

Life Sciences Practice Group Newsletter



Sánchez Devanny secures for the first time in Mexico injunctions ordering the COFEPRIS to grant a Drug Marketing Authorization based on equivalence to a foreign Authorization

Mexico has issued several official communications recognizing that requisites imposed by certain foreign agencies to approve pharmaceutical products and medical devices are equivalent to those established under national laws and regulations.

These communications include recognition of approvals by:

- The WHO prequalification program
- Swissmed
- The FDA
- EMA
- Health Canada
- The Australian Therapeutic Goods Administration.
- WHO/PAHO reference regulatory agencies

Whereas some of these communications have existed for many years, their use had not been widespread, specifically because applicants did not receive a clear advantage from them on regulatory timelines; products submitted for approval under these communications would be studied on a first in-first out basis, along with all other submissions.

This situation changed –at least on paper- on November of 2020, as the Ministry of Health Issued a communication that included a significant reduction to regulatory timelines, as it established:

- A 5 working day term to issue product marketing authorizations filed under equivalency agreements, and
- A 3 working day term to issue requirements to applicant, in case the information was not complete, and
- A tacit affirmative response –meaning that the approvals would be considered as granted if the terms expire.

In spite of this communication the Mexican Regulatory Agency – COFEPRIS- has not observed the shortened deadlines; marketing authorizations have not been issued, for what has now been several months, and the regulator has publicly recognized that they are facing severe backlog.

As a way to counter the inactivity of COFPRIS, - and at the request of one of our clients in the pharmaceutical industry- we designed a regulatory/litigation strategy.

In the corresponding trial, we have secured favorable injunctions for our client. In the decision, the Court has established:

- That the likelihood of a favorable decision on the merits favors our client, based on legal arguments derived from the above-mentioned expedited approval communications.
- That COFEPRIS must allow our client to undertake all activities associated to a granted marketing authorization.

We are confident that we will be able to obtain an eventual favorable decision on the merits, which will further solidify the positive effects derived from this injunction.

Furthermore, the legal strategy can be replicated to benefit other clients and expedite their marketing authorization processes, when facing similar situations.

At Sánchez Devanny we have substantial experience representing companies in the life sciences industries, including advisory on regulatory scenarios, administrative litigation, and crossover with IP rights.

This newsletter was jointly prepared by Juan Luis Serrano (jserrano@sanchezdevanny.com) Mariajosé Ayala (mjayala@sanchezdevanny.com), and Rodrigo Calderón (rcalderon@sanchezdevanny.com).

Sánchez Devanny is a leading Mexican law firm that provides **full-service legal advice** both to Mexican and international clients.

We build enduring client relationships because we make every effort to understand our clients' businesses and expectations, to serve as an ally, and to provide **complete, accessible and personalized advice**.

Contact

Alberto Campos-Vargas
jacampos@sanchezdevanny.com

Maria Luisa Mendoza-López
mmendoza@sanchezdevanny.com

Eduardo Sotelo-Cauduro
esotelo@sanchezdevanny.com

Turenna Ramírez-Ortiz
tramirez@sanchezdevanny.com

Juan Luis Serrano-Leets
jserrano@sanchezdevanny.com

Mexico City:

Av. Paseo de las Palmas #525 Piso 6
Col. Lomas de Chapultepec, 11000
Ciudad de México
T. +52 (55) 5029 8500

Monterrey:

José Clemente Orozco #335 Piso 4
Despacho 401 Col. Valle Oriente, 66269
San Pedro Garza García N.L.
T. +52 (81) 8153 3900

Queretaro:

Av. Antea #1090, Piso 2 Int 206
Col. Jurica, 76100
Querétaro, Qro.
T. +52 (442) 296 6400



www.sanchezdevanny.com

© Sánchez Devanny ® 2022

Sánchez Devanny refers to SánchezDevanny Eserverri, S.C., a leading Mexican law firm that provides full service legal advice both to Mexican and international clients.

This publication contains general information only and is just for informative purposes. Sánchez Devanny is not rendering legal advice or services by means of this publication. To obtain legal advice or services and before making any decision or taking any action that may affect your business you should consult a qualified professional advisor.

Sánchez Devanny provides legal services in the areas of Corporate and M&A; Corporate and Project Finance; International Trade and Customs; Real Estate, Infrastructure, and Hospitality; Tax; Labor, Social Security, and Immigration; Corporate Governance and Regulatory Compliance; Energy, Natural Resources and Environmental; Life Sciences; Intellectual Property, Entertainment, and Sports Law; Litigation and Alternative Dispute Resolution; Antitrust; Financial Institutions and Services; Private Wealth Management and Estate Planning and Data Privacy and Information Technology to both public and private clients, especially in the automotive, retail, pharmaceutical, manufacturing, real estate, and energy industries.