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Mexico
Life Sciences

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This country-specific Q&A provides an overview of life sciences laws and regulations applicable in Mexico.

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Mexico: Life Sciences

1. Please briefly summarize your country's legislative framework for medicinal products (including biologicals), medical devices, food, and food supplements

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

- The General Health Law[1];
- The Regulation for Health Supplies[2];
- The Regulation on the Health Control of Products and Services[3];
- Mexican Official Standards (NOMs);[4]
- The Mexican Pharmacopoeia;[5]
- The COFEPRIS' Rules listing healthcare products that do not require a marketing authorization in view of their low risk to human health (COFEPRIS Rules);
- Amendments to the Equivalence Decree to import health supplies without marketing authorization.
- Regulatory Certainty Strategy for the Pharmaceutical Sector: Biosimilars

Footnote(s):

1 https://www.ordenjuridico.gob.mx/leyes.php#gsc.tab=0

2 Ídem

3 Ídem

4 https://dof.gob.mx/busqueda_detalle.php?textobusqueda=Norma+Ofici#gsc.tab=0

5 https://www.farmacopea.org.mx/

2. With regards to medicinal products and medical devices, how is the regulatory process structured in your jurisdiction from R&D through market approval until post-marketing vigilance, and what rules does it follow? Please briefly describe.

Regarding medicinal products and medical devices:

Medicinal products

Allopathic 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 COFEPRIS New Molecules Committee.

Generics

Applicants for marketing authorizations must prove that their products are bioequivalent to the innovator product. On May 3rd of 2021, the NOM setting the test to prove that a generic drug is interchangeable with a reference drug was updated (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 authorizations in violation of patent rights.

Biologic New molecules

When it comes 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 of the active pharmaceutical ingredient and the medicinal product, analytical methods, summaries, manufacturing licence, prescribing information, label, and a pharmacovigilance programme.

For innovative products manufactured abroad, additional requirements apply, particularly a certificate for export, a letter of representation with apostille and a legal representative with address in Mexico. In cases where the good manufacturing practices certificates are not issued by an agency recognised by COFEPRIS, such as the US Food and Drug Administration or the European Medicines Agency, an in-person inspection will be required.

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 essentially:

- 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.
- Comparative efficacy and safety clinical tests to show similarity between both the follow-on and the product of reference.

Once approved, close pharmacovigilance should be followed.

Recently, COFEPRIS published its Regulatory Certainty Strategy for the Pharmaceutical Sector: Biosimilars, the purpose of this strategy is to promote the development of biocomparable biotechnological medicines, establishing an institutional and regulatory framework, aligned with international standards, in order to promote the capacity of the industry in all phases of research and production of these products.

Orphan drugs

Orphan drugs were introduced to the General Health Law and the *Mexican Pharmacopeia* several years ago. In practice, they are approved by a particular procedure, following rules for new molecules when applicable and appropriate. Still, there are many ambiguities in the regulations.

Medical devices

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

Class I encompasses products that are well known in medical practice, for which safety and efficacy have been proven, and are not usually introduced into a patient's body; Class II encompasses 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 encompasses 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, 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.

Also, there is a list of medical devices that are considered as low risk for the purpose of obtaining marketing authorization, and those products that due to their nature, characteristics and use are not considered as health inputs, and therefore do not require marketing authorization as well, this list is periodically updated.

3. What is the regulatory process for food supplements, from first notification to the competent authorities until post-marketing vigilance in your country, and what regulations are applicable here? Please briefly describe.

In terms of food supplements, the regulatory process is to notify COFEPRIS trough a "Notice operation" the commercialization of the product 30 days before starting operations.

Food supplements do not require marketing authorization and post-marketing vigilance. Instead of that, COFEPRIS advise to interested parties to perform a food supplements classifications consult in which the labeling and the quali-quantitative formula are reviewed before submitting the Notice operation. The regulations applicable here are:

- The General Health Law;
- The Regulation on the Health Control of Products and Services;
- The Regulation of the General Health Law on Advertising[6];
- Mexican Official Standard (NOM), NOM-251-SSA1-2009, Hygienic practices for the processing of food, beverages or food supplements[7];
- The Mexican Herbal Pharmacopoeia[8];
- Agreement amending the one determining the additives and adjuvants in foods, beverages and food supplements, their use and sanitary provisions[9];
- Agreement determining the plants prohibited or permitted for teas, herbal infusions and edible vegetable oils[10].

Footnote(s):

6
https://www.ordenjuridico.gob.mx/leyes.php#gsc.tab=0

7

https://www.dof.gob.mx/normasOficiales/3980/salud/salud.htm

[8] https://www.farmacopea.org.mx/

[9] https://dof.gob.mx/nota_detalle.php?codigo=5437267&fecha=16/05/2016#gsc.tab=0

[10] https://www.dof.gob.mx/nota_detalle.php?codigo=4958062&fecha=15/12/1999#gsc.tab=0

4. What are the ongoing obligations in your country after a marketing authorization for medicinal products has been obtained or a conformity assessment been carried out for medical devices?

The Mexican Official Norm for Pharmacovigilance, NOM-220-SSA1-2016[11] (NOM-220), establishes mandatory provisions regarding pharmacovigilance that apply to all medicines (including biologicals).

Regarding medical devices, through the Mexican Official Norm for Technovigilance NOM-240-SSA1-2012[12] (NOM-240) establishes mandatory provisions regarding technovigilance that apply to all medical devices.

NOM-220 requires marketing authorization holders to have registered a Pharmacovigilance Unit before COFEPRIS, and NOM-240, requires marketing authorization holders to have registered a Technovigilance Unit as well.

For both units are applicable to have manuals and standard operating procedures, a qualified person which oversee the unit who should receive, sort and report adverse effects.

For the case of medicines (including biologicals), the Pharmacovigilance unit have to elaborate Periodic Safety Reports and submit those before COFEPRIS, have a pharmacovigilance plan (in case of new molecules), which must include provisions for monitoring adverse effects in patients caused by the product at every stage of treatment.

The National Commission for Pharmacovigilance should verify that plans to manage risks, and, if applicable, require to implement an intensive pharmacovigilance plan.

Footnote(s):

[11] https://www.dof.gob.mx/nota_detalle.php?codigo=5601541&fecha=30/09/2020#gsc.tab=0

[12] https://dof.gob.mx/nota_detalle.php?codigo=5275834&fecha=30/10/2012#gsc.tab=0

5. Which are the competent national authorities having the regulatory oversight over medicinal products, medical devices, food, and food supplements and what are their respective responsibilities?

The Mexican authority who oversights medicinal products (including biologicals), medical devices, food, and food supplements is the Federal Commission for Protection against Sanitary Risk (COFEPRIS), incorporated in the Undersecretary for Prevention and Promotion of Health of the Ministry of Health.

Between its responsibilities are:

- Enforcing the regulatory framework;
- Looking after medicines, medical devices, food, food supplements, cosmetics, personal care products, vegetable nutrients, pesticides and other health-related products;
- Compliance with the good manufacturing practices;
- Control de exportation / importation of products;
- Monitor public and private health services.

6. Please briefly describe the procedure of challenging regulatory decisions (e.g., denial of marketing authorization) made by the competent regulatory authority in relation to medicinal products, medical devices, and food supplements.

There are some procedures to challenge regulatory decisions made by COFEPRIS as follows:

Prevention letter

The prevention happens before the expiration date of the procedure, only once per procedure and when COFEPRIS needs more information related with the submitted issue to review and take a decision (whether it is refused or not). Once the prevention letter is delivered to the applicant, there are 5 working days available to respond to COFEPRIS' inquiries described into the prevention, if

not the procedure is discarded, and a new procedure has to be submitted before this authority.

Refusal

For refusals there two ways that COFEPRIS proceed with a procedure:

a. When COFEPRIS had reviewed all the information that was given to them with the application for the procedure and decide that the issue do not accomplish the applicable regulatory requirements and/or the technical support to prove that the product is safe and efficient for its intended use. The authority delivers a refusal letter to the applicant in which are described the causes along with the legal fundament. This leads to discard the application and start a new one.
b. When the procedure comes to an end on the expiry date and the authority has never issued any related official notice, then it is considered discarded, and the applicant have to star another new procedure.

The procedure or venues to challenge regulatory decisions (e.g., denial of marketing authorization) made by the competent regulatory authority in relation to medicinal products, medical devices, and food supplements (COFEPRIS) are as follows:

- Review recourse, contesting COFEPRIS´ final decisions (e.g., denial of marketing authorization), this recourse is studied and resolved by the hierarchical superior.

The term to file the recourse is of 15 working days as from the notification of the decision.

- Nullity Trial before the Federal Courts for Administrative Affairs (FCA).

The term to file the recourse is of 30 working days as of the notification of COFEPRIS' initial decision or its decision to the review recourse.

- The decision issued by the FCA could be appealed by the affected party in a last stage before the Federal Circuit Courts (FCC).

The term to file the appeal before the FCC is of 15 working days as of the notification of FCA's decision.

- Alternately, in case of a direct violation to the constitution or international treaties, it could be possible to file an unconstitutional action "so-called amparo" before the Federal District Courts.

It is necessary to take into account that the decision issued by the Court is not final and can be challenged by the party that considers it contrary to its interests before the Federal Circuit Courts.

The estimated time frame for this trial is around 15 to 24 months, and the final stage before a Circuit Court takes 6 to 8 months.

The ordinary venue to challenge a marketing authorization granted to a third party that may violate patent rights is an appeal before the Federal Court of Administrative Affairs contesting the unlawful granting of a marketing authorization.

7. Please briefly describe the legal framework and the relevant regulatory procedure (e.g., application process, requirements, approval, denial) that applies in your jurisdiction to clinical trials for medicinal products and medical devices.

The legal framework and the relevant regulatory procedure that applies in Mexico about clinical trials for medicinal products and medical devices is based on international guidelines that control and rule ethics committee approval and performance of clinical trials in Mexico, such as:

- The Nuremberg Code;
- The Helsinki Declaration;
- World Health Organization guidelines;
- International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use guidelines.

These guidelines lead to create and enforce the national regulation as follows:

- The Federal Law on the Protection of Personal Data Held by Individuals;[13]
- The General Health Law;
- The Regulation of the Federal Law on the Protection of Personal Data Held by Individuals[14];
- The Regulation of the General Health Law on Health Research[15];
- The Mexican Official Standard (NOM), NOM-012-SSA3-2012, which establishes the criteria for the execution of research projects for health in human beings[16].

- Other NOM's and internal decrees.

Footnote(s):

13
https://www.ordenjuridico.gob.mx/leyes.php#gsc.tab=0

14 Ídem.

15 Ídem.

16
https://dof.gob.mx/nota_detalle.php?codigo=5284148&fecha=04/01/2013#gsc.tab=0

8. Is there a public database for clinical trials in your country, and what are the rules for publication?

There is a public database for clinical trials[17] which brings general information about those trials that have been authorized in México. The principal rules for its publication consist in submit before COFEPRIS the protocol of the clinical trial, get the protocol authorized, and the publication its performed by the authority.

Footnote(s):

17
http://siipris03.cofepris.gob.mx/Resoluciones/Consultas/ConWebRegEnsayosClinicos.asp

9. Please briefly summarize the rules that must be observed in your jurisdiction when using data from clinical trials?

The rules that have to be observed in Mexico when using data from clinical trials, is to guarantee to all experimentation subjects the privacy of their personal data through a written informed consent form between the experimentation subject and the authorized party by COFEPRIS (where the clinical trial is going to take part).

Other rule is that the sponsor (who is owner of the medicine or medical device to test), and the authorized party have to determine through an agreement the property and belonging of all the data gathered and created from the start until the end of the trial, in most of the cases the sponsor is the owner of that data.

10. Are there any trends and/or legislative proposals in your country on digitizing the process of conducting clinical trials (e.g., digitalization of the application process, decentralization of clinical trials)?

COFEPRIS has a virtual platform called DIGIPRiS, in which is available to applicants to submit specific procedures. Between November and December of 2023, COFEPRIS published that this platform is able to apply for authorizations for human research protocols and for modifications or amendments to the protocol authorization. Likewise, the applicants can consult all the procedures that have requested, see those that have been previously authorized and those that are in process, as well as visualize the status of the procedure from the application, evaluation, verification, signature, and resolution[18].

Footnote(s):

18
https://www.gob.mx/cofepris/acciones-y-programas/digipris-investigacion-y-ensayos-clinicos?state=published

11. What are your country's legal requirements for the authorization of manufacturing plants for medicinal products, medical devices, food, and food supplements? Please briefly describe.

Medicinal products

All the manufacturing plants of medicinal products in Mexico require a current manufacture license, good manufacture practices certificate and a health officer registered before COFEPRIS.

Allophatic New molecules

Essentially, applicants for marketing authorisations must prove the safety and efficacy of their products through standard clinical trials, according to the rules set out by the General Health Law, its regulations and NOMs of good manufacturing of medicines and active ingredients. Concurrently, they also have to request approval of their products as new molecules from the COFEPRIS New Molecules Committee. Research and development companies may benefit from a special procedure for first-time approval in Mexico for drugs that have been previously approved by a regulatory authority abroad.

Generics

Applicants for marketing authorisations must prove that their products are bioequivalent to the innovator product. They must provide information concerning dissolution

profiles or bioavailability studies regarding the reference product. COFEPRIS periodically issues a reference list of medicinal products. Recently, the NOM setting the test to prove that a generic drug is interchangeable with a reference drug was updated (NOM-177-SSA1-2013). Legally, COFEPRIS should not grant marketing authorisations for generics that breach exclusivity rights.

There is a linkage system between COFEPRIS and the Mexican Institute of Industrial Property (IMPI), which aims to prevent the granting of marketing authorisations in violation of patent rights. Under the linkage system, at the time of filing of the application, the applicant must either prove that it is the owner or licensee of the patent of the active ingredient in the product (recorded before IMPI), or state under oath that their application does not violate the list of products published in the *Linkage Gazette* and observes patent law.

Biologics New molecules

The essential dossier submission requirements for innovative products manufactured in Mexico are preclinical and clinical trials, certificates of good manufacturing practices of the active pharmaceutical ingredient and the medicinal product, analytical methods, summaries, manufacturing licence, prescribing information, label, and a pharmacovigilance programme. These requirements are necessary in order to obtain the corresponding marketing authorization.

For innovative products manufactured abroad, additional requirements apply. In particular, these are a certificate for export, a letter of representation with apostille and legal representative with address in Mexico. In cases where the good manufacturing practices certificates are not issued by an agency recognised by COFEPRIS, such as the US Food and Drug Administration (FDA) or the European Medicines Agency (EMA), an in-person inspection will be required.

As an incentive for innovation, research and development companies can benefit from a special procedure for innovative biotech products that have been approved by the FDA, the EMA, Health Canada, the Swiss Agency for Therapeutic Products (Swissmedic) or the Australian Therapeutic Goods Administration (TGA).

Biocomparables (follow-ons)

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

For these purposes, biocomparable applicants must essentially submit:

- In vitro studies or comparative non-clinical studies;
- A report of 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;
- Comparative efficacy and safety clinical tests to show similarity between both the follow-on and the product of reference.

Once approved, close pharmacovigilance should be followed.

COFEPRIS has been working on guidelines to perform biocomparability studies. They have issued guidelines for etanercept, filgrastim, infliximab, insulin and its analogous, rituximab, and somatropin.

Orphan drugs

Orphan drugs were introduced into the General Health Law and the Mexican Pharmacopeia several years ago. In practice, they are approved by a particular procedure, following rules for new molecules when applicable and appropriate, finally these authorized orphan drugs obtain an orphan product acknowledgement letter. However, specific rules would be welcomed.

Traditional herbal remedies

An herbal remedy can be described as the preparation of medicinal plants or their parts, individually or in combination, and their derivatives presented in pharmaceutical form, to which the relief for some participating or isolated symptoms of a disease is attributed by popular or traditional knowledge.

These products do not require a marketing authorisation per se, but it is necessary to submit an application before the regulatory agency to obtain an alphanumeric key prior to commercialisation.

Herbal medicines

This encompasses products made with plant material or some derivative of it. The main ingredient is the aerial or underground part of a plant or extracts and tinctures, as well as juices, resins, fatty oils, and essential oils, presented in pharmaceutical form, the therapeutic efficacy and safety of which have been scientifically confirmed in national or international literature. These

type medicines require a marketing authorisation to be commercialised.

Homeopathic products

This encompasses a homeopathic medicine, any substance or mixture of substances of natural or synthetic origin that has a therapeutic, preventive, or rehabilitative effect and that is prepared in accordance with the manufacturing procedures described in the Mexican Homeopathic Pharmacopoeia, or in those of other countries or other sources of national and international scientific information. These types of products require a marketing authorisation.

Medical devices

A notice operation, a good manufacture practices certificate and a registered health officer is applicable for all the manufacturing plants of medical devices in Mexico.

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

- Class I encompasses products that are well known in medical practice, for which safety and efficacy have been proven, and are not usually introduced into a patient's body.
- Class II encompasses 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.
- Class III encompasses 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, 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.

As an incentive, applicants can benefit from a special procedure for first-time approval in Mexico for certain devices that have been previously approved by the US FDA and Health Canada. This procedure is essentially based on a dossier filed with the foreign regulatory agency and can reduce approval time frames in Mexico by up to 30 working days. Industry participants have welcomed these new rules, but they are still being tested.

Food and food supplements

Food and food supplements do not require a marketing authorisation. Manufacturers or those responsible for their marketing in the country must submit an operation notice 30 days before starting operations.

12. Please briefly describe the typical process of distributing medicinal products, medical devices, and food supplements in your country, encompassing, if applicable, the wholesale distribution of products.

Medicinal products

For distributing medicinal products, the requirements for all distributors in chain supply included pharmacies depend on the type of medicines, but all of them require a registered health officer before COFEPRIS.

To distribute and sell psychotropic and narcotic drugs that 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, do not require a specific permit but in fact requires a manufacture license for all those who mange this kind of medicines.

Prescription medicines (i.e., antibiotics, antivirals, oncologicals, and immunosuppressives) can be dispensed only if the consumer gives the received written prescription to a pharmacy. Dispensers must keep original prescriptions regarding antibiotics, antivirals, oncologicals and immunosuppressives, among others.

Unless they are over-the-counter products, medicines must be made available only through authorised drug stores and prescription medicines can be sold to patients only with a physician's prescription. All those distributors and pharmacies who handle prescription medicines (non-psychotropic and non-narcotic drugs) need an operation notice to function.

Medical devices

For all the distributors of medical devices (class I, II and III) a manufacture license is not required, they only have to submit an operation notice.

Food supplements

Food supplements do not require a marketing authorisation. Distributors or those responsible for their marketing in the country must submit an operation notice 30 days before starting operations.

13. Please briefly describe the pricing and reimbursement rules, if any, for medicinal products, medical devices, and food supplements in your jurisdiction?

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

Private-sector price control is based on a scheme of self-regulated maximum retail price (MRP) covering patented products only and is overseen by the Ministry of Economy. Pharmaceutical company participation is voluntary. Under the price control, each product's MRP must not exceed an international reference price, estimated as the average price in six major markets, and a market factor. There are no established sanctions for MRP violations.

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

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

Regarding public acquisition of innovator drugs covered by patent rights – their price is negotiated in bulk between the patent or licence holder and a government commission for price negotiation. The negotiation proceedings end with a single yearly price for all public sales.

Off-patent drugs are purchased through public tender proceedings, where a reference price is set, based on previous purchasing experiences (ie, a maximum amount that can be paid for a specific drug), and the lowest bidder is assigned the tender.

Since the government is the main drugs purchaser, pricing for publicly acquired drugs helps regulate prices in the private sector.

Prices for patented drugs are negotiated with a government commission and set for every public acquisition. When patent rights have expired (or in some cases when there is more than one participant in the market), drugs are acquired through public tender proceedings based on previous purchasing prices.

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

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

The IMSS is the largest public-sector drugs purchaser. Public institutions may have their own formulary, such as in the case of the IMSS, whose formulary contains fewer drugs than the National Formulary.

Additionally, in the case of the ISSSTE, a prescribed medicinal product can be dispensed in a private pharmacy registered with this public insurer, provided that it is not available within ISSSTE facilities and under certain conditions. The ISSSTE reimburses the cost of that product to the pharmacy according to previous agreements.

In 2014, the National Formulary has included some orphan drugs and the Mexican Supreme Court ordered the IMSS to request the MoH evaluate the inclusion of orphan drugs in the National Formulary before considering its purchasing.

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

While the Ministry of Economy is empowered to raise observations in the scheme of self-regulated maximum retail price, the Commission for Drug Price Negotiations, which is made up of several public offices, including the Ministries of Economy and Health, negotiate with the patent holder or licensee to establish a single price of a patented drug for all sales to the public sector. Likewise,

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

14. What legislative framework applies to the advertising for medicinal products, medical devices, and food supplements in your country?

The primary legislation on advertising of medicinal products and medical devices is the General Health Law's regulations regarding advertising (RLGSMP)[19] and opinions issued by the Advertising Council. The Intellectual Property Law[20] and the Federal Consumer Protection Law[21] also have provisions on advertising. The Federal Commission for Protection against Sanitary Risk (COFEPRIS) and the Federal Consumer Bureau (consumer legal framework) are the regulatory authorities in this field.

The Council of Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA) has issued the Integrity, Ethics and Transparency of Health Supplies Companies Code –(CIETEMIS)[22] which complement the legislation for the advertising of medicinal products and medical devices.

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

There are also opinions issued by the Advertising Council, which include representatives from the Ministry of Health (MoH), the academic and scientific communities, the business sector, and the media and consumer groups.

Footnote(s):

[19] www.ordenjuridico.gob.mx/Documentos/Federal/pdf/wo88538.pdf

[20] www.diputados.gob.mx/LeyesBiblio/pdf/LFPPI.pdf

[21] www.diputados.gob.mx/LeyesBiblio/pdf/LFPC.pdf

[22] https://cetifarma.org.mx/wp-content/uploads/docs/docs/CIETEMIS-2021eng.pdf

15. What laws apply to patents and trademarks for medicinal products, medical devices, and food supplements in your country?

- Intellectual Property Law
- General Health Law;[23]
- General Health Law Regulations for Healthcare Products;[24]
- Mexican Official Standards (NOMs);[25]
- Mexican Pharmacopoeia;[26]
- COFEPRIS' Rules listing healthcare products that do not require a marketing authorisation in view of their low risk to human health (COFEPRIS Rules);[27] and
- Amendments to the Equivalence Decree to import health supplies without marketing authorisation.[28]

Footnote(s):

[23] https://www.diputados.gob.mx/LeyesBiblio/index.htm

[24] Ídem

[25] https://dof.gob.mx/busqueda_detalle.php?textobusqueda=Norma+Ofici#gsc.tab=0

[26] https://www.farmacopea.org.mx/

[27] https://www.dof.gob.mx/nota_detalle.php?codigo=5376857&fecha=22/12/2014#gsc.tab=0

[28] https://www.dof.gob.mx/nota_detalle.php?codigo=5621987&fecha=22/06/2021#gsc.tab=0

16. Please briefly describe how patent infringements in relation to medicinal products and medical devices are addressed in your jurisdiction, including possible defense strategies and legal proceedings against patent infringements.

In general, medicine patent violations in Mexico are addressed through procedures brought before the administrative authority. In this sense, article 386 of the Federal Law on Industrial Property (LFPPI, per its Spanish acronym) confers on patent holders or patent licensees the right to act against third parties who violate the exclusive rights conferred on them by the patent.

In this regard, the Mexican legal system allows that third

party to be any person, or even the federal and local government itself, including centralized and decentralized public administration bodies. It also makes it possible for the person bringing the action to be a national or a foreigner, since both must receive the same treatment before the Mexican patent office.

On the latter, it is important to emphasize that, coupled with the possibility that the individual may initiate the action, the IMPI itself may initiate the action ex officio, this results in a strange procedure in which the plaintiff himself acts as the contentious authority that resolves the technical issue, thus making it difficult for the defendant to defend itself, since the IMPI acts as an authority and party at the same time.

Thus, to bring a patent infringement action, the patent holder or licensee must demonstrate the following:

1. That is the title holder or registered licensee of a granted patent, valid and in force.
2. That a third party is using, manufacturing, offering for sale or importing the patented

invention without the authorization of the title holder or licensee.

In addition, the plaintiff may apply for injunctions before the IMPI, for which a bond sufficient to guarantee the damages must be filed, which can be revoked if the defendant grants a counterbond.

Once the IMPI issues its resolution, the bonds, if any, are returned or delivered to the winning party, which is done independently of the damages that may be claimed by the affected owner. On this, until November 5, 2020, IMPI was the only competent authority to receive the infringement actions of patents or the invalidity of patents; however, with the new law, it is possible to go to courts in civil matters to claim them.

Regarding the venues to appeal IMPI's decisions, previously only the so-called amparo was possible, filed before a District Court; however, with the Federal Law of Administrative Procedure, it is now allowed that the decisions of the administrative authorities, such as the IMPI, could be challenged by means of review recourse, filed before IMPI itself or by means of an appeal filed before the Federal Court for Administrative Affairs (FCA).

In case of filing the review before IMPI, the decision issued to resolve such review recourse may be appealed before the FCA, whose decision also can be challenged before the Federal Circuit Courts, as well as if it is directly opted to challenge IMPI's decision before the FCA.

Mexico has also sought to implement a culture in which people no longer necessarily resort to jurisdictional procedures for the resolution of disputes, but rather resolve them through alternative settlement mechanisms.

That is why the LFPPI provides for a whole conciliation procedure for patent violation cases, which are not yet very common to see in practice.

However, as for the defense strategies that exist in the Mexican patent system, there is currently the so-called "Linkage", which is a cooperation and communication system between COFEPRIS responsible, among other functions, for granting marketing authorizations for the import, production, storage and marketing of allopathic medicines and IMPI, which is empowered to confer and protect industrial property rights, including temporary privileges for the exclusive use of inventions through the granting of patents.

This system can be summarized in the obligations of both authorities: IMPI issues every six months an Allopathic Medicines Gazette with current patent, including those product patents according to its drug substance, excluding processes patents, on the other hand, IMPI, issuing the opinions that COFEPRIS requires regarding the scope of protection of the patents listed in the Gazette.

Likewise, COFEPRIS is obliged to review this list of product patents and grant marketing authorizations to the holders or licensees of the relevant patents, or, where appropriate, to suspend or deny marketing authorizations for patents of drug substances issued in the Gazette until the validity of such patents ends, when applicants for marketing authorizations are different from the holders of published patents and alternatively will review the list of products listed in the Linkage Gazette according to their active ingredient.

It is important to note that the Mexican Linkage System contemplates the so-called Roche-Bolar clause in which applicants for generic medicines can submit their application for health registration, as well as use patented products to perform and submit studies, clinical tests and analysis necessary to obtain a health authorization or registration, without any liability for patent violation, provided that they are carried out three years before the end of the validity of the patent listed in the gazette, in the case of chemically based medicinal products and eight years in the case of biotechnological medicinal products and of course the use is limited to obtaining such authorizations.

17. Does your jurisdiction provide for restrictions on the use of trademarks for medicinal products, medical devices, food, and food supplements?

No, Mexican legislation does not properly provide restrictions on trademark registrations for medicines, medical devices, food and food supplements, since for their granting, all provisions that are applicable to trademarks in general must be complied with. However, what could be differentiated in their case is the subject matter covered by this brand, since it is talking about health issues, and therefore it must comply with the requirements that the law on health matters provides. The fact that the product is in accordance with health legislation is undoubtedly essential for the registered trademark to be able to effectively interfere in the market, since it is useless to have a trademark, if the product related to it does not comply with health legislation.

It is also important to note that Mexican legislation provides for certain restrictions on the advertising of medicines, which is associated with the disclosure of the brand and the product covered by it. These restrictions are contained in both the General Health Act and the Federal Telecommunications and Broadcasting Act, in the chapter corresponding to advertising.

Also, it is worth mentioning Article 23 of the Health Inputs Regulation establishes the following:

“The commercial name of the medicinal products, when used, shall be subject to the following:

I. The commercial name of two or more Inputs, when orthographically or phonetically similar, shall be differentiated by at least three letters of each word;

II. The same commercial name of another medicine with marketing authorization in force, revoked or in the process of registration, shall not be used; and

III. The same commercial name may only be used in the case of different pharmaceutical forms or different dosages with the same active ingredient and registered by the same laboratory”.

According to the above, the use of Commercial Names is classified as follows:

I. A name that is orthographically or phonetically similar to another. In this case, they must be differentiated by at least three letters per word.

II. Denomination identical to that of another drug with sanitary registration in process, in force or revoked. In this case, it cannot be used, unless it is the same laboratory, and it is for a different pharmaceutical form or dose of the same active ingredient.

In this respect, is worth mentioning that we consider this “three letter rule” is contradictory to the IP Law.

Lastly, the IP Law provides that the following shall not be registrable as trademarks:

(…)

IV.- Signs that considering all their characteristics as a whole are descriptive of the goods or services they intend to distinguish.

The above, means that the commercial name of a medicinal product may not describe the use or treatment for which it is intended.

18. Please briefly describe the product liability regime for medicinal products, medical devices, and food supplements in your country.

There is the Official Mexican Standard NOM-059-SSA1-2015, Good Manufacturing Practices of Medicines.

The General Health Law (LGS, per its Spanish acronym) considers in its Title Twelfth the Sanitary Control of Products and Services in Import and Export. In this context, the LGS defines health control as the set of actions of orientation, education, sampling, verification and, if necessary, application of security measures and sanctions, exercised by the Ministry of Health.

To guarantee the sanitary control of medicines, the law seeks that the whole process of the products is carried out in hygienic conditions, without adulteration, contamination, or alteration.

The general law states that, to obtain a marketing authorization of biotechnological medicines, the applicant must comply with requirements and tests that demonstrate their quality, efficacy, and safety. Subsequently, once marketed, pharmacovigilance should be carried out.

In addition to these provisions, the LGS considers additional measures to ensure effective health control of medicinal products, ensuring their safety, efficacy, and quality.

However, it is common to find defective medicines on the market that endanger the health of consumers. For this reason, the Regulations on Health Supplies, which details

the content of the LGS on medicines, establishes in its articles 224 to 232 sanctions and security measures to address this situation, which, are part of the health control practiced by the authority.

About safety measures, the regulation provides that verifiers must take immediate action, with the approval of the health authority, if health conditions pose a health risk. These measures may be granted by telephone and must be ratified, modified, or revoked within a maximum period of five days.

On the other hand, regarding sanctions, the law provides that the health authority shall apply the corresponding sanctions depending on the specific case, in situations where the provisions of the Regulations are violated, without prejudice to the penalties that may be applied in the event of a crime.

In Mexico, there is no specific system for indemnification to compensate damages caused by medicinal products and/or medical devices. The only way to claim damages or monetary compensation is through litigation, since the law does not have any disposition that admits the possibility of an indemnification by the State if the damages were caused by an adverse event of these products. This eventual compensatory action operates on the grounds of the civil and general principles of law.

From the civil standpoint contingency, the indemnification for damages is regulated by the Federal Civil Code, which sets forth the rules of objective (no-fault) responsibility, by providing that when an affectation is caused by a hazardous substance (as it may be a vaccine), the person responsible of causing harm or damages must proceed with the civil indemnification. The corresponding provisions of the Civil Code establish that the indemnification is due, without the need of proving any intention to cause the damage.

During the Civil Trial, for the determination of the damages that can be compensated, plaintiff must prove that the damage was directly caused by the product, and an eventual negligence of the supplier/s. Therefore, a diligent, rigorous, truthful, and well prosecuted process of obtaining the marketing authorization of the product could help as counterargument in an eventual civil action to avoid or to diminish the contingency. Eventually, the dispute would be focused that the product directly caused a harm or damage by negligence during or after the approval or it can be alleged that regardless the marketing authorization and the corresponding standards and efforts conducted by the holder or responsible of the MA there was a harm where the holder of the MA or the manufacturer is responsible.

19. Please provide a short overview of risks of liability (criminal liability, serious administrative / civil liability) and enforcement practice with regards to medicinal products (including biologicals), medical devices, foods, and food supplements.

Federal Commission for the Protection against Sanitary Risks (COFEPRIS) can request reports from marketing authorization holders, and make on-site inspection visits in 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 authorizations. 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/facility.

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

Regarding criminal responsibilities, several offenses are provided for in the General Health Law (LGS), which lists various actions constituting criminal offenses and administrative responsibility.

Among them, we can find the following actions, which merit the following administrative penalties and sanctions:

- Article 464, provides that whoever adulterates, counterfeits, contaminates, alters, or allows the adulteration, counterfeit, contamination or alteration of **food, non-alcoholic beverages** or any other substance or product of human use or consumption, with health risk, shall be liable

from one to nine years' imprisonment and a fine equivalent from one hundred to one thousand days' general minimum wage.
- Article 464 bis, mentions that whoever authorizes or orders the distribution of **medicines** in poor condition that endanger health, will be condemned from six months to two years in prison or pecuniary penalty from 500 to 5 thousand days of the current general minimum wage.
- Article 464 ter, states that whoever adulterates, counterfeits, contaminates, alters, or manufactures **medicines** without the requirements mandatory by law, shall be condemned to 3 to 15 years' imprisonment and a fine of 50.000 to 100.000 days' general minimum wage.

Also, anyone who counterfeits or adulterates the packaging, labeling, legends or information of a **medicine**, shall be condemned 9 years' imprisonment and a fine of between 20.000 and 50.000 minimum wage, as well as if it carries out acts of trade on medical samples.

Anyone who sells or offers for sale, commercialize, distributes or transports counterfeit, altered, contaminated or adulterated **medicines, drugs, raw materials or additives**, whether in establishments or in any other place, or sells or offers for sale, trades, distributes or transports materials for packaging or wrapping of medicines, drugs, raw materials or additives, their legends, information containing identification numbers or codes, which are counterfeit, altered, contaminated or adulterated, shall be condemned to 1 to 9 years' imprisonment.

Whoever sells, offers for sale or trades **medical samples**, shall be condemned to one to nine years of imprisonment and a fine equivalent to twenty thousand to fifty thousand days of minimum wage.

Article 464 Quarter, stablish that anyone who adulterates, falsifies, contaminates, alters or allows the adulteration, falsification, contamination or alteration of **medical devices**, their final containers for use or manufactures them without the corresponding marketing authorization, shall be condemned to three to fifteen years of imprisonment and a fine of fifty thousand to one hundred thousand times the Unit of Measurement.

Also provides that whoever sells or offers for sale, commercialize, distributes, brings into the country or transports for commercialization purposes, adulterated, falsified, contaminated or altered **medical devices**, in any place or by any means; or sells or offers for sale, trades, distributes, brings into the country or transports for commercialization purposes, material for packaging or packing of such health supplies, labeled with falsified or counterfeit information containing identification numbers or codes, shall be condemned to one to nine years of imprisonment and a fine of twenty thousand to fifty thousand times the Unit of Measurement.

The same penalty as in the previous paragraph shall be imposed on anyone who adulterates, falsifies, or permits the adulteration or falsification of **medical device packaging** material, labeling, its legends or the information contained therein or its identification numbers or keys.

20. Does your jurisdiction provide for a specific legislative and regulatory framework for digital health applications (e.g., medical apps)? If yes, please briefly describe the relevant framework.

Although developing, the field of digital health is still relatively new in Mexico and its application in real life settings is still limited. There are no specific healthcare regulatory schemes for digital health; the field is instead being covered by schemes which regulate medicinal products and medical devices, namely:

the General Health Law (in Spanish, “Ley General de Salud”);

the Health Law Regulations over Healthcare Products (in Spanish, “Reglamento de Insumos para la Salud”);

Official Mexican Standards (NOMs), particularly the NOM-241-SSA1-2012 setting good manufacturing practices for medical devices and NOM-137-SSA1-2008 for the Labelling of Medical Devices;

the Mexican Pharmacopoeia; and

In Mexico, the Federal Commission for the Protection against Sanitary Risks (COFEPRIS) may already be addressing the need for regulations for mobile medical applications, especially for those that present health risks.

Also, COFEPRIS has created a Working Group on Innovative Regulation for SaMD. This is important as companies seeking to implement SaMD in the Mexican market are governed by foreign standards and are outside Mexican regulations.

These types of actions seek to ensure high standards to protect the integrity of users with products tested before being introduced in the country. In this way COFEPRIS

seeks to make regulations a more democratic exercise.

The objectives of COFEPRIS regarding the regulation of SaMD is the evaluation of NOM 241 SSA1 2020 and the detection of necessary modifications that can be addressed by COFEPRIS.

The Working Group is conformed by medical and pharmaceutical companies, as well as academic institutions such as the National Council of Science and Technology (Conacyt), the College of Biomedical Engineers.

21. Does your jurisdiction provide for laws or certain legal measures to ensure the supply of medicinal products and medical devices, or are such rules envisaged in the future? If yes, please briefly describe those rules.

In terms of the fourth paragraph of article 4 of the Political Constitution of the United Mexican States, every person has the right to health protection. Regarding this right, the Supreme Court of Justice of the Nation has issued several criteria and has established that it has, among other purposes, the benefit of health and social assistance services that satisfy the needs of the population.

Likewise, it determined that health services are understood as the actions aimed at protecting, promoting and restoring the health of the individual and the community; that public health services are classified into three types: medical care, public health and social assistance; and that basic health services are, among others, those consisting of: (i) medical care, and (ii) the availability of medicines and other essential inputs for health, for which purpose there will be a basic list of inputs of the health sector.

Therefore, the right to health, in addition to implying the right of individuals to enjoy the highest possible level of physical and mental health, implies in turn the right to access and availability of medicines of proven quality, safety and efficacy, since this is the only way to achieve the full enjoyment of this fundamental right.

In this regard, the First Chamber of the Supreme Court of Justice of the Nation established that the provision of health services requires that they be of quality in all their forms and levels, so that scientific approval of medicines and health supplies is necessary, since this is a way in which the enjoyment of the right to health is guaranteed; as can be seen in the following jurisprudence:

Epoch: Ninth Epoch, Record: 167530, Instance: First Chamber, Type of Thesis: Jurisprudence, Subject(s): Administrative Tesis:1a./J. 50/2009, Page: 164.

RIGHT TO HEALTH. ITS PROTECTION IN ARTICLE 271, SECOND PARAGRAPH, OF THE GENERAL HEALTH LAW.[29]

Also, article 77 bis 35 of the General Health Law, states that the public agency Health Services of the Mexican Social Security Institute for Welfare (IMSS-BIENESTAR) is the health institution of the Mexican State in charge of providing free health services, medicines and other associated supplies for the comprehensive care of people who are not affiliated with social security institutions, under the assumption of concurrence with the states, regardless of the health services provided by other public or private institutions.

In order to achieve its purpose, Health Services of the Mexican Social Security Institute for Welfare (IMSS-BIENESTAR) shall have, among others, the following functions:

I. To provide health services free of charge and ensure the supply of medicines and associated supplies and other elements necessary for the care of persons without health insurance.

In an attempt to comply with the above, recently the Mexican Government authorities headed by President Andrés Manuel López Obrador inaugurated the “Megafarmacia del Bienestar”, which has the capacity to store 286 million pieces of medicines, in order to fully comply with the right to health protection through an efficient supply mechanism.

Ministry of Health Jorge Alcocer Varela highlighted that the launching of the “Megafarmacia del Bienestar” is proof of the Mexican Government's commitment to fulfill the right to universal and free access to effective medicines and medical treatments, including those of high cost.

He stressed that this act is part of the structural transformation of the entire distribution system for medicines, healing materials and health supplies, to expand availability and accessibility, without discrimination[30].

Footnote(s):

[29] The right to health, among several elements, includes: the enjoyment of quality health services in all its forms and levels, understanding quality as the requirement that they be medically and scientifically appropriate, that is,

that there be trained medical personnel, scientifically approved medicines and hospital equipment in good condition, and adequate sanitary conditions. It follows from the above that to guarantee the right to health, it is necessary that health services are provided with quality, which is closely related to the control that the State has over them. In other words, to guarantee the quality of health services as a means of protecting the right to health, the State must take the necessary actions to achieve this end. One of these actions may be the development of public policies and another, the establishment of legal controls. Thus, one way to guarantee the right to health is to establish regulations or controls aimed at ensuring that health service providers meet the necessary conditions of training, education, experience and technology, in establishments with adequate sanitary conditions and where scientifically approved drugs and hospital equipment are used and in good condition, as provided by the ordinary legislator in Article 271, second paragraph of the General Health Law." https://sjf2.scjn.gob.mx/detalle/tesis/167530

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https://www.gob.mx/salud/prensa/458-megafarmacia-del-bienestar-inicia-operaciones

22. Are there any specific compliance standards in your jurisdiction for the marketing of medicinal products and medical devices (e.g., codes of conducts of industry associations, etc.)? If yes, please give a brief overview of the relevant standards.

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

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

Relevant Mexican Official Standards:

- Medicinal products labelling (NOM- 072-SSA1-2012).
- Installation and operation of 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).
- Good manufacturing practices for active ingredients (NOM-164-SSA1-2015).

23. Please state 3-5 key decisions by courts or regulatory authorities that have been issued recently and that are relevant for the life sciences sector.

In recent years, the Supreme Court has issued several relevant determinations in this area:

1. First, it established that the absolute ban on the marketing of cannabis constitutes a violation of the human rights to freedom of trade and to work, since it does not exceed the proportionality test, by not addressing the specific case that, for example, it can be the use of cannabis for medical, scientific, or industrial purposes.
2. Second, since the shortage of medicines in Mexico is a very popular issue, the Supreme Court established that, when there is a shortage of medicines and the individual has to buy them on his own, it is appropriate to be reimbursed for the expenses made, this is in repairing the legal sphere of the individual, whose right to health was violated due to the lack of medicines in the Social Security institutions.
3. Third, it established that the absolute prohibition of recreational cannabis use is not a necessary measure to protect people's health and public order. In contrast, the Court proposed that, rather than prohibiting it absolutely, certain limitations or prohibitions should be established to regulate its consumption.

24. What, if any, are the key legal and regulatory trends in your jurisdiction with regards to the digitalization of the local healthcare system and with regards to the use of artificial intelligence in the life sciences sector? Please briefly describe.

– On February 27, 2024, was published the proposal draft decree enacting the Federal Law that regulates Artificial Intelligence of the senator Ricardo Monreal Ávila, of the

Morena Parliamentary Group, which would have as main purposes:

i. Regulate the development, commercialization and use of artificial intelligence systems;
ii. To guarantee respect for the human rights of consumers and users and to avoid any form of discrimination when using artificial intelligence systems;
iii. To protect intellectual property rights; and
iv. To facilitate the national development of artificial intelligence systems.

– On May 24, 2023, was published the proposal draft decree enacting the LAW FOR THE ETHICAL REGULATION OF ARTIFICIAL INTELLIGENCE AND ROBOTICS of the Deputy Ignacio Loyola Vera, which would have as main purposes:

i. Establish public policy guidelines in the United Mexican States for the ethical regulation of the use of Artificial Intelligence and robotics within the national territory.
ii. To promote the creation of Mexican Official Standards, based on ethical principles, for the proper use of Artificial Intelligence (AI) and Robotics for the benefit of Mexican society, always respecting human rights, gender parity, without any discrimination based on race, ethnicity, religion, social class, or economic position.
iii. – Regulate the use of Artificial Intelligence (AI) and Robotics in its use for governmental, economic, commercial, administrative, communicational and financial purposes so that its use is always based on ethical and legal compliance.
iv. To create and regulate the Mexican Council of Ethics for Artificial Intelligence and Robotics (CMETIAR);
v. To create the National Statistical Network for the use and monitoring of Artificial Intelligence and Robotics.
vi. To link the autonomous organisms with the regulation of the use of Artificial Intelligence within the national territory, establishing the National Institute of Statistics, Geography and Informatics, as the generating center of information on the use of AI within the United Mexican States.

– The Deputy Favio Castellanos presented on August 25th, 2023, an initiative with a draft decree that amends and adds various provisions to the General Health Law to establish regulations for the safe use of Artificial Intelligence in the Mexican Health System.

It proposes different things, among them, to establish that it is the responsibility of the Ministry of Health to promote the development of Artificial Intelligence in order to make different aspects more efficient, such as precision, protection and quality. It also proposes to add a provision establishing the protection of sensitive personal data, both digital and physical, and to stipulate that Artificial Intelligence in the healthcare system refers to systems based on digital algorithms that mimic human intelligence and can perform cognitive tasks in an autonomous or assisted manner.

It is important to mention that the proposal does not aim for artificial intelligence to be a replacement for healthcare professionals, but rather to function as a support tool.

25. Please briefly highlight 3-5 key developments or trends in your jurisdiction with regards to the life sciences sector as you consider them relevant. This may include legislative proposals, market activity, etc.

– Due to the non-compliance with the fifth transitory article of the Federal Law for the Protection of Industrial Property, which establishes the cooperation of IMPI and COFEPRIS to create a technical collaboration mechanism to give due notice to the title holder of any MA application filed related to any patent published in the Linkage Gazette, Olivares developed a strategy to oblige both authorities to implement the collaboration mechanism provided for in the aforementioned article complying with the obligations in the international treaties.

– As mentioned in the previous question, there are some proposals to regulate Artificial Intelligence (AI) in the healthcare system. The proposals oversee the development of AI to enhance efficiency, precision, protection, and quality in healthcare. It also emphasizes protecting sensitive personal data, intellectual property rights and defines AI in healthcare as digital algorithm-based systems mimicking human intelligence for autonomous or assisted cognitive tasks. Importantly, the proposal underscores that AI is intended to complement healthcare professionals rather than replace them, serving as a support tool in the healthcare system.

– The Ministry of Health and COFEPRIS have outlined a “Regulatory Certainty Strategy for the Pharmaceutical Sector: Biosimilars”. Its main objective is to promote the development of biosimilar biotechnological drugs in Mexico, establishing a regulatory framework aligned with

international standards to strengthen the industry's capacity at all stages of research and production. The strategy proposes the creation of a Good Regulatory Practices Committee, a Biosimilars Specialized Unit (UEBio), and a collegiate body of experts to evaluate the evidence of biosimilars.

In addition, it seeks regulatory harmonization with international standards and recertification as a level IV Regulatory Agency. It plans to update the regulatory framework for bioequivalence and biocomparability studies, the definition of a regulatory framework for Risk Analysis, and the intensification of Pharmacovigilance. Continuous training programs for distributors and points of sale are also proposed, as well as the creation of homologated criteria for the dispensing of medicines.

– Also, COFEPRIS introduced a digital platform named DIGIPRiS. This platform facilitates the submission of different procedures related to regulatory compliance or approvals. Specifically, COFEPRIS announced an update to DIGIPRiS between November and December 2023, allowing applicants to submit requests for authorizations regarding human research protocols and modifications to existing protocol authorizations. Moreover, applicants can monitor the progress of their submissions on the platform, tracking them through various stages such as evaluation, verification, signature, and resolution. This digital system streamlines the application process and provides transparency for applicants regarding the status of their requests.

COFEPRIS emphasizes the need to clarify the scope of the Roche-Bolar Clause, mainly through the elimination of the temporary nature of the exception determined to initiate the development of biosimilar drugs in the country, through amendments to the law and the creation of guidelines to improve the interpretation and scope of the bolar clause for the development of biosimilar drugs are proposed, and the Linkage and clinical data protection system. Finally, the creation of a Council for National Pharmaceutical Development with the participation of the Ministry of Economy and Conahcyt is proposed to promote investment in scientific projects and the development of biotechnology for pharmaceutical purposes.

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