generic and innovative pharmaceutical industries continues. To obtain this protection, litigation would still arise against the eventual refusals of COFEPRIS to recognise regulatory protection for more than five years for biologics and at least three years for new indications.

The amendments to the USMCA will not necessarily result in adverse decisions since the wording of NAFTA 'establishing at least five years of protection' remains the same as it has been since 1994 with NAFTA.

Moreover, there are favourable precedents with the NAFTA wording, obtaining more than five years of RDP for biologics. Therefore, the main grounds for a legal action trying to obtain more than five years RDP for biologics also remain.

The Agreement on Trade-Related Aspects of Intellectual Property Rights is still in force and is implemented through the Code of Commerce. In addition, the internal guidelines issued by COFEPRIS and several favourable legal precedents in this regard remain.

Other international treaties will be in force, including the treaty between Mexico and the European Union that binds the parties to recognise at least six years of RDP for both small molecules and biologics, although this treaty is not yet in full force.

Finally, the RDP provisions of the Comprehensive and ProgressiveAgreementfor Trans-Pacific Partnership have been suspended.

Freedom of information

9 To what extent and when can third parties make freedom of information applications for copies of research data submitted by applicants for authorisation to market medicinal products or medical devices?

According to the General Law of Access to Public Data, personal data and all data of applications under assessment are classified. Thus, health authorities usually reject freedom of information applications for data contained in marketing authorisation applications for medicinal products and medical devices. However, in some cases, they may allow release of certain information that is considered public information.

Regulation of specific medicinal products

10 Are there specific rules for approval, and rewards or incentives for approval, of particular types of medicinal products, such as traditional herbal and homeopathic products, biologicals and biosimilars, controlled drugs, orphan drugs and those for paediatric use?

Pharmaceutical products

New molecules

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COFEPRIS analyses all medical devices and, if applicable, the software that enables them to work. Mobile medical applications are a new area that COFEPRIS may address in the future with particular regulations, especially if they present health risks.

Post-marketing surveillance of safety

11 What pharmacovigilance or device vigilance obligations apply to the holder of a relevant authorisation once the product is placed on the market?

The NOM for pharmacovigilance, NOM-220-SSA1-2016 (NOM-220), establishes mandatory provisions regarding pharmacovigilance that apply to all medicines.

NOM-220 requires marketing authorisation holders to have a pharmacovigilance plan, which must include provisions for monitoring adverse effects in patients caused by the product at every stage of treatment.

The notice of adverse effects (grade 2) must detail the product's international non-proprietary name, distinctive name, batch number and manufacturer's name.

The National Commission for Pharmacovigilance should verify the plan to manage risks and, if applicable, require the implementation of an intensive pharmacovigilance plan.

Regarding medical devices, the marketing authorisation holder is required to have registered a technovigilance unit before COFEPRIS. The unit should have manuals and standard operating procedures. A qualified person, who should receive, sort and report adverse effects, should be in charge of the unit.

Other authorisations

12 What authorisations are required to manufacture, import, export or conduct wholesale distribution and storage of medicinal products and medical devices? What type of information needs to be provided to the authorities with an application, what are the fees, and what is the normal period of validity?

Companies manufacturing medicinal products in Mexico must be approved by COFEPRIS through a manufacturing licence or authorisation. Manufacturers must renew their licence every five years, subject to the relevant tests, particularly regarding GMP.

Any import of drugs, health products or raw materials for drugs must be approved by COFEPRIS. A marketing authorisation is needed unless an exemption applies. The import of a minimal quantity of products without a marketing authorisation can be approved in certain circumstances (eg, for clinical trials and orphan drugs, or 'necessity').

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

Sanctions

13 What civil, administrative or criminal sanctions can authorities impose on entities or their directors and officers for breach of the requirements concerning controlled activities?

COFEPRIS can request reports from marketing authorisation holders and make on-site inspection visits of the manufacturing, distribution or storage facilities.

COFEPRIS can initiate ex officio legal proceedings to sanction non-compliance. Ultimately, these legal proceedings can result in the revocation of authorisations. 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 advertisements. 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 the closure of the corresponding establishment or facility.

The imposition of administrative sanctions does not exclude civil and criminal liability. Administrative infringers can incur penalties ranging from a fine of up to 20,000 times the minimum wage to final closure of the establishment. Repeated infringement is also considered to be 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 General Attorney and the Customs Office to investigate and prevent counterfeit and illegal medicine activities.

Exemptions

14 What, if any, manufacture and supply of medicinal products is exempt from the requirement to obtain an approval to market?

No medicinal product is exempt from requiring marketing authorisation in Mexico unless it is a magistral formula, which is a medicine compounded in a local pharmacy to fit the unique need of a patient according to a detailed facultative prescription of a physician, under certain conditions and requirements, such as the requirement that the pharmacy needs regulatory approval to do so.

Parallel trade

15 Are imports allowed into your jurisdiction of finished products already authorised in another jurisdiction, without the importer having to provide the full particulars normally required to obtain an authorisation to market? What are the requirements?

The import of medicinal products requires a marketing authorisation, unless an exemption applies. These exemptions for medicines are essentially for lab tests, clinical trials, raw materials for assembly processes for export, special treatments for illnesses with low prevalence and social interest, personal use and donations.

Regarding medical devices, the exceptions are essentially lab tests, clinical trials, personal use, physician use, donations and used devices.

In January 2020, the Ministry of Health published a decree in the Official Gazette whereby the government allows the importation of medicinal products already authorised in another jurisdiction (the United States, Canada, Switzerland and the European Union). Certain requirements must be complied with before importation.

AMENDING AUTHORISATIONS

Variation

16 What are the main requirements relating to variation of authorisations for medicinal products and medical devices?

Marketing authorisation holders can apply for adjustments to their marketing authorisations, but applicable requirements depend on the type of adjustment (eg, legal or administrative information, manufacturing site or indication of use).

Renewal

17 What are the main requirements relating to renewal of authorisations for medicinal products and medical devices?

Marketing authorisations must be renewed every five years. Applicants must prove their product complies with good manufacturing practices, safety and efficacy standards, pharmacovigilance and labelling standards, among other applicable provisions.

In May 2021, the requirements to apply and eventually obtain a renewal were reduced.

Transfer

18 How easy is it to transfer the existing approvals or rights to market medicines and medical devices? How long does this take in general?

The transfer of a marketing authorisation requires compliance with certain formalities and procedures, which should not be difficult if the applicant meets the applicable requirements. To transfer a marketing authorisation to a new holder, an application must be submitted to the Federal Commission for Protection against Sanitary Risk (COFEPRIS).

According to the Health Law Regulations, COFEPRIS must decide on a transfer application within a period of 20 days following the filing date. In practice, this period varies, and it can be extended if further data or documents are requested.

COFEPRIS may serve the applicant during this 20-day period with a request for information or documents, granting the applicant with a term to respond that cannot be less than five working days. If no response is provided within the granted term, the application is considered as cancelled.

If COFEPRIS does not serve any request or decision on the applicant during the 20-day period, the application is considered approved.

RECALL

Defective and unsafe products

19 What are the normal requirements for handling cases of defective or possibly unsafe products, including approvals required for recall and communication with health professionals?

The Official Mexican Standard on Good Manufacturing Practices for Medicinal Products (NOM-059-SSA1-2015) requires the marketing authorisation holder to employ a programme to recall products that do not meet quality standards in an appropriate and efficient manner. This programme must include:

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

Marketing authorisation holders must report any product recall decision to the Federal Commission for Protection against Sanitary Risk, providing details of the products and the causes leading to the recall.

PROMOTION

Regulation

20 Summarise the rules relating to advertising and promotion of medicinal products and medical devices, explaining when the provision of information will be treated as promotional. Do special rules apply to online advertising?

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

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

The National Chamber of the Pharmaceutical Industry (CANIFARMA) has a code of ethics that includes provisions on advertising. Although these provisions are not mandatory, failure to comply can result in a suspension of rights as a member of the chamber or exclusion from it.

The RLGSMP defines advertising as an activity comprising all creation, planning, performance and distribution processes of advertisement to promote the sale or consumption of products and services. Thus, it is considered that providing information will be treated as advertising when it promotes the sale or consumption of products.

Electronic advertising falls under the general rules for advertising in article 2 of the RLGSMP. COFEPRIS is increasing its monitoring of online advertisements for medicinal products and medical devices, which to date has been less stringent than advertising on television and radio. The Code of Good PromotionPracticesstates that online promotion of prescription-only medicines addressed to healthcare professionals must be duly approved by the corresponding authorities. The advertising must be disclosed on scientific websites. The sponsor must be clearly identified.

Inducement

21 What regulations exist to discourage the provision of inducements to healthcare professionals to prescribe, sell, supply or recommend use of a particular medicinal product or medical device?

There are several bodies of law that refer in general terms to the relationship between the pharmaceutical industry and healthcare professionals, such as the General Health Law and the Health Law Regulations (including those that concern the regulatory control of healthcare activities, establishments, products and services). Industry codes of practice complement these regulations.

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

Affiliate members of the National Chamber of the Pharmaceutical Industryare required to follow these codes. CETIFARMA supervises members' and adherents' compliance.

These bodies of law and codes set important sanctions to discourage the provision of inducements to healthcare professionals to prescribe, sell, supply or recommend use of particular products.

Reporting transfers of value

22 What requirements apply to recording and publishing details of transfers of value to healthcare professionals and organisations by companies marketing medicinal products or medical devices?

The Code of GPP and the Code of GPI allow CETIFARMA to require members to record any valuable support given to healthcare professionals, institutions or patient organisations. According to their guidelines, members will make information concerning donations granted available to the public on a yearly basis to promote transparency.

ENFORCEMENT OF ADVERTISING RULES

Enforcers

23 Describe the bodies involved in monitoring and ensuring compliance with advertising controls for medicinal products and medical devices, distinguishing between any self-regulatory framework and control by the authorities.

In accordance with the General Health Law, the Federal Commission for Protection against Sanitary Risk (COFEPRIS) is in charge of monitoring and ensuring compliance with advertising controls.

The primary legislation for the advertising of medicinal products and medical devices is the General Health Law and its Regulation. These norms are supplemented by guidelines published by COFEPRIS. This agency is part of the Ministry of Health and controls the advertising of medicinal products and medical devices. 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 Code of Ethics and Transparency of the Pharmaceutical Industry;
- the Code of Good PromotionPractices; and
- the Code of Good Practices of Interaction of the Pharmaceutical Industry with Patient Organisations.

Affiliate members of 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.

Sanctions

24 What are the possible financial or other sanctions for breach of advertising and promotional controls for medicinal products or medical devices?

COFEPRIS has specific authority to order the suspension of an advertising activity in breach of the legal framework. This order must be followed by both the responsible party and the media channel within 24 hours. COFEPRIS may warn companies with approved products to modify advertisements that are presumably in breach of the legal framework. If not modified, or the modification is considered to not comply with the legal provisions, COFEPRIS may suspend the advertising activities and impose a fine. Decisions and orders issued by COFEPRIS may be appealed before itself or the federal courts.

The penalties for failing to comply with the rules related to advertising are the suspension of advertising activities ordered either to the responsible party or directly to the media, and the imposition of a fine to each one, which can range from 2,000 to 16,000 times the minimum wage. The responsibility for imposing these penalties falls directly on the Ministry of Health through COFEPRIS.

COFEPRIS constantly monitors advertising activities throughout the country, particularly regarding drug-like products, and has been directing the efforts of coordination agreements related to publicity, as well as the enforcement of the same. There has also been a strong coordinated effort between COFEPRIS and pharmaceutical companies tending to the self-regulation of advertising, which is still monitored. COFEPRIS has imposed large fines against specific over-the-counter medication manufacturers for using misleading advertising related to its products, inciting the public to self-medicate and to take their products at the first symptom without consulting a doctor.

PRICING AND REIMBURSEMENT

Pricing

25 What are the controls imposed on pricing of medicines and medical devices and reimbursement by national social security systems that are applicable to manufacturers, distributors and pharmacists?

Price control in the private sector is based on a self-regulated maximum retail price (MRP) scheme covering patented products, overseen by the Ministry of Economy. Under 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.

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.

Under that scheme, price review, and eventual changes, is done annually. The new administration is implementing modifications frequently, which may impact the frequency of price change. The austerity measures that have recently been taken by the government will continue and may result in a more frequent price review.

Public insurers dispense medicinal products prescribed by their healthcare professionals. Products are prescribed from a basic medicinal products list, which public insurers base on the national formulary issued by the Ministry of Health. Public insurers acquire those listed products mostly by public tender processes. The Mexican Institute of Social Security is the largest public sector buyer of drugs.

For direct purchasing of patented products, the CNDP analyses the effectiveness of the drugs and relevant therapeutic alternatives and the feasibility and implications of an eventual substitution with equivalent medicines. The CNDP also conducts an economic evaluation of the cost-effectiveness of patented medicines compared with potential substitutes.

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

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

OFF-LABEL USE AND UNLICENSED PRODUCTS

Off-label use

26 May health professionals prescribe or use products for 'off-label' indications? May pharmaceutical companies draw health professionals' attention to potential off-label uses?

The Code of Good PromotionPractices sets forth that information about 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.

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

Unlicensed products

27 What rules apply to the manufacture and importation and supply to healthcare providers of unlicensed medicines or medical devices?

The manufacturing, importation and supply of a medicinal product to a healthcare professional requires that the product has been approved.

Compassionate use

28 What rules apply to the establishment of compassionate use programmes for unlicensed products?

COFEPRIS authorises the use of drugs for compassionate use. The regulation for such use is the same as that for clinical trials, mainly:

- the General Health Law;
- the Health Law Regulations;
- Health Research in Human Beings (NOM-012-SSA3-2012);
- the Code of Good Practices of Advertising of the National Chamber of the Pharmaceutical Industry (CANIFARMA);
- theCANIFARMA Code of Ethics; and
- various Official Mexican Standards.

SALE AND SUPPLY

Regulation

29 Are there special rules governing the dispensing or sale of particular types of medicinal products or medical devices?

Prescription medicines, such as antibiotics, can be dispensed only if the consumer provides a written prescription. Dispensing over-the-counter medicines does not require a specific permit. Psychotropic and narcotic drugs are prescribed using a special notebook monitored by the Federal Commission for Protection against Sanitary Risk (COFEPRIS) and dispensed through local pharmacies authorised by COFEPRIS.

In general, there are no special rules governing the sale or purchase of medical devices; however, this may depend on the level of risk involved in their use and whether a prescription would be required.

Online supply

30 What laws and guidelines govern online dispensing, sale and supply of medicinal products and medical devices?

Medicinal products and medical devices may be sold online provided this is carried out by authorised pharmacists in authorised pharmacies. Prescription medicines can be sold to patients only with a physician's prescription. Dispensers must keep original prescriptions for antibiotics.

UPDATE AND TRENDS

Forthcoming legislation and regulation

31 Is there any current or foreseeable draft legislation or other rules that will affect the regulation of pharmaceuticals and medical devices? What is likely to change, and what steps need to be taken in preparation?

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

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

This decree, as with the decree 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, they would be considered as equivalent to those in the Mexican legislation. Moreover, this latest decree reduces requirements and timelines in connection with the prosecution of sanitary approvals.

General Health Law Regulations for Healthcare Products

On 31 May 2021, the Federal Official Gazette published the decree 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 Federal Official Gazette published the Regulations of the General Health Law on Sanitary Control for the Production, Research and Medicinal Use of Cannabis and its Pharmacological Derivatives as it was 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.

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Federal Law for the Protection of Industrial Property Regulations

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, has entered into force. The Federal Law for the Protection of Industrial Property Regulations is currently being drafted.

Health emergency decrees issued as a result of the covid-19 pandemic

- 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.
- 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.

Proposal of a new Federal Commission for Prevention and Protection Against Sanitary Risks Law

Recently, the Draft Decree Issuing the Law of the Federal Commission for Prevention and Protection Against Sanitary Risks was presented to the Senate. However, it appears that it will be a while before there is any relevant news in connection with the discussion of this proposal.

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