The Pharma Legal Handbook

Mexico

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms · Cannabinoid Drugs, Medicinal Cannabis and Opioid Drugs · Orphan Drugs and Rare Diseases · Localization · Biosimilars and Biologics

PHARMA BOARDROOM

Mexico

The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in Mexico.
It is a must have for any company operating in the country or looking to enter the market.

Prepared in association with Olivares and Associates, a leading Mexcian law firm, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

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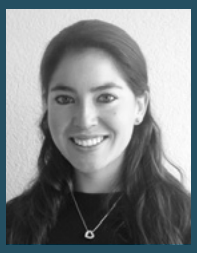
Alejandro joined OLIVARES in 1996 and became a partner in 2005. He Co-chairs the Life Sciences & Pharmaceutical law and industry group and also he coordinates the litigation department. Alejandro has been crucial to the heart of Mexico's intellectual property legal system as one of the few true patent-regulatory litigation experts in Mexico.

Alejandro has spearheaded a ten-year litigation strategy that has incorporated regulation changes and lobbying which has resulted in an important precedent for the patent linkage regulation and life terms of pipeline patents in Mexico. As a result of his involvement, he has been selected as the delegate to represent AMIIF, the industry association for R&D pharmaceutical companies who do business in Mexico, in the Trans-Pacific Partnership (TPP) negotiations.

Alejandro has successfully litigated for pharmaceutical patents and pioneered administrative court actions to seek recognition of DPE rights (protection for safety and efficacy data), which are not specifically recognized by Mexican laws



INGRID ORTÍZ

Ingrid joined OLIVARES in 2011. She studied law at Monterrey Institute of Technology and Advanced Studies (by its acronym in Spanish "ITESM", Tecnológico de Monterrey) in Mexico City.

Ingrid is member of the Life Sciences & Pharmaceutical law at OLIVARES. Her practice is mainly focused on Intellectual Property Litigation, Regulatory and Administrative Litigation; as well as Regulatory and Compliance advisory.

Her main areas of practice allow her to interact with the Mexican sanitary agency, the Federal Commission for Protection against Sanitary Risks (by its acronym in Spanish "COFEPRIS"), the Mexican Patent and Trademark Office (by its acronym in Spanish "IMPI"), and the Courts of law, such as the Federal Court of Tax and Administrative Affairs, the Federal District Courts and the Federal Circuit Courts.

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01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

The authority responsible for applying and enforcing the regulatory framework in relation to drugs, biologicals, and medical devices is the Federal Commission for Protection against Sanitary Risks (COFEPRIS), which is a decentralized agency of the Ministry of Health.

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

The primary legislation for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices is the General Health Law (Ley General de Salud) (HL) and its Regulations. These laws and regulations are supplemented by Guidelines and Official Norms (NOMS) published by COFEPRIS.

Price control in the private sector is based on a scheme of self-regulated maximum retail price (MRP) only covering patented products, overseen by the Ministry of Economy. Pharmaceutical companies' 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, plus a market factor. There are no established sanctions for violations of the MRP. In private sector, there is no reimbursement in Mexico.

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

Public acquisitions are supported by the Committee for the Negotiation of Drug Prices (CNDP).

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

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

The political party currently governing in Mexico (MORENA) is promoting an amendment to the scheme of self-regulated maximum retail price (MRP), which consist, in general terms, that the Ministry of Economy in collaboration with the Ministry of Health shall guarantee, through a transparent process and taking into consideration differentiated policies, the access to medications and inputs to people in situations of poverty. In addition, the price control would be regulated and annually reviewed by these Authorities.

On August 11, 2020, the Mexican Congress published the Decree amending Article 1 of the Public Sector Procurement, Leasing and Services Law, through which the Mexican Government is now empowered to acquire medicines through intergovernmental organizations, such as UNOPS, without having to observe the procedures set forth in the applicable Law and Regulation on public procurement.

According to UNOPS' guidelines, the process is made up of different stages grouped within three phases identified as:

1. Pre-Bidding Process (market research, requirements definition and identification of potential suppliers).
2. Bidding Process (publication of the bases and call for bids and/or invitations for negotiation, bid management, evaluation and award).
3. Post-Bidding Process (contract management and logistics). The distribution to the final destination will be in charge of INSABI.

Therefore, during these proceedings UNOPS is entitled to negotiate the prices of the supplies.

3. What are the steps to obtaining authorization to develop, test, and market a product?

Manufacturers must obtain a marketing authorization from COFEPRIS to sell any medicinal product. Requirements and timeframes vary among new molecules, biologics, and follow-on products.

The Health Law Regulations sets out the following approval timeframes for small molecules:

- 180 calendar days for medicines, including an active pharmaceutical ingredient (API)/therapeutic indication already approved in Mexico.
- 240 calendar days for medicines not approved in Mexico but which are approved abroad.
- 180 calendar days for new drugs (a meeting with the New Molecule Committee is required).

The approval timeframe for biologics and biocomparables is 180 calendar days.

These timeframes may vary in practice.

3.A. NEW MOLECULES

Essentially, applicants for marketing authorizations must prove 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 have to request approval of their products as new molecules by the New Molecules Committee of COFEPRIS. A new molecule:

- An active ingredient or drug not approved world-wide (new molecular entity)
- An active ingredient or drug already available in other countries but with limited clinical experience or disputed information, without approval in Mexico
- A drug which is a non-marketed combination of two or more active ingredients; and

- An active ingredient or drug already available in the market, but to be marketed for a new therapeutic indication.

R&D companies can benefit from a special procedure for drugs to be approved for the first time in Mexico, if they have been previously approved by:

- The European Medicines Agency;
- The US Drug and Food Administration;
- Health Canada;
- The Swiss Agency for Therapeutic Products (Swissmedic); and
- The Therapeutic Goods Administration in Australia.

In 2012, COFEPRIS published new rules to set out this procedure. This is essentially based on the dossier filed with the foreign regulatory agency, to reduce approval time frames by up to 60 working days. Industry participants have welcomed and used these new rules.

3.B. GENERICS

Applicants for marketing authorizations have to prove basically that their products are interchangeable to the innovator product. They have to provide information concerning dissolution profiles or bioavailability studies regarding the reference product. COFEPRIS periodically issues a list of reference 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 authorization for generics breaching 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 authorizations in violation of exclusive rights. According to the IP Regulations, every six months the IMPI must publish a gazette that includes patents covering allopathic medicines (Linkage Gazette). The initial IMPI position was that only patents relating to a compound were relevant to linkage review (excluding formulation and use of patents). In 2012, for the first time the IMPI included formulation patents in the Linkage Gazette, in accordance with a 2010 ruling of the Mexican Supreme Court (Jurisprudence No. 2a./J.7/2010, Federal Judicial Gazette, No. XXXI, page 135). Under the linkage regulations, at the filing of the application, the applicant must prove that it is the owner or licensee of the patent of the active ingredient of the product (recorded with the IMPI), or state under oath that their application does not violate the list of products published in the Linkage Gazette and observes patent law.

As a result of the entering in force of the USMA (July 1, 2020), and the New IP Law (November 5, 2020), the linkage system will be eventually modified.

The general terms for patent linkage were included in the new IP Law (similarly to the current linkage system). The wording establishes the listing of patents related to allopathic medicines in terms of the corresponding Regulation. Details and the battle on linkage will follow in the discussion over the eventual amendments in the Regulation.