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# Year in review: 2023

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**Introduction**

2023 has been a very complex year for life sciences-related legal provisions in Mexico.

This is not only due to the direct effects in this sector arising from the covid-19 pandemic, but also to the perspective that the current Mexican administration has on all health-related products and services.

The technological and scientific advances and developments that this sector underwent over the past couple of years has advanced at an extraordinary pace that the applicable legal statute governing these kinds of products and services has not kept up with.

Probably one of the most relevant issues arising from these technological developments has been the increased use of digital platforms and tools that enable the promotion, use and marketing of heavily regulated products and services bound for their use in health-related matters either by humans or animals.

This also applies to new products and technologies developed over the past few years, not only in the pharmaceutical products arena or direct health and healthcare services, but also in connection with other products bound for human, animal and agricultural consumption and use.

These new products and services represent a formidable challenge from the legal perspective, since, in many cases, these are not contemplated or covered by the existing legal framework.

Unfortunately, the Mexican government has a prohibitionist and restrictive perspective when it comes to these new products and services, rather than a regulatory perspective where these products are subject to specific regulation and limitations.

Interestingly, this restrictive and prohibitionist trend has been strengthened as of the issuance of jurisprudence from the Supreme Court of Justice that permits the decriminalisation and, in some cases, legalisation of the use of cannabis for diverse purposes. These purposes include industrial and recreational use which, for several years now, have not been properly implemented by the authorities. The authorities have insisted on maintaining total restriction of these products' importation, manufacture and/or marketing in Mexico.

It appears that even though the judicial power has established that, from a constitutional perspective, total prohibition and restrictions are against the free personality development right, the general position of the executive branch is to restrict and forbid the use and marketing of diverse products and services based on the alleged risk to human, animal and plant health.

In addition to the specific regulation and restrictions to products and services, relevant changes regarding the public health services operation were implemented during 2023. These range from the cancellation and disappearance of public trusts and institutions related to medical services, institutions and services rendering, to the cancellation of diverse Mexican official standards (NOMs) for specific medical procedures and products. This situation has been viewed by many as a way to avoid the rendering of public health services in connection with these procedures and products.

It is also worth mentioning that the presence of military personnel within the health regulatory agency, Federal Commission for the Protection Against Sanitary Risks (COFEPRIS) has increased dramatically. This situation has clearly derived in a "different" approach to the possible discussion or understanding of the application and interpretation of the applicable legal provisions by individuals or legal entities engaged in regulated products importation, marketing, or exportation.

This article provides an overview of the main developments that took place in the Mexican life sciences legal sector in 2023 and expected developments for 2024.

**Official standards**

During 2023, a considerable number of NOMs related to goods and services subject to sanitary control in Mexico were amended, repealed or implemented.

Possibly the most relevant matter related to NOMs was the projected cancellation of over 30 health related NOMs which was published on 1 June 2023.

Many of these NOMs are directly related to the specific technical aspects of prevention, detection, diagnosis and attention of diverse maladies such as:

- obesity;
- diabetes;
- diverse kinds of cancers; and
- addictions.

The cancellation of some NOMs related to health education and hospital attention services was proposed.

Due to a considerable number of complaints and even legal remedies implemented against these proposed amendments and cancellation, this cancellation process has been suspended and a more detailed analysis of the amendments and/or reasoning behind this cancellation process offered by the Mexican health authorities has been started.

Although this intended cancellation does not, per se, imply that the NOMs included in this list would have been amended or cancelled, it was widely believed that a potential cancellation would result in a lack of commitment by the Mexican government. The government would likely not include certain services and maladies treatment with those offered by the public health services.

Another relevant NOM amended during 2023, was NOM-177-SSA1-2013, which refers to the specific testing and procedures that must be followed to evidence the nature of a medicinal product as interchangeable.

This amendment clearly derives from the diverse experiences learned during the covid-19 pandemic, and the legal lack of a regulatory basis in connection with goods and services required during these kinds of health emergencies.

Other NOMs related to "health" matters from the labor perspective were also implemented and amended during 2023 in order to provide workers with a better health environment in the workplace, with a focus on metal health issues.

**Public health services**

Some of the most relevant changes in health-service-related matters is the new public health systems implementation, which completely changed the Mexican health system, increasing the centralised nature of the health services authorities.

The main purpose of this change has been established as the consolidation of the medical and health services that will be universal, public, gratuitous and of a preventive nature, which, to date, does not appear to be working the manner or with the efficiency alleged by the executive branch.

The alleged purpose of this new health service is to provide medical services to people who do not have formal social security services and grant them access to medical professionals and necessary goods (eg, devices, medicines and materials) as well as the ability to render any kind of health service in a local and non-centralised manner.

It is questionable whether the centralisation of the health services administration will achieve the proposed objectives and whether this centralisation will effectively comply with the purpose announced by the executive branch. From a practical perspective, it appears that these amendments, rather than providing more efficient health services, has done the total apposite.

**Publicity**

Publicity and marketing strategies for goods have been very restricted over the past few years.

The Federal Consumer Protection Law (CPL) has been amended and focused on the restriction and limitation of the "claims" and information for different products and services.

The consumer protection and health authorities claim that the reason for this is due the risks associated with these products, particularly the risks related to child and adult obesity which has been considered a major health problem in Mexico for the past several administrations.

The focus on the publicity and marketing strategies restriction had been, under the applicable statute, focused on:

- television;
- cinema;
- radio;
- publications;
- billboards; and
- other similar media.

This focus made it virtually impossible to control publicity carried out via social media or digital platforms. This kind of publicity was one of the most common alternatives used to carry out marketing strategies and publicise diverse regulated products.

This derived in certain amendments to the CPL, the General Health Law Publicity Regulations and even some attempts to amend the federal telecommunications provisions.

The amendments were unclear and, in many cases, their application difficult, if not impossible. Additionally, many of these amendments could be considered a violation to diverse constitutional principles.

The publicity of products such as food, beverages, dietary supplements and cosmetics (which previously were only subject to a notice before the Mexican health authorities) are now subject to a specific permit issued prior to their broadcasting in any kind of media.

These permits must be filed prior to any kind of broadcasting activity and, although specific periods for the authorities to solve these requests have been established, it has also been established that in those cases where if the response is not issued in time, it will be denied.

This situation has clearly affected these industries due to the lack of a timely response by the competent authorities to the publicity authorisation requests, as well as the costs involved, since each filing is subject to payment of governmental fees as well as the actual cost of the time and processes related to these activities.

**Chemical industry, precursors and essential chemicals**

It is a fact that illegal drug trafficking has dramatically increased in recent years, particularly the exportation of illicit drugs from Mexico to the United States.

Among the most relevant drugs that are being exported from Mexico are chemical or synthetic drugs, such as methamphetamines and fentanyl.

It has been determined that these drugs were manufactured in Mexico with raw materials originating from different Asian countries, particularly China.

Due to this situation, the health and public safety authorities have taken a very strong position on the control and traceability of these products, many of which also have a very broad use in the manufacturing of:

- industrial products;
- cleaning products;
- machinery; and
- equipment cleaning and maintenance.

In 2023, very relevant amendments to the Federal Law on Precursors, Essential Chemical Products and Machinery for the Manufacturing of Pills, Capsules and Tables (FPL) were enacted.

Through these amendments, stricter controls were imposed on the diverse processes related to these kinds of products, such as the:

- importation;
- warehousing;
- production;
- marketing; and
- exportation.

These controls are mainly focused on the traceability of products and "know your client" obligations, as well as administrative controls related to the number of sales, acquisitions, imports and exports of these products.

Also, diverse actions, omissions and lack of proper administrative controls are now considered to be criminal offenses rather than mere administrative infractions.

The main adverse effects of these new provisions is the complexity of the information and documents required in each stage of the processes involving these substances, as well as the fact that, until the first weeks of December 2023, no regulations or administrative clarifications to these amendments have been formally published.

Additionally, the FPL establishes that the health authorities must be notified of all transactions involving these kind of products within 24 hours of the transactions taking place. However it is not yet clear whether this obligation should be computed or whether the effects be considered as of the legal obligation existence or after the actual process (importation, sale, entry into warehouse, etc,) is carried out.

The health authorities have also established that all these notices only be filed electronically through the implemented database or system. This will limit the ability of individuals or entities engaged in these kinds of products to approach the authorities directly for guidance, support or rulings regarding the interpretation or implementation of these provisions. Notably, this system wasn't implemented until the first few weeks of December 2023.

**Food, beverages and cosmetic products**

As previously mentioned, in the food and beverage arena, there have been very relevant amendments to publicity and marketing. However, other restrictions and limitations have also been implemented in a more substantive manner.

Particular interest has been given to:

- food with high calorie content, so-called "junk food";
- energy drinks; and
- drinks based on herbs and other plants and plant extracts that have been considered to have pharmacological or other potential narcotic or psychotropic effects, but which are not formally nor specifically contemplated by the applicable statute.

The ingredients and components of dietary supplements have been limited by the health authorities based on "potential" risks or the "unrecognised" nature or effects of plants and ingredients.

This position goes against the legal basis since, from the health authority's perspective, all ingredients or substances that are not expressly recognised by them are deemed forbidden. Thus they clearly ignore diverse legal principles and precedents in the sense that "any and all goods, services and actions, not expressly considered as forbidden must be deemed as permitted".

Additionally, in 2023, two other very relevant restrictions were put in into place. One was the limitation of the use of trans fats in the manufacture of human-bound food and beverages. This prohibition, although substantially congruous with the potential health hazards of these products, was not clear as to the situations in which trans fats should be considered ingredients. There are some instances where trans fats are used not as an ingredient but as a manufacturing or production aid.

The unregulated and unclear restriction of the use of these kinds of products in the food and beverage industry has resulted in additional costs and limitations in the manufacturing of these products. This situation is ultimately affects the final consumer.

Surprisingly, the executive branch, in view of many illegal and unconstitutional actions, decided to restrict the importation and use of human-feeding-bound products of transgenic corn, based on the alleged risk of using transgenic products.

Although the restriction is specifically focused on the human food industry and has been expressly exempting industrial products manufacturing or animal feeding bound products, it has come from very relevant costs and limitations to the importation and use of this products.

This situation has come from very relevant complaints and potential legal actions from Mexico's most important trade partners, the United States of America and Canada, which are some of the largest exporters of corn considered for purposes of such limitation as transgenic and which have very relevant sales of this product into Mexico.

This restriction and limitation resulted in potential trade remedies to diverse Mexican products into both countries being delayed until the finalisation of communications and until controversy solutions provisions have been contemplated by the United States, Mexico and Canada Free Trade Agreement.

**Tobacco and alternative nicotine products**

During 2023, the Mexican government insisted on limitations and restrictions being placed on vaping and heated tobacco devices. The government not only wished to do this through the actual restriction and limitation to the importation and marketing of these kind of devices, which has been challenged through constitutional remedies an in most cases solved in a favorable manner to the affected parties, but also through the limitation on their use in public places.

Under the current statute, most courts have said that restrictions on the importation and marketing of these devices is unconstitutional and thus have provided federal justice protection upon requesting parties. These resolutions have provided these parties with the ability to import and market these products.

Due to these resolutions, the executive branch issued diverse amendments to the applicable regulations to establish new limitations in connection with the places where these goods may be used.

Under these new regulations, rather than focusing on the importers, marketing agents and retailers of these products, the authorities have changed the focus to premises where tobacco and nicotine products may be used, as well as the premises and businesses where the products may be sold to the final consumer.

These provisions were focused mainly on restaurants, hotels, factories, offices buildings and nearly any kind of construction, limiting the use of such products in such premises. These provoked a number of businesses, especially those in the entertainment industry as the regulations were beyond the scope of the law.

The limitation to exhibit or even have publicly visible tobacco and other nicotine products was focused mainly on convenience stores, and prohibited businesses from publicly exhibiting or placing these products where they could be visible to the consumers.

These restrictions are way beyond what is set forth in the applicable Law and, thus, were considered by many as contrary to the constitutional legality principles. Consequently, several constitutional appeals were filed either directly by the affected parties as well as by chambers or other business associations.

Tobacco and nicotine products are the best example of a product subject to the restrictions and prohibitionist policies that the current administration has implemented under the "forbid all, regulate none" perspective.

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