

A **secure** and **controlled**  
regulatory and business  
environment for your operations  
in Mexico



**COFEPRIS MEXICO**



→ **Registering** and **managing** your products  
in Mexico

Medical devices

Pharmaceuticals / Drugs

Sanitary products

Food & supplements



# Fundamentals

## for doing business in Mexico

To market health products in Mexico, you must first register with the appropriate local agency: **COFEPRIS, Mexico Federal Commission for the Protection against Sanitary Risk.**

This registration must be obtained before any commercial application for the following types of products.

- Medical Devices
- Pharmaceuticals and drugs
- Sanitary Products
- Food & supplements

This administratively complex process involves a high level of risk. Our services are intended to reduce this risk (commercial, legal, and technical) by taking these time-consuming steps for you.

## Good to Know

Beyond navigating complex administrative issues, our work deals with a number of practices unique to Mexican business culture.

- Registration must be requested through a local and reputable Mexican company that will own these records **EXCLUSIVELY** for five years,
- The company must be in good standing and fully authorized by COFEPRIS,
- This procedure is different and more complex than FDA,
- The application process takes 6 to 12 months at least before your registration goes into effect,
- The registration is always held by the company that filed the application.

## Only three options to access the Mexican Market

- 1 **Having your own local branch** (creation, merger/JV or acquisition): this approach involves the registration of your subsidiary and products in order to bring your products to Brazil or Mexico. This option is usually slow and costly (medical staff hiring, etc.) and best justified for proven markets and businesses with high investment capacity and international infrastructure.
- 2 **Using a local distributor:** you will need to find and negotiate with a local distributor knowing that it usually carries several competing brands and often focus on one region or state. Statistically, this option most of the time, results in failure within 24 months and becomes very costly.
- 3 Joining forces with a trusted third party recognized by ANVISA/COFEPRIS, **Mandala** (master distributor), get you up and competing faster and at much less cost with lower risk.

	Cost	Implementation	Risk Level
1 <b>Having your own local subsidiary</b>	<b>High</b> <ul style="list-style-type: none"> <li>- Property investment(s),</li> <li>- Employing a doctor and/or pharmacist,</li> <li>- Business trips.</li> </ul>	<b>12 to 18 months</b> <ul style="list-style-type: none"> <li>- Creating a business structure,</li> <li>- Registering your affiliate,</li> <li>- Registering your products.</li> </ul>	<b>Medium</b> <ul style="list-style-type: none"> <li>- Legal risks (Brazilian/Mexican contract),</li> <li>- Salary and wage risks,</li> <li>- Commercial failure risks,</li> <li>- Autonomy, and independence.</li> </ul>
2 <b>Outsourcing to one of your local distributors</b>	<b>Moderate</b> <ul style="list-style-type: none"> <li>- Negotiating and ratifying a contract,</li> <li>- Often with a reference product and high commission,</li> <li>- Annual negotiation.</li> </ul> Registration taxes can be paid by the local company	<b>10 to 12 months</b> <ul style="list-style-type: none"> <li>- Language and translation barriers in carrying out your requests,</li> <li>- Lack of responsiveness and transparency from the distributor</li> <li>- Difficulties to train the distributor to your products</li> </ul>	<b>High</b> <ul style="list-style-type: none"> <li>- Legal risks (Brazilian/Mexican contract law),</li> <li>- Commercial risks (competing products),</li> <li>- Risks associated with the ownership of your registration (exclusive rights),</li> <li>- Obligation to rely on Distributor.</li> </ul>
3 <b>Working with trusted third party specialized in regulatory issues (Master Distributor)</b>	<b>Low</b> <ul style="list-style-type: none"> <li>- Presentation of a clear and accurate estimate,</li> <li>- Fixed amount per product (with discounts for multiple products),</li> </ul>	<b>8 to 10 months</b> <ul style="list-style-type: none"> <li>- Expedited process based and established relationship with ANVISA/COFEPRIS,</li> <li>- Your own dedicated bilingual contact,</li> <li>- Documentation and case management should be included,</li> <li>- Transparency and full autonomy.</li> </ul>	<b>Low</b> <ul style="list-style-type: none"> <li>- No salary, administrative or overhead costs,</li> <li>- Operated by a solid and trusted third party who can provide local assistance whenever you need it,</li> <li>- No exclusivity agreements,</li> <li>- Choice of commercial partners (local distributors) and control of sales volume.</li> </ul>

# The keys to your success in Mexico

MANDALA Mexico is a company specializing in the import-export business, whose aim is to facilitate access to the Mexican market for all companies in the health and medical industries.  
**MANDALA Mexico IS YOUR TRUSTED THIRD PARTY.**

## More than 25 experts worldwide at your service:



**Daniel ROSENTHAL**  
President



**Stephan FONTANEL**  
Vice President



**Julie VISSEYRIAS**  
Chief Financial Officer



**Benoît VISSEYRIAS**  
Chief Operating Officer



**Virginie MORIN**  
International Development Manager



**Laurent HERNANDEZ**  
Chief Executive Officer Brazil



**Alexandre ALVES LIMA**  
Chief Technical Officer



**Christiane BINET**  
South Europe Development Manager



**Julian CARRET**  
International Development Manager



**Clariana GOMES**  
Pharmacist, Project Manager



**Carolina NEVES**  
Pharmacist, Technical Responsible



**Christopher LANG**  
Brazil Manager



**Alice MARTINIER**  
Marketing Department



**Laura FONTANEL**  
Mexico Manager



**Sabrina RIZZOTTO**  
Sales administration Manager

**MANDALA Mexico** delivers a custom solution for the registration and integration of internationally manufactured health products (from France, Germany, UK, USA, China, India, etc.) within the Mexican market.

Known and recognized by COFEPRIS for its competence and international compliance, MANDALA Mexico's team brings respect and credibility to the entire process of building relationships with regulatory agencies and distributors.

MANDALA Mexico has all licenses and accreditations to authorize us as an importer, exporter and distributor of health product.

### MANDALA Mexico - member of MANDALA International

**MANDALA International** is the world's leading consultant for innovative companies specializing in the medical/cosmetic sectors that seek guidance for their regulatory, financial, and administrative issues.

Whatever the size of your company or if you are already doing business in Mexico, MANDALA International will help you to optimize your development and investment.

#### MANDALA International is also:

→ **MANDALA Brasil** (the service is similar to the one offered in Mexico)

#### → MANDALA Service Provider:

- Research and select distributors in every Brazilian or Mexican state.
- Provide Legal and regulatory analysis.
- Organize and register your company according to the various local requirements.
- Manage your local operation.

#### → CROTHAWK & MANDALA Associés (France only):

- Obtains public grants and financial incentives to facilitate export (specifically to Brazil and Mexico), innovation and R & D for cosmetic and medical products.
- Organizes the French Pavilion at the Hospitalar convention (Sao Paulo) in partnership with the French Trade Commission and Ubifrance.

**MANDALA International** is a trusted and reliable European company, recognized for its efficiency and expertise when it comes to South American markets.

Plus: 4 Project Managers, 2 specialized translators/interpreters, 2 jurists, 1 IT Manager, 1 legal affairs manager..."

## Our solution

### We aim to:

- Become your regulatory partner,
- Be your administrative and commercial intermediary,
- Register your products and/or business using our local network,
- Keep and host your records and licenses,
- Import and distribute your products (medical devices, pharmaceutical, dental, sanitary products, and drugs, etc).

### This solution has many advantages:

- You remain independent and autonomous,
- You choose all local distributors freely,
- You can determine for yourself when and how you want to sell your products (Master Distributor),
- We take care of your regulatory and administrative requirements,
- We bring you the guarantee of a European organization with a solid team of professionals that is respectful of legal and ethical principles.

MANDALA Mexico also offers **additional benefit** with our customized service:

### Studying and Finding the right Distributors for you:

Do you want to better understand the market before you decide to invest there?

We deliver a specific three months assignment, including:

- A study of the market and specific business opportunities,
- Research and a selection of the best regional distributors (solid, reliable and authorized by COFEPRIS), specializing in your products,
- A study of financial and regulatory issues.

Our service includes a week in Mexico conducting face-to-face meetings with qualified local distributors and/or potential partners.

# A proven approach, safe and secure

## Optional pre-study:

### → Market and Distribution Survey <sup>2</sup>

- 3 months survey
- Meetings with future and potential partners, distributors, etc... for a week in Mexico

While Mexico represents a growing market with a population of 110 million inhabitants and is the second largest medical device market in Latin America behind Brazil, it is also one of the most confusing, and time-consuming (administrative and protectionist) markets to navigate, one requiring considerable investment resources.

Our dedicated guidance is intended to help and let you access this country's business culture making it easier for you to make realistic and cost beneficial decisions, while at the same time leaving you free to choose your distributors and buyers.

## 01.

### → First Meeting and Personalized Consultation

- Presentation of our sales teams and techniques.
- Examination and Corroboration of your penetration strategy, the products, and the market.

## 02.

### → Authorization to Carry Out a Preliminary Analysis

- Securing and Assessing the legal and economic framework.
- Pricing based on the number of products concerned.

## 03.

### → Audit and Preliminary Findings

- Determination of the product category (single, family, or system).
- Definition of regulatory prerequisites (registration or notification).
- Evaluation of classification within the definition of COFEPRIS, the National Health Surveillance Agency of Mexico. <sup>1</sup>
- Identification of other required certifications.

## 04.

### → Services and Contract

- Determination of fees for necessary registration or notification.
- Assessment of COFEPRIS taxes.
- A five-year economic business plan for hosting.
- Examination of all legal and regulatory requirements.

## 07.

### → Monitoring and Securing Business Environment

- Maintain records.
- Alert you to changes in regulatory requirements and certifications.
- Audit selected distributors to ensure legal compliance, COFEPRIS requirements, and financial health. <sup>2</sup>
- Issue and track Import Letters.

## 06.

### → Official Mexican Publication (COFEPRIS website)

- Proofreading of the registration certificates.
- Ensure the issuance of administrative documents.
- Start selling your product!

## 05.

### → Procedure for registration or notification

- Writing and developing appropriate presentation documents.
- Validating certifications.
- Filing and following up with relevant agencies.

#### Notification:

Class I and Class II

#### Enregistrement:

Class I – low utilization risk, limited contact with the patient, e.g. bandages, anesthesia trolleys, compresses... etc.

Class II – higher risk for the patient / established contact with the patient, e.g. endoscopes, resins for dental surgery... etc.

Class III – high risk / body implants, e.g. orthopedic implants, bone resins... etc.

<sup>1</sup> - The classification COFEPRIS differs from that of the FDA or CE. Medical products are classified according to the **degree of risk that a patient runs** when using a product :

2 -

As a holder of the registry, we validate the ability of your distributors and buyers to market your products. We will also provide you with a list of reliable and trusted distributors, who may be interested in your products, on request.