# THE LIFE SCIENCES LAW REVIEW

ELEVENTH EDITION

**Editor**
Peter Bogaert

THE LAWREVIEWS

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# PREFACE

The eleventh edition of *The Life Sciences Law Review* covers a total of 24 jurisdictions, providing an overview of legal requirements of interest to pharmaceutical, biotechnology and medical device companies. The chapters are arranged so as to describe requirements throughout the life cycle of a regulated product, from discovery to clinical trials, the marketing authorisation process and post-approval controls. Certain other legal matters of special interest to manufacturers of medical products – including administrative remedies, pricing and reimbursement, competition law, special liability regimes and commercial transactions – are also covered. Finally, there is a special chapter on international harmonisation, which is of increasing importance in many of the regulatory systems that are described in the national chapters.

The past year showed a transition from the covid-19 pandemic to more normal health conditions, but also an enhanced awareness of new challenges. During the two preceding years, manufacturers of healthcare products, together with healthcare professionals and services, focused on the development and testing of vaccines, other drugs, biologics, diagnostics and personal protective equipment. This was done on an expedited basis, and regulatory agencies have reviewed marketing applications with unprecedented speed and efficiency. Manufacturers and international organisations have also worked closely together in an effort to ensure equitable access to vaccines and other important healthcare products in low- and middle-income countries, but much work remains to be done. Regulators are now making preparations for later emergencies and are also drawing lessons from the experience gained during the pandemic for the development and assessment of new health products in important therapeutic areas. Efforts to support effective and equitable access to key products at a more international level also continue.

Given the constant challenges and quick developments, it is vitally important that lawyers who advise companies in the life sciences sector and the business executives whom they serve have a working knowledge of the regulations and policies that govern drugs, biologics and medical devices. It is equally important to keep up to date with developments in the regulatory systems that govern access to the market, pricing and reimbursement, advertising and promotion, and numerous other matters that are essential to success. It is our hope that this year's publication will be especially helpful in this respect.

All of the chapters have been written by leading experts within the relevant jurisdiction. They are an impressive group, and it is a pleasure to be associated with them in the preparation of this publication.

**Peter Bogaert**
Covington & Burling LLP
Brussels
February 2023

**Chapter 14**

# MEXICO

*José Alberto Campos-Vargas*[1]

## I INTRODUCTION

The Mexican Federal Constitution establishes health as a fundamental human right and provides the basis for the government to enact provisions related thereto. Article 73 of the Constitution grants the Mexican Congress authority to issue laws regarding health matters. Under this provision, the government has enacted diverse laws and regulations concerning medicines, pharmaceuticals, devices, food and beverages, dietary supplements, tobacco, vaping, cannabis and other goods and activities deemed to have an impact on human health. These provisions have particular relevance owing to the covid-19 pandemic and its effects on the general health situation in Mexico in past years.

The main law in this area is the Mexican General Health Law (the Health Law), which provides that certain products, including, pharmaceuticals, narcotics, devices, food and beverages, dietary supplements, and diverse processes related to these, are subject to sanitary control – this being comprehensive of manufacturing, packaging, handling, transportation, distribution, warehousing, etc.

The Health Law specifies that the authorities in charge of medicines, devices and most other regulated products are: the President of Mexico, the General Health Board, the Ministry of Health[2] and state governments (on state jurisdictional matters).

The Ministry of Health has the broadest jurisdiction regarding these goods and activities. Moreover, the Health Law details the specific areas of competence for the diverse authorities in health matters, including the particular roles of the executive branch, the Health Board, state governments, etc.; other laws also establish particular competence for these authorities such as the Tobacco Law, the Federal Law on Quality Infrastructure, the Foreign Trade Law and the Law on Import and Export Duties Law, which regulate, among others, the possibility to import diverse products in Mexico.

In addition to Congress' authority to enact laws, the executive branch has the authority to issue regulations that clarify or specify the content of existing laws, without extending beyond or contravening the law being interpreted.

Among the most relevant regulations are the Health Law Regulations for Health-Related Goods (the Goods Regulations), the Health Law Regulations for Health Research (the Research Regulations) and the Regulations of the Health Law in Publicity Matters (the Publicity Regulations), etc.

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2 Through the Commission for the Protection Against Sanitary Risks (COFEPRIS).

Products and services imported, marketed or rendered in Mexico are also subject to Mexican official standards (NOMs). These are administrative guidelines that establish technical specifications, characteristics, processes, operation requirements, etc., in the Mexican territory. Before these are issued, the corresponding government entity (e.g., COFEPRIS) prepares and issues draft guidelines that permit interested parties to participate in their creation or amendment. In some particular cases, it is also possible for the authorities to issue emergency NOMs, which have a limited time of validity. Likewise, other relevant concepts regarding the technical aspects of these kinds of goods are included in the Pharmacopeia and its diverse supplements or appendixes.

Other provisions can be issued by the authorities as internal guidelines, decrees or accords, which may or may not be published in the Federal Official Gazette. Again, these kind of provisions were of particular relevance during the covid-19 emergency because of the necessity to take immediate actions to control the pandemic, many of which were not been fully compliant with the applicable legal provisions and procedures.

During the past few years, there has been a clear tendency to 'control' health-related or controlled services and products has been to impede or restrict their formal importation. Through this strategy, the federal government has, rather than controlled the actual marketing of these goods within Mexico, restricted their availability when these are of foreign origin.

Diverse precedents regarding the nature of health provisions and the interpretation of health as a constitutional and human right and its prevalence upon other such rights and vice versa have occasionally been issued by the courts against other fundamental human and constitutional rights.

## II THE REGULATORY REGIME

Pharmaceuticals, devices and other products and services that have effects on human health are regulated at the federal level. These include, among others: research; food and beverages; human tissue and DNA; psychotropic and narcotics; toiletries and cosmetics; toxic substances; publicity; tobacco, vaping and alcoholic beverages; and medical software and telemedicine.

The Health Law and other provisions establish general licence, procedure and penalty requirements applicable to these goods and activities. Regulations, NOMs, guidelines and the Pharmacopeia establish additional or more specific requirements to each type of product and service.

### i Classification

The Health Law, its regulations and other provisions provide specific definitions of medicines, medical devices and other products and services subject to sanitary control. In some cases, where specific legal provisions have not been enacted, it is quite common to have the competent authorities resort to provisions based on 'similarities' or broad general concepts within other provisions. These determinations based on similarities greatly increased during the covid-19 pandemic, and products that were not considered regulated or that, because of their dual or variable use, were not in practice regulated by the health authorities have been under scrutiny of the authorities for the past several months. This same situation has been fairly common to new technologies that are formally unregulated or at the best partially regulated in Mexico, as could be telemedicine, new nicotine products, artificial intelligence used in medical services and devices, technologies with the possibility of dual use for medical and recreational purposes, wellness, novel food and beverage products, etc.

***Medicines***

The Health Law defines medicines as substances having therapeutic, preventive or rehabilitative effects identifiable on pharmacological, physical, chemical and biologic characteristics, and classified based on diverse criteria such as: allopathic, homeopathic, herbal remedies, prescription, controlled prescription, over the counter, vitamins, biotechnological, orphan drugs, traditional medicines, etc.

In addition, other regulated products include toxins, anti-toxins, vaccines, serums, parenteral preparations, blood products, microbial and fungal preparations, hormones, and enzymes.

***Medical devices***

The Health Law identifies six main types of medical devices (medical equipment, prostheses and functional aids, diagnostic agents, dental products, surgical material and hygienic products), which are classified based on their risks, safety and efficiency into three classes: Class I, well-known in medical practice and not body-invasive; Class II, known in medical practice or body-invasive for periods shorter than 30 days; and Class III, new or recently accepted in medical practice or remaining in the body for periods greater than 30 days.

Certain NOMs and internal criteria include additional requirements for products that, although not formally medical devices under the Health Law or its Regulations, have been included under its scope by the authorities, as possible new technologies (apps and software), electric and electronic products used in 'wellness', holistic therapies and similar procedures, telemedicine services, etc. It appears to be a general trend of the health authorities to attempt regulating products which, although not having as their specific purpose to be used as a medical device (in a broad perspective) could eventually be used by health professionals for diagnosis, treatment or other similar purposes, including electronic products using apps and software available in a general manner through the internet or other similar media.

### ii Non-clinical studies

There is no specific restriction regarding the use of non-clinical studies. The party performing the non-clinical study is solely responsible for assuring good laboratory practices and that these studies do not represent a risk to human health. Under certain state legal provisions, certain risks exist of interpretations that may lead to restrictions for these activities. Under the current health situation, many non-clinical studies have been initiated through the use of information and data transfer in an international manner through electronic systems. This situation has created a general uncertainty as to whether such kinds of data or information transfer could fall within the scope of what is considered a non-clinical study and the consequent legal requirements that such would have to meet. Likewise, diverse legal provisions regarding the use of animals for non-clinical studies or trials have been enacted at the federal and local level.

### iii Clinical trials

In contrast with non-clinical trials, clinical trials are subject to extensive regulation. The Health Law, the Research Regulations and specific NOMs regulate clinical trials. These may involve research on prophylactic, diagnostic, therapeutic and rehabilitative resources; bio safety risks; DNA and biotechnology; and radiation.

Clinical trials are classified based on the risk they may pose to the test subjects and are divided into non-risk research, minimum-risk research, and greater-than-minimum-risk research.

Research involving human beings requires authorisation prior to its commencement. The performing parties must provide the authorities with information regarding the scope and purpose of the research, the main investigator, approval of the institution's committees and informed consent of the subjects.

In principle, clinical research should only be carried out at health institutions under the direction of a principal investigator who is a health professional, member of such institution and the latter guarantees possible damages arising therefrom, medical treatment required and potential indemnification to subjects.

Certain legal concepts associated with clinical trials, such as clinical research trial agreements and sponsorship and activities, are not regulated by Mexican law; however, in practice the authorities have issued internal criteria, compliance with which is required to obtain the authorisations, and included some references in NOMs or other administrative criteria.

Currently, it is a fairly common activity for legal entities or individuals to carry out data and information collection of a medical or investigative nature through new technologies (apps, software and similar means) that are not specifically regulated as information considered as a clinical trial subject to permits and authorisations. There have been some attempts by the health authorities to consider that these data transfers may constitute a clinical trial subject to the applicable legal provisions; however, to date, the applicable legal statue would be inapplicable to these kind of procedures, because of that part of the clinical trial concept that necessarily includes the participation of domestic institutions and protocol authorisations to Mexican residents, which, in many cases, may not be feasible in cases of information transfers through electronic means. Likewise, the mere transfer of data is not, under the current applicable statute, a regulated activity that could fall within the concept of a clinical trial. Furthermore, for Mexican legal purposes, those entities without a physical or legal presence within Mexico are not considered liable or subject to the provisions governing life sciences matters. During the past several months, and owing to the increase in data collection processes bound for use in health-related matters, political debate has arisen, resulting in required additional and more restrictive regulations and measures in this area.

### iv Named-patient and compassionate use procedures

Only one exception exits for using a product before it has received marketing authorisation (MA). This is in the case of clinical trials that may save a patient's life or health, or eliminate pain, provided the patient has supplied written consent.

Notwithstanding, the Mexican courts have issued recent criteria establishing that irrespective of the restriction to import and use regulated products subject to MA, the health authorities must permit their use considering the greater relevance of the human right for life in relation to the general health protection and exclusivity of cleared products.

Some relevant cases have been presented in the prior years before COFEPRIS, many of which have been even subject to further judicial review and, in some cases, constitutional procedures that have been favourably solved to the petitioners. Most of these precedents have considered that the human right for access to health should be considered as having a preference over formal requirements or general requirements applicable to regulated products.

### v Pre-market clearance

Currently, only medicines and medical devices require registration with COFEPRIS, granted based on available information regarding their safety, among which are: technical and scientific data; therapeutic efficacy and safety; use and prescription; labelling; and certificates from country of manufacturing.

If the product is considered safe, registration is issued and the products can be manufactured, imported and marketed in Mexico. As an alternative to the general registration process, this information can be pre-reviewed by a private authorised entity, and a fast-track registration may be granted. This kind of registration is also available for products holding MA in jurisdictions with which mutual recognition agreements have been executed.

Both Mexican and foreign laboratories that manufacture pharmaceutical products may obtain MA. For medical devices, it is not necessary to have manufacturing premises in Mexico or abroad to obtain MA; however, the requesting party must be registered with COFEPRIS and provide the required documents.

In November 2020, the Executive Branch ordered the Ministry of Health and COFEPRIS to issue the corresponding marketing authorisations for diverse regulated products within a five-day period following the filing of the corresponding dossier. This order and express issuance of the corresponding MA will depend on the existence of an MA issued by other countries with mutual recognition agreements and that the complete dossier is duly filed. Likewise, during the past year, a number of administrative provisions regarding the facilitation of these procedures have been issued, whether recognising foreign authorities' authorisations or criterion or providing the requesting parties with the possibility to provide the required information and documents in a less formalistic manner and even after the corresponding authorisation has been granted.

### vi Regulatory incentives

#### *Patent term extensions*

Mexico does not provide patent term extensions or grant delays. However, as a signatory of the United States–Mexico–Canada Agreement (USMCA), ratified and mandatory as of 1 July 2020, it shall enhance intellectual property protection for pharmaceutical products, because, under this agreement, the member parties must 'make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process'.

#### *Link between regulatory approval processes and patent expiry*

The Regulations for the Industrial Property Law and the Goods Regulations establish a linkage mechanism to observe patent rights. This has been subject to a considerable number of litigation actions since its enactment.

#### *Data and marketing exclusivity*

Data and marketing exclusivity for pharmaceutical products is an obligation under USMCA, which has only been regulated through an internal guideline from COFEPRIS.

### vii Post-approval controls

Holders of MAs must maintain the conditions upon which they were granted while these are in force. Changes thereto may result in cancellation. Changes to the background upon which an MA was issued must be filed for approval. The health authorities may verify that premises where processes are carried out meet the necessary good manufacturing practices or sanitary conditions.

In the specific case of pharmaceutical vigilance, in addition to the general procedures set out by the Health Law, those of the applicable NOM and certain provisions in the Mexican Pharmacopeia, must also be satisfied. This vigilance has greatly increased during the past year, especially in connection to regulated products other than pharmaceuticals and duly registered medical devices, including, among others, controlled substances and products that, although not bound to be used in the medical industry, may be used for illegal activities and products.

### viii Manufacturing controls

Medicines, devices, food and beverages, tobacco and other regulated products' manufacturing is subject to sanitary control and includes requirements regarding premises where related 'processes' are carried out. In some cases, laboratories or other kinds of premises may be authorised to process products subject to this requirement through the issuance of a sanitary licence. The Health Law establishes different types of premises that may be authorised to operate in Mexico, including factories or laboratories of medicines, homeopathic or herbal remedies or biological products for human use, etc.

Premises where pharmaceutical products are manufactured must as a general rule: evidence 'good sanitary practices'; have quality control laboratories; appoint specific individuals with the health authorities as representatives of the entity; and provide, as required, information regarding products, services, processes and, as the case may be, specific administrative controls. A very relevant increase in the verification and manufacturing controls that involve substances that can be considered as psychotropic, dual-use or chemical precursors was the rule during 2021. Many of these substances and products, although not formally subject to control by the health authorities, have been assimilated or considered as subject to the same controls and requirements that similar substances bound or used specifically by the pharmaceutical industry may have, a situation that clearly complicates the operation of these industries.

Additionally, these premises must meet specific operational and manufacturing requirements set out in certain NOMs depending on the kind of products to be manufactured. A general trend has been the increased regulation and review of operations involving chemical products that may be used in, among others, the pharmaceutical industry, as well as their use in illegal products and activities, irrespective of the lack of regulation and restrictions for many of these products.

### ix Advertising and promotion

The Publicity Regulations define the term 'publicity' as any activity that includes all creation, planning, playing and broadcasting processes of advertisements in communication media with the purpose of promoting the sale or consumption of products or services.

The Health Law differentiates between publicity intended for health professionals and for the public, the former being that regarding the characteristics and use of medicines, medical devices and medical or scientific information used for publicity or promotional

purposes restricted to specialised media and based on the content of the products' MA and the latter intended for the public at large, which requires specific permits and is only applicable to over-the-counter medicines and herbal remedies.

Promotional materials regarding pharmaceutical products and medical devices in Mexico are not subject to authorisation, provided these do not include information other than the names of the products and the entity manufacturing or distributing them, or both. Likewise, activities carried out involving health professionals are generally not subject to restriction, because it is possible to organise or sponsor congresses, sessions, courses, etc. regarding products, and to provide sample products, gifts, hospitality and entertainment. Most of the authority's verification efforts in these topics have been focused on dietary supplements and products that could have dual or similar use to those considered medical devices and that are offered or marketed through social media or informal markets. In addition to publicity for such goods, food and beverage products, currently subject only to a notice regarding their publicity, will be subject to specific permits and authorisations based on the alleged risk to public health that the authorities have determined that such products may represent.

### x Distributors and wholesalers

Distribution and wholesale of pharmaceutical products and devices are 'processes' subject to sanitary control by the Mexican health authorities and subject to restrictions and conditions depending on the specific type of sanitary licence.

The Health Law and applicable regulations establish different premises subject to sanitary control and specific requirements for each. Generally, premises for the wholesale and distribution of pharmaceutical products and medical devices are subject to compliance with specific requirements for warehousing, transportation and control.

Several additional requirements and restrictions for the distribution and wholesale of pharmaceutical and devices bound for the public sector have been enacted during the current administration, many of which have been established through administrative guidelines or internal criteria rather than through formal laws or regulations.

### xi Classification of products

The Health Law and corresponding regulations set the rules and conditions for classifying pharmaceutical products, medical devices and other regulated products and services. This classification determines the conditions for marketing goods and specific permits and authorisations for related processes. The specific criterion for products classification may be determined by the health authorities, and specific provisions regarding the nature and characteristics of such products may also be found in NOMs and the Pharmacopeia and its Annexes.

### xii Imports and exports

The Health Law identifies importation and exportation of goods as a 'process' subject to sanitary control and general requirements. Specific requirements apply based on the product and its tariff classification.

For products imported into Mexico, these requirements include importers' licences and the appointment of authorised customs brokers.

Importation triggers import duties based on the tariff classification and value of goods and value added tax plus other government fees.

Non-tariff requirements are also applicable. For medicines and pharmaceuticals, these are generally subject to the issuance of an import or export permit by COFEPRIS. Medical devices are generally only subject to presentation to the customs authorities of the corresponding MA.

Other products subject to controls may include those bound for wellness purposes, certain kinds of food and beverage and other apparently unrelated items that may represent a health risk. During the past year, the Mexican government has taken a position where rather than controlling the manufacturing or marketing of regulated products, these have been restricted in their importation, either increasing the amount of duties and taxes or most commonly through the issuance of additional non-tariff requirements and restrictions, which could be licences, permits, marking and labelling requirements, etc.

### xiii Controlled substances

Controlled substances include all psychotropic and narcotic substances. The list of such goods is included in specific chapters of the Health Law, which establishes the general requirements applicable to these goods and their classification based on their use and effects.

Under the Health Law, psychotropic substances are divided into several categories based on their use and potential risks.

Processes involving these substances and those considered as raw materials for manufacturing illegal drugs are subject to specific controls, set forth in the Federal Law for the Control of Chemical Raw Materials, Essential Chemical Products and Machinery for Tablet and Pill Manufacturing and its regulations. This also provides specific regulations regarding production, sale, acquisition, importation, exportation, transportation, warehousing and distribution of certain chemical products, and apparatus for the manufacture of tablets and pills, specific permits and control and reporting requirements.

In 2017, diverse amendments to the Health Law were published, including amendments establishing the possibility to obtain MA for pharmaceutical products deriving from cannabis, and a new law specifically regulating cannabis products has been expected for a couple of years now. In this same regard, during 2021, the health authorities were particularly focused on the verification and restriction of operations involving these kind of products, whether these were specifically bound for the pharmaceutical or medical industries or whether these were effectively bound for industrial, hygienic or other similar purposes. These actions derive from efforts focused on the limitations of raw materials and components used in the illegal production of controlled and restricted substances.

### xiv Enforcement

Mexican health authorities may verify at any time the due compliance of applicable provisions of process involving these goods and services. COFEPRIS is generally in charge of these verification procedures, which must meet requirements in the Health Law and the Federal Law on Administrative Proceedings. These procedures must always be served in writing, and the scope and purpose of the verification must be established clearly. Once this procedure notice is served, the authorities may initiate the review and verification of documents, premises and processes.

The verification procedures in health matters must meet the general guidelines and requirements for these types of matters included in the Constitution, the Health Law and the Federal Law on Administrative Proceedings.

All reviews and actions carried out by health authorities in these processes must be included in minutes and finalised with a written resolution in which the findings or potential infractions committed are set out. The determination of the commission of an infraction must always set out the factual background and legal basis upon which it is considered as such and may be challenged through the applicable legal remedies.

During the covid-19 pandemic, many verification processes and procedures have been put in the charge of the local health authorities of the different Mexican states. This has resulted in a number of procedures and legal remedies that have to be filed in accordance with local procedural provisions.

## III PRICING AND REIMBURSEMENT

Pricing and reimbursement can be broadly divided into two sectors: the private sector and the public sector.

### i Private sector

As a general rule, sales to the private sector are subject to contractual terms and not subject to particular requirements. Some rules and industry policies have been enacted to establish maximum sales prices for new drugs.

### ii Public sector

In Mexico the government is a direct provider of health services, through different institutions, including the Social Security Institute; the Institute of Security and Social Services for State Workers, which provides services for federal government employees; the Ministry of Defence; the National Oil Company; and the state health bodies.

The new administration incorporated an Institute of Health for Well-Being, replacing the former Popular Insurance System (Seguro Popular) intended to provide health coverage for individuals not covered by other public health systems.

Medicines and devices used in these institutions are directly purchased by the Mexican government through a combination of public tenders and direct acquisition proceedings.

The Health Law includes some specific restrictions regarding the maximum prices for medicines offered for sale to the public at large, it being necessary to include these maximum prices in the labelling. As mentioned above, most medicine sales to government health providers are subject to specific bidding procedures under the Law on Acquisitions, Leases and Services of the Public Federal Administration; however, some exceptions to this general rule are applicable. Similarly, the Mexican social security system relies on the direct rendering of health-related services by the competent government agencies; no reimbursement procedures exist for goods directly acquired by the population covered by the public healthcare system.

## IV ADMINISTRATIVE AND JUDICIAL REMEDIES

Administrative infringements may be determined independently of possible criminal offences arising from acts or omissions set forth by the corresponding legal provisions. The applicable legal remedy depends mainly on the type of fine or penalty applied to a legal entity or individual, as well as the reasons for that determination. In general, the penalties for failure to comply with obligations set out by the corresponding legal provisions can be fines, seizures, foreclosure of premises, destructions of goods, etc.

Various legal remedies exist for challenging decisions or determinations regarding possible infringements of health-related provisions. These are administrative appeal and the administrative litigious procedure.

### i Administrative appeal

Under the Health Law, acts by the health authorities may be challenged through an administrative appeal.

The administrative appeal may confirm, cancel or amend the resolution in specific terms, or order issuance of a new resolution. The resolution of the administrative appeal may be further challenged through the administrative litigious procedure before the Federal Administrative Justice Court.

### ii Administrative litigious procedure

Alternatively, resolutions may be challenged through an administrative litigious procedure (nullity petition) before the Administrative Justice Court, based on the Federal Law on Litigious Administrative Procedures.

The nullity petition may confirm the resolution, declare it null and void, declare partial nullity, or declare nullity for a specific purpose.

Unfavourable or partially favourable resolutions to a nullity petition may be challenged through a constitutional remedy before the Federal Court of Appeals. In specific cases, the resolution issued by an administrative authority may also be directly challenged through filing of this remedy when the resolution implies the direct violation of constitutional principles.

## V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYERS

Mexican law provides no specific rules regarding financial relationships between pharmaceutical and medical device companies with prescribers and payers, except in some very limited cases involving public health service officials. In the case of acquisitions by government agencies, the Federal Law on Public Servants is applicable in connection with the prohibition to provide any kind of gift to an individual who holds public office when the gift is directly related to his or her activities.

## VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

Under Mexican law, there is no specific procedure or system for the compensation of possible injuries or damages arising from use of medicines or medical devices. Individuals who are affected or damaged by a medicine or medical device may file a lawsuit (ordinary civil procedure) to request the compensation of damages. Under Mexican law, only direct damages may be requested, if a direct relationship between the product and the damage can be duly evidenced.

## VII TRANSACTIONAL AND COMPETITION ISSUES

### i Competition law

The Law of Economic Competition (the Competition Law) does not include specific provisions regarding medical devices and pharmaceutical products in Mexico. These product types are subject to the general provisions of the Competition Law. Owing to the nature of the pharmaceutical and medical devices business in Mexico, however, these industries tend to be severely scrutinised by the competition authorities, especially in the case of sale to government agencies.

### ii Transactional issues

Under Mexican law, no specific provisions or regulations pertain to transactional issues regarding legal entities engaged in the pharmaceutical or medical devices business. In practice, however, various issues may be encountered in the event of mergers, acquisitions, spin-offs and sales of assets in connection with these industries. Thus, the transfer of MA, licences and authorisations by virtue of the aforementioned transactions may take considerable time to be finalised. Likewise, any change to the manufacturing processes or the grounds on which an MA was issued must be duly reported to the health authorities and, in some cases, may be considered a 'change' or amendment to the conditions upon which a such authorisation was granted.

## VIII CURRENT DEVELOPMENTS

Mexico is the second-largest medicine market in Latin America after Brazil, and one of the most developed, with high regulatory standards and a well-developed life sciences industry. With the change of government after the 2018 election, several public policy changes were enacted that considerably affect the life sciences sector. These include a change in government procurement rules, and amendments to rules regarding national treatment for entities from countries with which Mexico has entered into free trade agreements, etc. Likewise, the covid-19 pandemic derived in complex and varied amendments to the procedures and timing involved in most processes regarding pharmaceutical products and medical devices and particularly those used for the treatment of this malady.

These amendments have forced life sciences companies to participate in a more active manner in these kinds of proceedings as well as to evaluate with greater care their participation in business with the Mexican public sector.

Another change was the replacement of the Seguro Popular with the National Institute for Health and Well-Being. In addition, it has been established that it is necessary to create a National Drug Formulary for a National Health Compendium, which is expected to have a broader scope than the current one, a situation that in practice has derived from the lack of certain medicines and medical procedures to the necessary restructuring of the competent institutions and budgets.

The new administration has taken very specific positions in connection with life sciences industries and health-related matters, the most relevant being those regarding the following topics.

### i Cannabis

Although a law has been awaiting finalisation by Congress for a couple of years, there have been scarce developments in this regard owing to debates on the possibility of having Mexican and foreign investors participate in this market. Participation therein had been intended to be restricted only to certain communities and, in particular, to indigenous groups.

The original intention of the law was to regulate the recreational use of cannabis and the decriminalisation of its use; however, greater attention to the possibility of its industrial and commercial use has been contemplated, but no specific approach or resolution has been clearly established as to the actual regulation of cannabis for such purposes.

### ii Software as a medical device

Some efforts to regulate software as a medical device have been made; at the time of writing there is not yet clear regulation, and the diverse proposals lack formal procedures in this regard. Although it has become a growing trend in Mexico, the final provisions are still far from being clearly established in the applicable statute. However, most technology-related medical activities are currently being reviewed by the competent authorities, and some proposals regarding their future development have been discussed. Interestingly, most of these proposals are focused on greater restrictions and the potential liability of medical professionals rather than on a release or facilitation of the use of such technologies for the rendering of medical-related services.

### iii Vaping and tobacco

One of the most controversial subjects currently being addressed by the health authorities is vaping, heated tobacco and new nicotine products.

The restriction and control of vaping is a global trend. Because of Mexico's legal structure, vaping is still not contemplated as one of the products regulated by the applicable provisions. However, the health authorities have considered a national health emergency in this regard and thus have attempted to restrict the importation, sale and use of these products.

These restrictions, owing to their nature and characteristics, have been challenged by diverse entities and individuals engaged in this industry having obtained favourable results from the competent courts and even final pronunciations of the unconstitutionality of these absolute restrictions by the Mexican Supreme Court. Notwithstanding this, the executive branch issued a decree whereby the importation of vapers and vaping liquids is deemed forbidden. As such, although it is possible to market and sell vaping products in Mexico, it is not possible to actually import these into the country. During 2021, a Decree amending the import restrictions to electronic cigarettes was issued; however, it was repealed some weeks afterward, retaking an absolute restriction of the importation of these goods. In this regard, traditional tobacco products, and especially their advertising, has been strongly targeted by health and consumer protection authorities. Further, new regulations regarding the restriction of the manufacturing, sale and use of tobacco products and other nicotine products is expected to be issued during the first months of 2023. Likewise, diverse states in Mexico have included in local legislation diverse provisions restricting or forbidding the use of tobacco products, heated tobacco, vapers and other similar products in public places. Although these restrictions do not refer to the products themselves (which are governed at the federal level) they have a notorious effect on the marketing and use of such.

### iv Food and beverages

Another relevant matter during the new administration is the rules and provisions regarding food and beverage labelling. During the last quarter of 2019, Congress amended the Health Law and added diverse articles specifically related to food and beverage products' labelling. The main purpose of these amendments is to provide, in the clearest manner possible, information to the consumer as to the actual caloric content of products and possible elements of risk for their health such as salt, sugars, fats, caffeine, etc. The applicable provisions in this regard entered into force in October 2020 and, although challenging, have already been implemented by the medium and largest food and beverage manufacturers and retailers in Mexico. New provisions regarding the marketing of these products have been included in the corresponding regulations and are bound to restrict and limit e-publicity and marketing campaigns, through the requirement of permits (rather than notices) for broadcasting in television, radio, cinema and social networks' advertising of these kinds of products.

### v Dietary supplements

The importation and marketing of dietary supplements was less restricted during the past administration; however, the current administration has given special attention to their importation and marketing requirements. The core of activities and specific actions by the authorities has focused on the advertising and marketing through electronic means. Most of the verification and restriction of these kinds of products has been done through the limitation of sale through electronic marketing platforms.

### vi Wellness

Wellness is a concept that has been progressively increasing its presence in diverse jurisdictions. Mexico is no exception, and a very noticeable increase in the marketing of these kinds of products has taken place during the past couple of years.

Many of these 'wellness' products fall within the grey line of a 'medical' device, because often they allege that their use may help improve certain medical conditions or bodily functions or that their use may improve an individual's general health and are, in the end, machines or apparatuses that are in contact with the human body.

The health authorities have increased their review and enforcement of these kinds of goods. However, because of their nature and marketing strategies, on many occasions it is difficult to enforce the applicable provisions and when enforced these may go beyond the actual scope of the applicable provisions.

Finally, many of the health-related authorities are being restructured by the current administration; thus, practical issues in the day-to-day relationship with these are a definitive trend, which it is hoped will diminish once these restructures are implemented.

### vii Government participation in pharmaceutical products production, marketing and general regulation

Possibly one of the most relevant developments regarding pharmaceutical and medical devices in Mexico is the greater participation of existing government entities and the creation of new government bodies in charge of diverse activities related to the importation and public supply of these products.

Based on a number of amendments to the applicable provisions, the competent government authorities may now import pharmaceutical products for their use with the

public administration even if these lack the corresponding marketing authorisations. Specific rules and less stringent requirements are set forth for the public administration to acquire, use and distribute regulated products and in the latest case, a considerable number of officials currently serving in COFEPRIS have a military and navy background, thus approaching and discussing diverse topics related to products and services regulated by COFEPRIS with these new officials is considerably different than in the past. In this same regard, and owing to the implementation of electronic platforms for procedures to be followed before COFEPRIS derived from the social distancing policies implemented during the covid-19 pandemic, the possibility of discussing specific issues with the competent official thereat has been greatly restricted.

**Appendix 1**

# ABOUT THE AUTHORS


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José Alberto Campos-Vargas is a partner at Sánchez Devanny who heads the life sciences and foreign trade practice groups that deal with diverse legal issues regarding products such as medicines, medical devices, food and beverages, cosmetics, cannabis, tobacco, and new nicotine technologies and health services, among others. He has more than 25 years of experience advising clients in connection with their operations in Mexico with highly regulated products either by the Ministry of Health or the Ministry of Agriculture and other related authorities in such products' processes regarding importation, warehousing, manufacturing, marketing, transportation, etc.

He has advised clients in industries highly regulated by the Mexican health and agricultural authorities in connection with strategic planning of Mexican operations, including obtaining licences, authorisations and permits of diverse kinds, planning for mergers, acquisitions and spin-offs of entities that carry out highly regulated activities or that involve the use of these kinds of products and new technologies, as well as those rendering services related to health. Likewise, he has advised a considerable number of legal entities in connection with the publicity and marketing strategies for regulated products and services, in connection with the planning and development of labelling and technical requirements compliance, as well as with the planning, review and authorisation of marketing materials all the way to litigious procedures before authorities such as COFEPRIS, SENASICA and PROFECO.


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