“Regulatory Outlook in Latin America”

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AGENDA

- General regulatory landscape in LATAM
- Key current regulatory trends
- Ongoing Regulatory Challenges
- Reflections

General Regulatory landscape in LATAM

Regulatory Agencies in LATAM Recognized as Regional Reference Authorities by PAHO/WHO

anmat
Administración Nacional de Medicamentos, Alimentos y Tecnología Médica

ANVISA
Agência Nacional de Vigilância Sanitária

Instituto de Salud Pública
Ministerio de Salud

invima
Instituto Nacional de Vigilancia de Medicamentos y Alimentos.

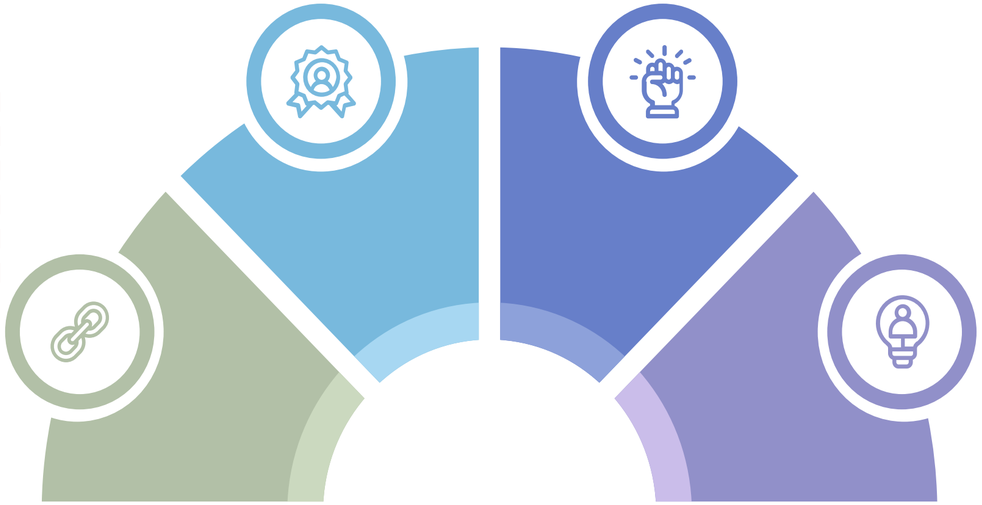
CECMED

COFEPRIS
COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS

General Regulatory landscape in LATAM

"They have achieved and advanced level of maturity in the regulation of medicines, GMP´s , Clinical studies, and pharmacovigilance.

"These agencies serve as examples of regulatory best practices and other innovations related to the region.



"They are responsible for ensuring the availability of safe, effective, and high-quality medicines and technologies.

ANMAT

National Administration of Drugs, Foods and Medical Technology (ANMAT) was created in 1992, is an agency decentralized from the National Public Administration

www.argentina.gob.ar/anmat

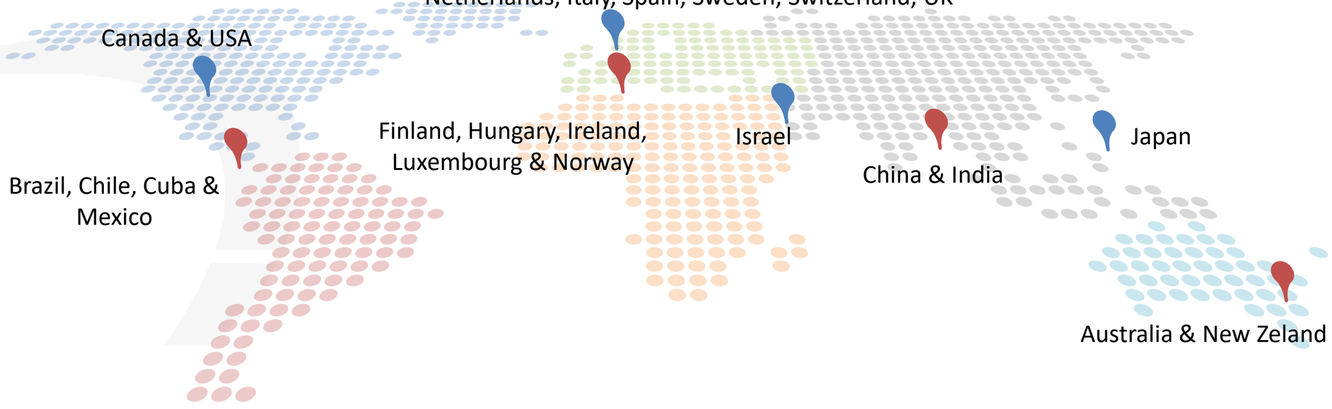
Regulatory Agency Activity Medium

Legal Framework

Decree 1490/92 – ANMAT
Decree 150/92 – Classification
Decree 4620/19 – Requirements Art.3
Decree 4621/19 – Requirements Art.4
Decree 2089/2018 – Commercialitation evidence
Decree 7729/11 – Biosimilars
Decree 9709/2019 – Batch release (Biologics)

Recognized countries (MA)

"High Sanitary Surveillance"
Annex I (Decree 150/1992)



"Trust Level"
Annex II (Decree 150/1992)

Language: Spanish

ANMAT

Fees

Annually updated
Type of product

Categoría	Producto o asunto	Código	Trámite	Importe
Especialidades medicinales	Artículo 3° Decreto 150/1992 (TO 1993)	2000	Registro inicial - Artículo 3° Decreto 150/1992 (TO 1993)	$ 513.000
Especialidades medicinales	Artículo 4° Decreto 150/1992 (TO 1993)	2001	Registro inicial - Artículo 4° Decreto 150/1992 (TO 1993)	$ 664.800
Especialidades medicinales	Artículo 5° Decreto 150/1992 (TO 1993)	2002	Registro inicial - Artículo 5° Decreto 150/1992 (TO 1993)	$ 1.497.000

Batch Release

First batch release – Decree 9709/2019

Biogologics, vaccines and radiopharamaceuticals

Stability

Biologics – Decree 7075/2011

Generics – Decree 4620/19
Aligned to ICH

Zone - II

Technical Guidelines

Biosimilars – Decree 7729/11
Decree 7075/11
Decree 3397/2012

First batch release – Decree 9709/2019

Price

Generics -50-70% cheaper than the reference

Biosimilars – 15-30% cheaper than the reference

Validity of the MA: 5 years

ANMAT/NEWS

ANMAT announces the appointment of its new head Luis Fontana has been appointed as the new head of ANMAT, with the aim of ensuring institutional continuity, strengthening technical leadership, and advancing toward more efficient and results-oriented management.

Submission of the Site Master File (AMS/SMF) to INAME This is done digitally via the TAD platform.

ANMAT updates the list of active pharmaceutical ingredients that must undergo bioequivalence/bioavailability studies

ANVISA

Agência Nacional de Vigilância Sanitária

National Health Surveillance Agency (ANVISA) was created in 1999 it is an autonomous agency but reports to the Ministry of Health

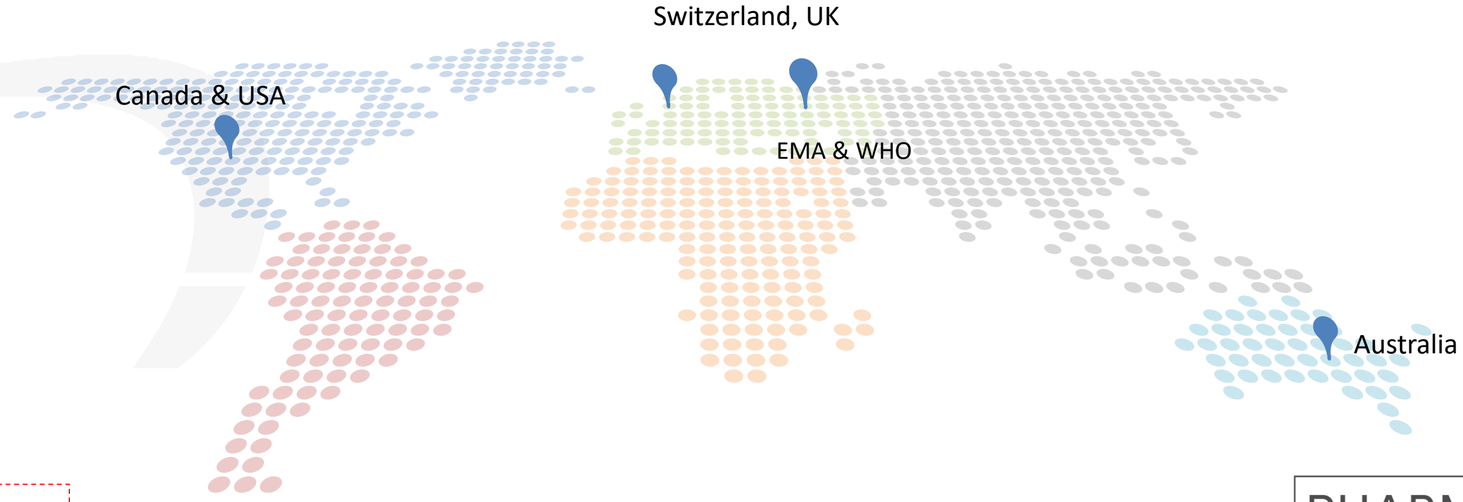
www.gov.br/anvisa/pt-br

Regulatory Agency Activity
High

Legal Framework

RDC 199/2017 – medicines, biologics
RDC 753/2022 – Marketing Authorization Generics
RDC 55/2010 – Biotechnological products
IN 184/2022 – Clasification
RDC 831/2023 – Prescribing information
RDC 768/2022 – Labelling
RDC 875/2024 - Extrapolation
RDC 318/2019 – Stability (not biologics)
IN 289/2024 – Reliance MA
IN 292/2024 – Reliance GMP

Recognized countries (MA)



Language: Spanish, English and Portuguese

ANVISA

Fees

RDC 198 / 2017
Size company, type of product

Fundamentação Legal	Lei 6360, de 23/09/1976, Decreto 79.094, de 5/01/1977, RDC 55, de 16/12/2010, RDC 47, de 08/09/2009, RDC 71, de 22/12/2009, RDC 68, de 28/03/2003, RDC 305, de 14/11/2002, RDC 222, de 28/12/2006, RDC 197, de 12/12/2017, RDC 187, de 08/11/2017					
Fato Gerador	4014					
Valor de Taxa	Grande I R$ 157.416,00	Grande II R$ 133.803,60	Média III R$ 110.191,20	Média IV R$ 62.966,40	Pequena R$ 15.741,60	Microempresa R$ 7.870,80

Voltar

Agência Nacional de Vigilância Sanitária

Cold Chain Validation

Guideline 2/2017 v.2
- Quality information from manufacturing site to final user
- Variable Conditions as weather, customs delays, mechanical failures.
- Temperature profile
- Worst case study

Stability

Biologics – RDC 412/2020 aligned to ICH Q5C and complementary guidelines

Generics – 318/2019
Guideline 28/2019 v1

Zone - IVb

Technical Guidelines

Biosimilars – RDC 55/2010
Reference drug – IN 875/2024
Extrapolation – RDC 875/2024
Biowaver – RDC 749/2022

Price

Generics – 35-50% cheaper than the reference
Biosimilars – 35% cheaper than the reference

ANVISA

Reliance		
Standard	**IN 289/2024**	**IN 292/2024**
Scope	**Marketing Authorization** API Medicines Biologics Vaccines	**Good Manufacturing Practices** API Cannabis Medicines Biologics
Levels	Optimazed procedure Total aplication Parcial aplication	Total Parcial Mutual recognition
Agencies	EMA, Health Canada, OMS, Swissmedic, MHRA, US FDA, TGA	PIC/S, ICH, EMA
Mutual recognition	No	List of countries (Annex - IN 292/2024) Under Agreements between ANVISA and the Agency
Valid since	April 2024	June 2024

Agência Nacional de Vigilância Sanitária

Validity of the MA: 10 years

ANVISA/NEWS

- **ANVISA participates in International simulated exercise for responding to health emergencies (100 days Mission)** The goal is to have a vaccine ready within 100 days if a new health problem appears."

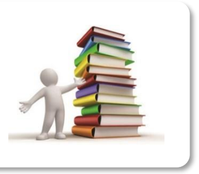
- **ANVISA launches new digital form for international users.** The new electronic form aims at providing a direct channel for citizens and businesses outside Brazil, to make it easier for users to clarify questions and request information.

INVIMA

National Institute for Food and Drug Surveillance (INVIMA) was established in 1992 and depends on the Ministry of Health

www.invima.gov.co

Regulatory Agency Activity Medium



Legal Framework

Law 9/1979 – Marketing Authorization
Decree 677/1995 – Marketing Authorization
Decree 1782/2014 – Requirements
Decree 1474/2023 – Renewal & Variations

Recognized countries (MA)

"Reference Countries"

France, Denmark, Germany, Netherlands, Sweden, Switzerland, UK & Norway

Canada & USA

EMA

Japan

Brazil & Argentina

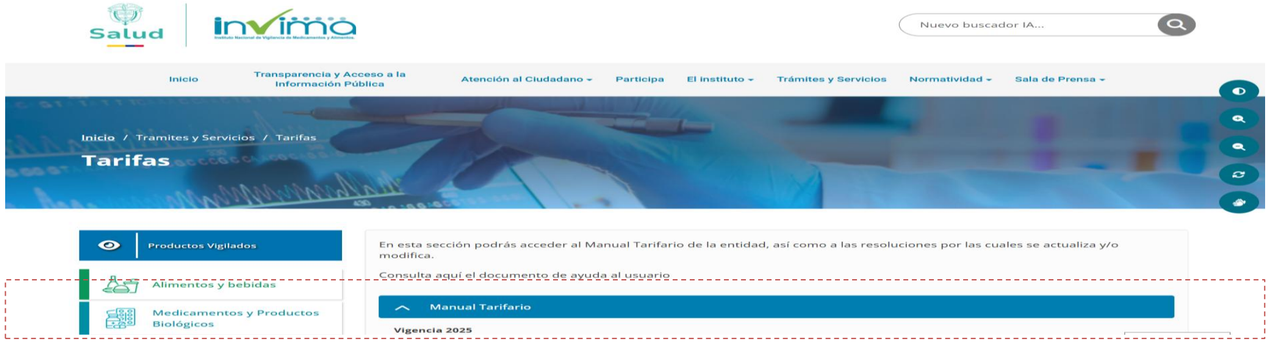
"Biologics" (Decree 1782/2014)

Language: Spanish

INVIMA

Fees

Annually updated



Cold Chain Validation

- Quality information from manufacturing site to final user
- Variable Conditions as weather, customs delays, mechanical failures.
- Temperature profile

Stability

Biologics –Decree 3690/2016

Generics – Decree 3157/2018

Zone - IV

Technical Guidelines

Generics – BE – Decree 1124/2016, only applicable for the medicines listed

Biosimilars – Decree 1950/2019

Price

Generics – 30-80% cheaper than the reference

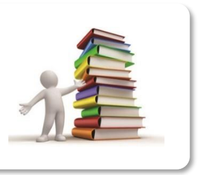
Biosimilars – 30-60% cheaper than the reference

COFEPRIS

Federal Commission for the Protection against Sanitary Risks (COFEPRIS) was established in 2001 and is a decentralized organ of the Ministry of Health

www.gob.mx/cofepris

Regulatory Agency Activity
High

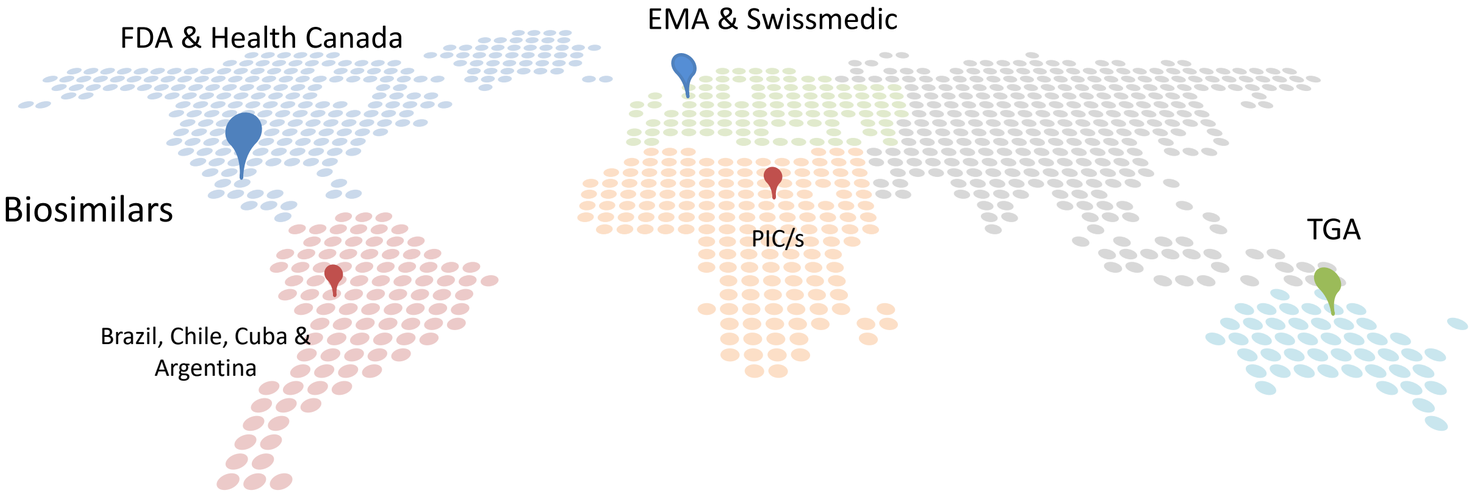


Legal Framework

General Health Law
Regulation of Health Supplies
Official Mexican Standards:

- NOM-073-SSA1-2015 – Stability
- NOM-177-SSA1-2013 and its variations – Generics & Biosimilars
- NOM-059-SSA1-2015 and its variations – GMP
- NOM-072-SSA1-2012 - Labelling
- NOM-257-SSA1-2014 – Biotechnological products

Recognized countries (MA)



Unilateral recognition

Language: Spanish and English

COFEPRIS

Fees

Annually updated, Official gazzete

Type of product

Salud Secretaría de Salud | COFEPRIS Comisión Federal para la Protección contra Riesgos Sanitarios

Comisión Federal para la Protección contra Riesgos Sanitarios

Tarifa aplicable a partir del 01 de enero al 31 de diciembre de 2025, publicada en Diario Oficial de la Federación el 30 de diciembre de 2024

Registros sanitarios

Insumos para la salud

Descripción del servicio	Artículo L.F.D.	Clave de pago	Importe		Por modificación, renovación o prórroga a cada registro, pagará el **75 %** del derecho que corresponda.		Por modificación de la Razón o Denomicación Social del titular del registro o cualquier otro cambio respecto al titular pagará el **50 %** de	
			Sin redondear	Redondeado	Sin redondear	Redondeado	Sin redondear	Redondeado
Por la solicitud y en su caso, el registro de Medicamentos Alopáticos, se pagará por cada uno, el derecho conforme a las siguientes cuotas:								
Medicamento genérico	195-A-I-a	400107	$106,958.50	**$106,958**	$80,218.87	**$80,219**	$53,479.25	**$53,479**
Medicamento molécula nueva	195-A-I-b	400107	$191,247.58	**$191,248**	$143,435.68	**$143,436**	$95,623.79	**$95,624**

COFEPRIS Comisión Federal para la Protección contra Riesgos Sanitarios

Cold Chain Validation

Official standard NOM-059

- Quality information from manufacturing site to final user
- Variable Conditions as weather, customs delays, mechanical failures.
- Temperature profile
- Worst case study

Stability

Official standard NOM-073

Zone – II (Zone III & IV are accepted)

Technical Guidelines

Biosimilars – NOM-257-SSA1-2014

Reference drug – COFEPRIS web page

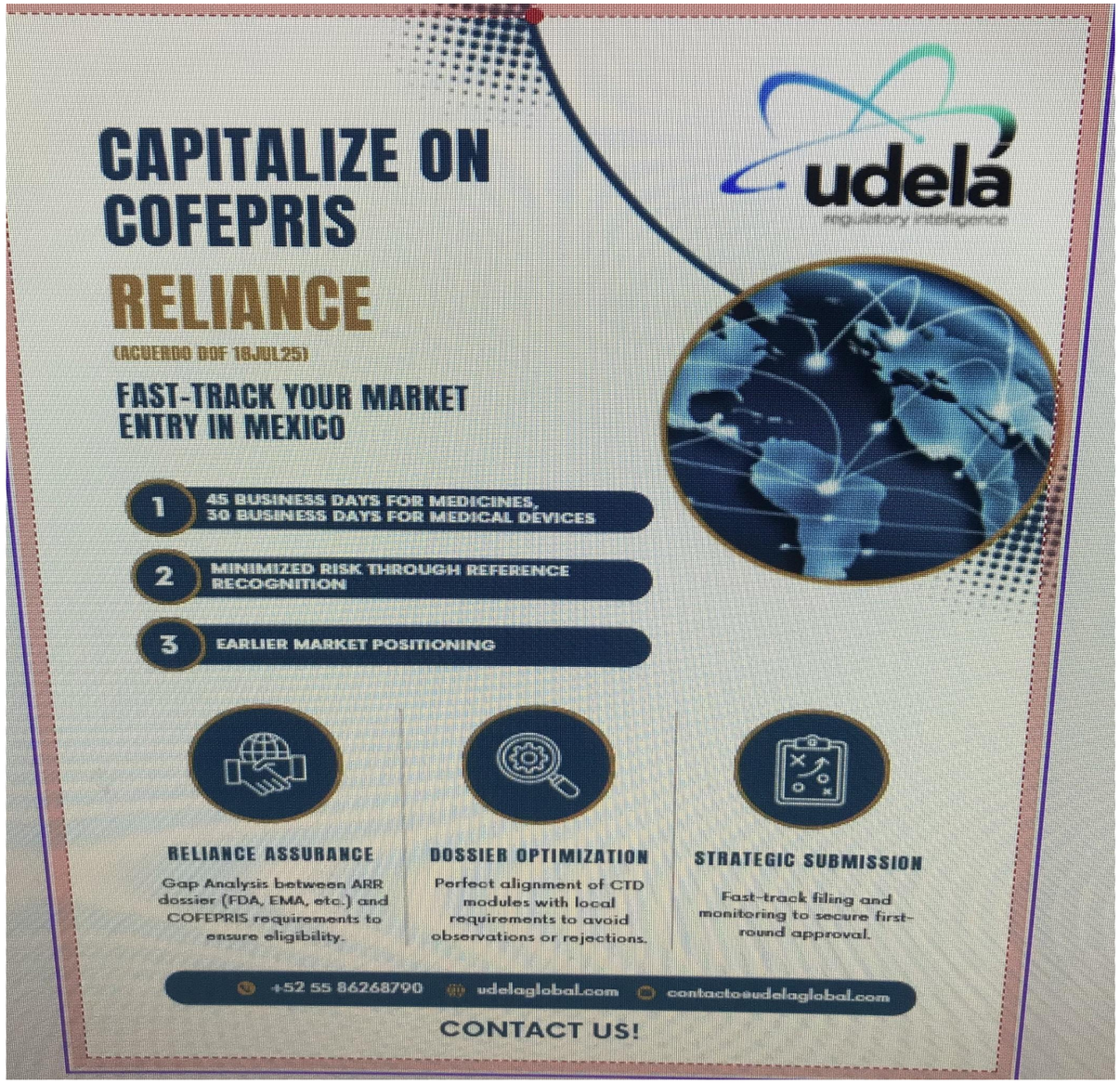
Price

Generics – up to 80% cheaper than the reference

Biosimilars – 20-40% cheaper than the reference

PHARMA SYNERGY

COFEPRIS/NEWS



COFEPRIS announces the appointment of its new head Dr. Victor Hugo Borja.

"COFEPRIS promotes regulatory improvement in the areas of medicines, herbal remedies and establishments"

"Health authorities advance actions for the implementation of NOM-262-SSA1-2024 on Good Clinical Practices.
A pilot program is being promoted to authorize priority clinical research protocols in 45 days.

Validity of the MA: 10 years

COMMON POINTS

Administrative & Technical information

CTD format

Partners

- Warehouse
- Legal Representative / MAH
- Distributor
- QC Lab
- Importer

Establishments

GMP´s recognition

Pre-submission meeting

Drug product

Stability test

Zone II

Zone IV

PHARMA SYNERGY

Key Current Regulatory Trends

Digitalization Initiatives

Introduction of electronic submission systems to streamline dossier evaluations

Alignment with International Standards

Many LATAM countries are aligning with global regulatory frameworks (e.g., ICH guidelines, WHO recommendations)

Faster Access Pathways

Several countries offer expedited approval processes for priority medicines, orphan drugs, and innovative products; also, Simplified registration for products already approved in reference markets.

Growing Market Demand

Increasing demand for innovative pharmaceuticals, generics, biologics, medical devices (ATMPs, Advanced Therapy Medicinal products)

Patent Expiry Opportunities

Many high-cost biologics and branded medicines are nearing patent expiration, creating opportunities for biosimilars to capture market share

ONGOING REGULATORY CHALLENGES

Regulatory Instability

Frequent policy changes driven by political shifts can impact regulatory timelines and market access strategies

Inconsistent availability of regulatory data and unclear communication channels with authorities

Approval Delays

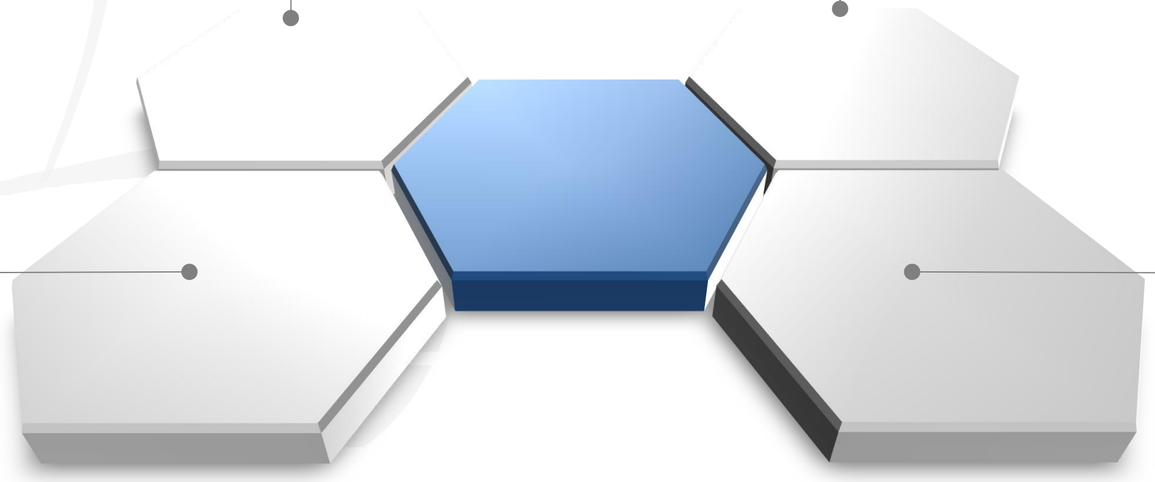
Prolonged review times in some countries due to limited resources or procedural inefficiencies.

Documentation Requirements

Country-specific formats for technical dossiers and local language translations.

Limited Regulatory Capacity

Under-resourced regulatory agencies may struggle to manage increasing submission volumes



REFLECTIONS

Why it is important to enter the LATAM market?

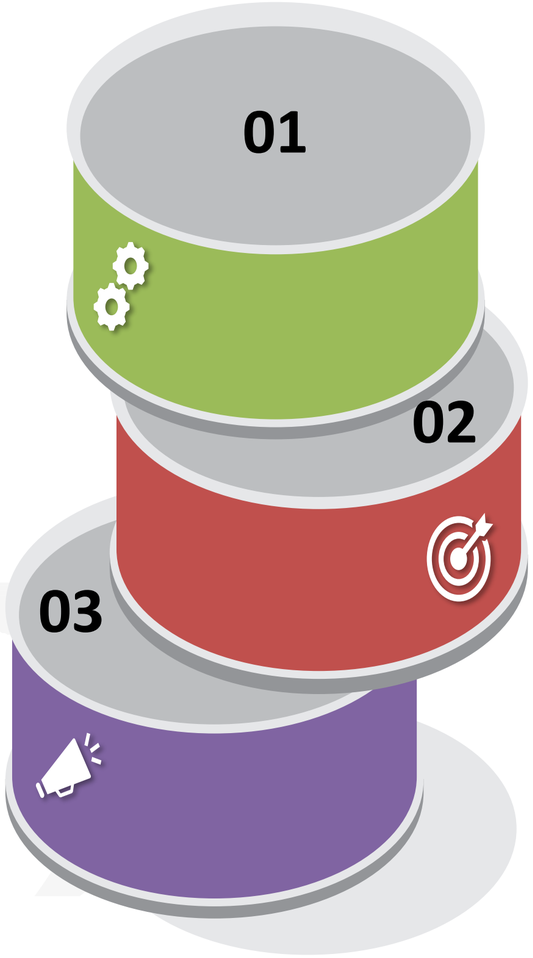
REFLECTIONS

01 – Expansion into high-growth markets

Latin America is a high-growth pharmaceutical market, driven by a large population, a growing middle class, and rising demand in chronic diseases, oncology, mental health, and age-related therapies.

03 – Partnerships (public-private)

Latin American governments are looking for strategic partners to support:
Vaccination programs, local production of essential medicines and clinical research initiatives.



02 – Technology and knowledge transfer

Enhancing healthcare systems while building scientific and industrial capacity across Latin America.

REFLECTIONS

Improved access to modern treatments for Latin American patients

“THANK YOU”

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