



Medisi<sup>®</sup>  
A M E R I C A

USA

MEXICO

BRAZIL

COLOMBIA

# TRADE IN MEXICO

- ★ Opportunities

- ★ Regulatory Considerations

# TRADE IN MEXICO

## ★ Opportunities

# LatAm Healthcare Sector



**Brazil, Mexico, Colombia, Chile, Argentina and Venezuela** combined represent the **3rd largest economy in the world** with a \$4.25 trillion GDP.

Their combined healthcare expenditure almost equal to China and India combined.

Brazil and Mexico represent more than 65% of the GDP of Latin America.



# Why Mexico?



- + 130 Million Population
- #1 Importer in Americas
- Import MDs market value of +-5 billion USD
- 93% Health Coverage
- OEM Manufacturing country with solid legal framework for trading



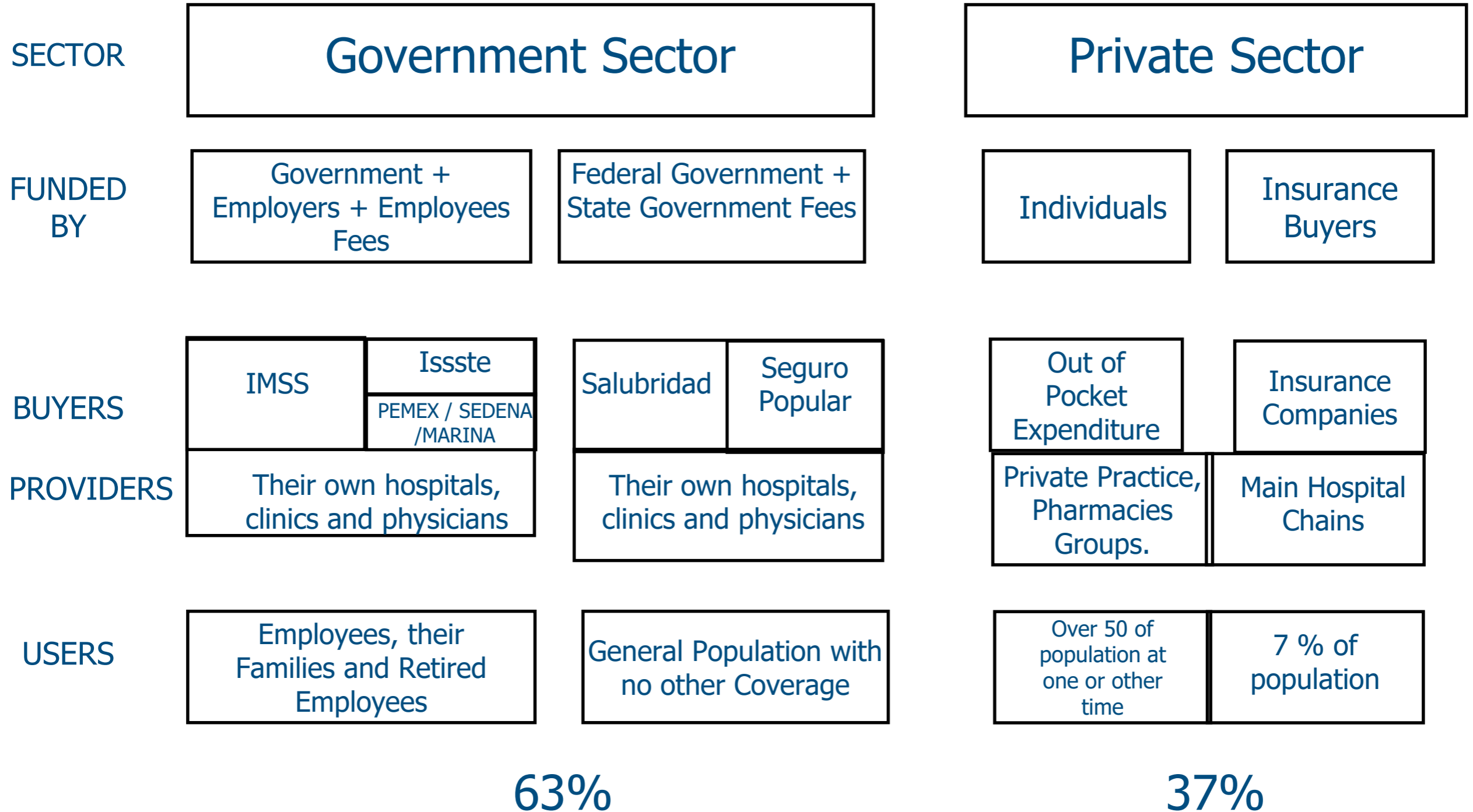
# Over 40 Double Taxation and Free Trade Agreements that guarantee your copyright and support your tax costs



## Mexico's Free Trade Agreements

Agreement	Coverage	Date of Signature	Entry into Force
North American Free Trade Agreement	Goods and services	December 17, 1992	January 1, 1994
Costa Rica – Mexico	Goods and services	April 5, 1994	January 1, 1995
Nicaragua – Mexico	Goods and services	December 18, 1997	July 1, 1998
Chile – Mexico	Goods and services	April 17, 1998	August 1, 1999
European Union <sup>a</sup> – Mexico	Goods and services	December 8, 1997	July 1, 2000 (goods) October 1, 2000 (services)
Israel – Mexico	Goods	April 10, 2000	July 1, 2000
Northern Triangle <sup>b</sup> – Mexico	Goods and services	June 29, 2000	March 15, 2001; June 1, 2001
EFTA <sup>c</sup> – Mexico	Goods and services	November 27, 2000	July 1, 2001
Uruguay – Mexico	Goods and services	November 15, 2003	July 15, 2004
Japan – Mexico	Goods and services	September 17, 2004	April 1, 2005
Colombia – Mexico	Goods and services	June 13, 1994	January 1, 2011 <sup>d</sup>
Peru – Mexico	Goods and services	April 6, 2011	February 1, 2012
Central America – Mexico	Goods and services	November 22, 2011	Pending <sup>e</sup>

# Health System





# Health System- Tender Buyers





GOBIERNO DEL ESTADO DE CHIAPAS



Gobierno del Estado de Sonora



SINALOA  
ES TAREA DE TODOS



Gobierno de Coahuila



Michoacán  
Gobierno del Estado



GOBIERNO DEL ESTADO DE TABASCO



AGUASCALIENTES



VERACRUZ  
GOBIERNO DEL ESTADO

TLX

CONSTRUIR Y CRECER JUNTOS  
GOBIERNO DEL ESTADO DE TLAXCALA 2017-2021



PODER EJECUTIVO DEL ESTADO DE QUERÉTARO



GUERRERO  
GOBIERNO DEL ESTADO



Gobierno del Estado de Sonora



Nuevo León  
GOBIERNO DEL ESTADO



Chihuahua  
GOBIERNO DEL ESTADO



Gobierno del Estado de Quintana Roo



Yucatán

CONSEJERÍA JURÍDICA  
Gobierno del Estado de Yucatán  
2012 - 2018

CRECER EN GRANDE  
CAMPECHE 2015-2021

GUANAJUATO  
Gobierno del Estado



NAYARIT  
GOBIERNO DEL ESTADO

SSN  
SERVICIOS DE SALUD DE NAYARIT



ZACATECAS  
TRABAJEMOS DIFERENTE  
2016 - 2021



Gobierno del Estado de Morelos



HIDALGO  
GOBIERNO DEL ESTADO



CDMX

CIUDAD DE MÉXICO



DURANGO  
GOBIERNO DEL ESTADO



JALISCO  
GOBIERNO DEL ESTADO

BAJACALIFORNIA  
GOBIERNO DEL ESTADO

Tam  
TAMAULIPAS



Oaxaca  
JUNTOS CONSTRUIMOS EL CAMBIO  
Gobierno del Estado



COLIMA  
GOBIERNO DEL ESTADO



GOBIERNO DEL ESTADO DE MÉXICO



SAN LUIS POTOSÍ  
H. AYUNTAMIENTO 2012-2015

# Opportunities

Government purchases represent at least 47% of the global market = **Public market is the best client BUT NOT the only valuable one.**

Price sensitive market= **Fair quality/Middle price products opportunity**

Half/Half private vs government market = **Multiple Prices strategies for same country**



# Challenges

Language / Culture



Complexity of Market Strategy  
Public/ Private



INTEGRATOR-Distributor- Subdistributor  
dependance



Sovereign Regulation



# Questions?

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BJ, CDMX 03900

Concepcion Beistegui 828  
BJ, CDMX 03100

# TRADE IN MEXICO

## ★ Regulations

# Where to begin?

## **A partner, a company or a holder?**

In order to obtain a sanitary registration in Mexico you need to be legally established and paying taxes in the country, so you either partner up with a national company, you open a company in Mexico or you hire a company to hold your sanitary registry.





## A partner, a company or a holder?

### **Partner**

They will know the market, speak the language but he will be the owner of your product and its strategy in the country for good or for worst

### **Company**

You will own your product and your market plan entirely but you will have to face the costs of open a business in a foreign country

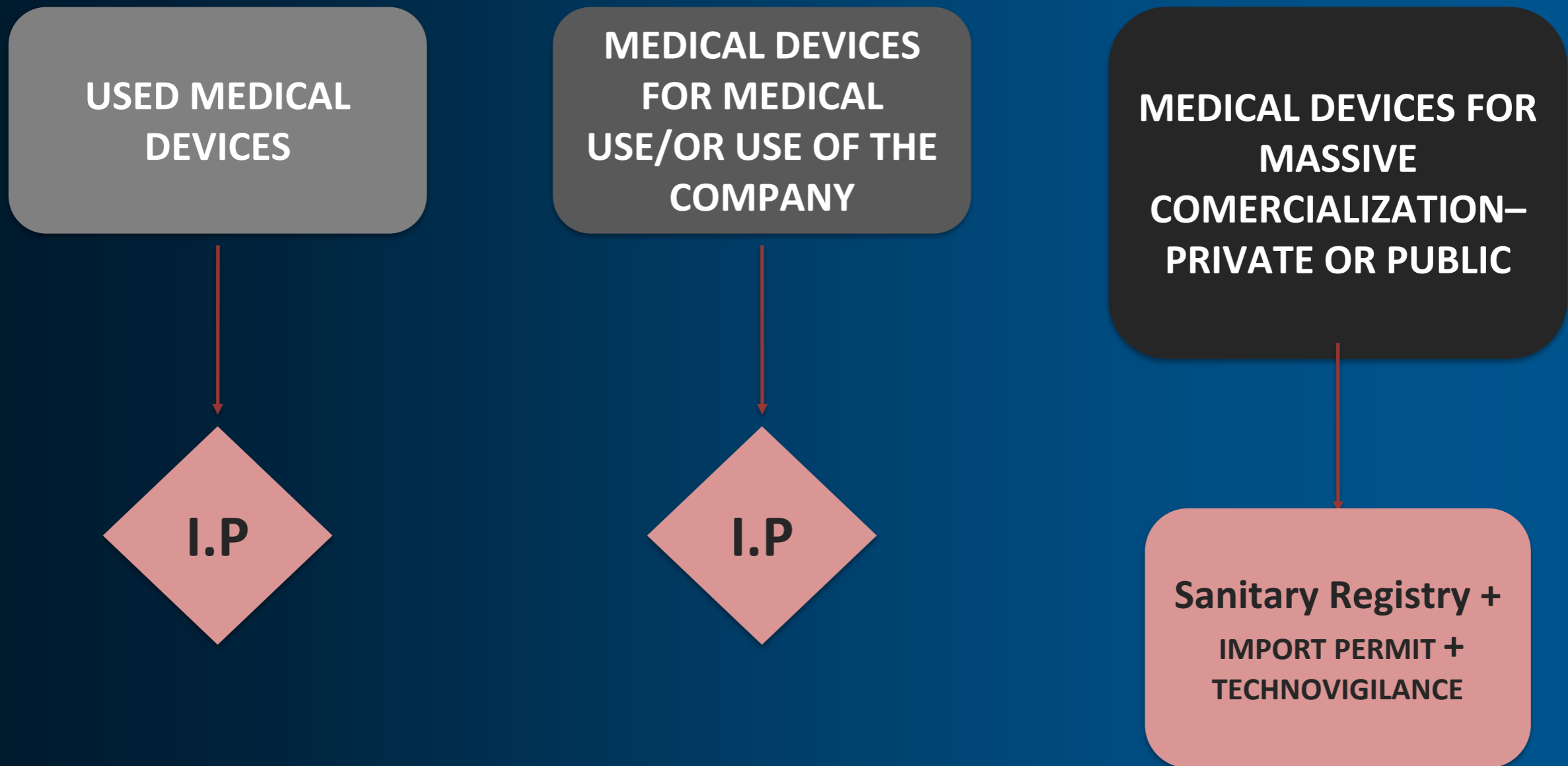
### **Holder**

You will own your product through a third party and will get the benefits of one or many partners without compromising your product's ownership.



# Where to begin?

## A regulation plan according to my commercialization plan



# The Global Need

MEDICAL DEVICES FOR  
MASSIVE  
COMERCIALIZATION –  
PRIVATE OR PUBLIC



Sanitary Registry +  
IMPORT PERMIT +  
TECHNOVIGILANCE

## Operations and Sanitary Responsible Notice:

Document presented to COFEPRIS where I state my activity, the location of my warehouse and the name of my sanitary responsible

## Sanitary Registry:

Authorization granted by COFEPRIS that will enable you to market and obtain an import authorization for 5 years. Only one owner possibility but multiple distributors and importers.

## Import Authorization, when applicable to Harmonized Code:

Posterior to the Sanitary Registry and enables you to introduce the product into the country for 180 days .

## Technovigilance- NOM 240 STANDARD:

Adverse incidents follow-up to post-marketed MD



# PATHS

¿Fast Track, Traditional or  
Third Authorized Party?

## Registry by Fast Track

List of requirements: 12 Points  
(+ **approvals FDA/HC/Japan** )

The most important part of these are the legal documents and a good summary of the overall functioning of the device instead of detailed validation tests per each point.

✓Legal Time to Answer: 30 Business Days



## SPECIFIC LEGAL REQUESTS

- 510 k or PMA, EIR, Certificate To Foreign Government, Recall Report
- Medical Device License, ISO 13485, ISO 17021 for the issuer of the 13485, Standards Council of Canada Accreditation for the issuer of the 13485
- Approval Letter issued by MHLW, Export Notice, Free Sales Certificate



# PATHS

¿Fast Track, Traditional  
or Third Authorized Party?

## Traditional Registry

List of requirements: 35 points in detail

General set of requirements similar to those for obtaining a CE Mark

Legal response time: 60 business days



### SPECIFIC LEGAL REQUESTS

- Free Sales Certificate
- Distribution letter from the manufacturer
- Good manufacturing practices (GMP) certificate issued by the health authority of the country of origin ISO 13485:2003 certificate



# PATHS

## ¿Fast Track, Traditional or Third Authorized Party?



### Third Authorized Party

List of requirements: 35 points in detail

General set of requirements similar to those for obtaining a CE Mark

Legal response time: 60 business days

✓ Time answer by third party: 5 days with possibility to widen the documentation up to 2 times

✓ Expected time for final answer from third party: 1.5 - 3 months

✓ Worst time for a TAP final answer: 8-12 months

✓ Response time offered by Cofepris to TAP Submissions : 1 - 3 months



What's the ACTUAL variation of the process?

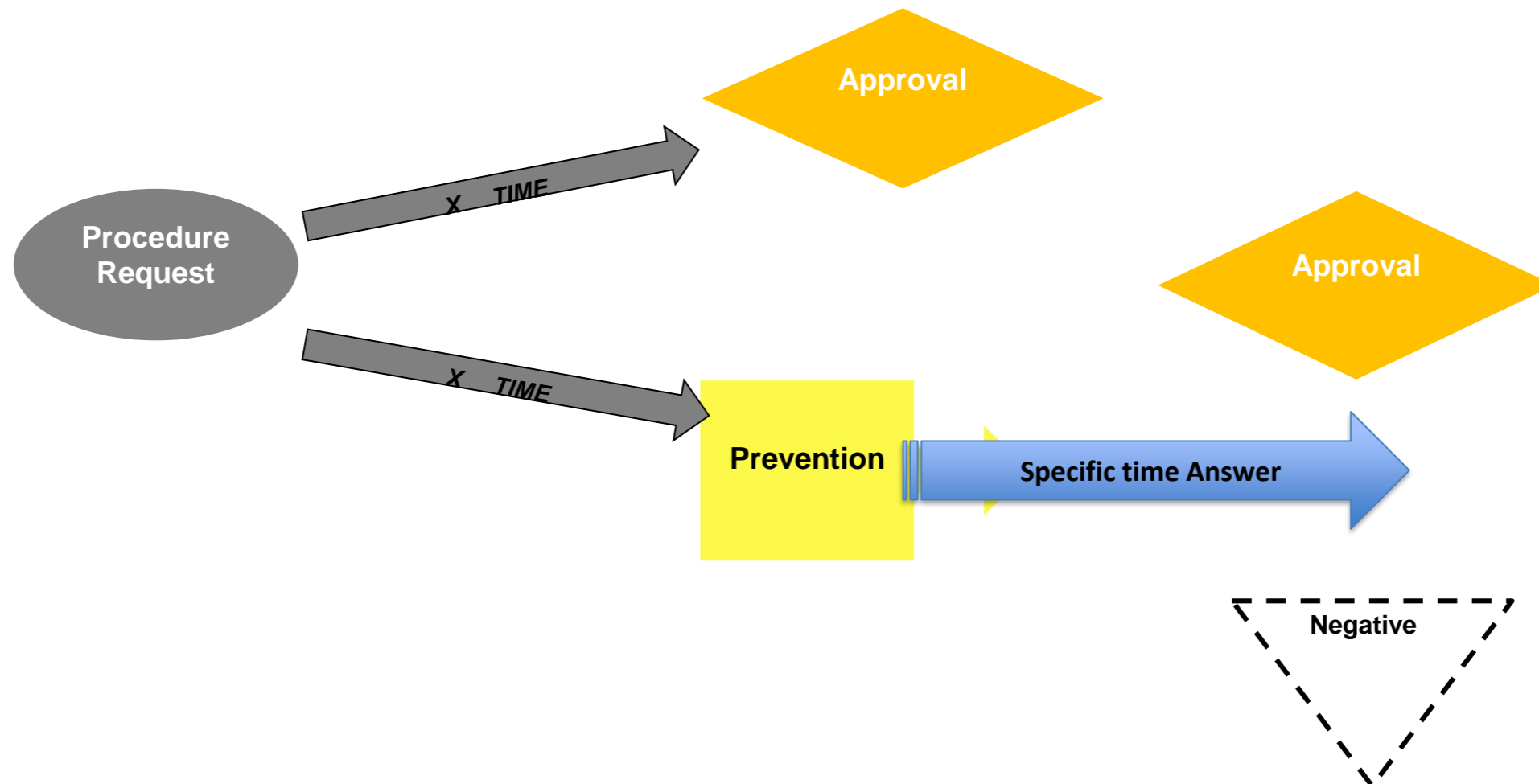
**Response time according to the route I decided or I was able to carry out with my application.**



# General Application Process



Comisión Federal para la Protección  
contra Riesgos Sanitarios





# Third Authorized Parties? Application Process



Comisión Federal para la Protección  
contra Riesgos Sanitarios

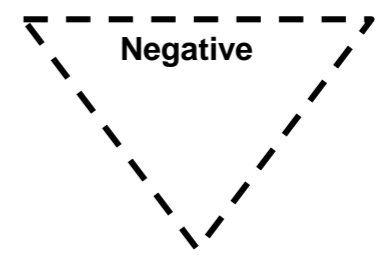
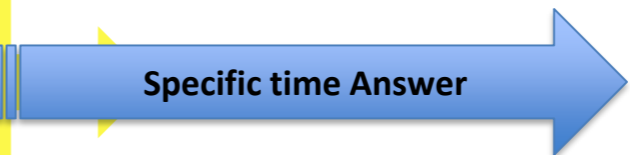
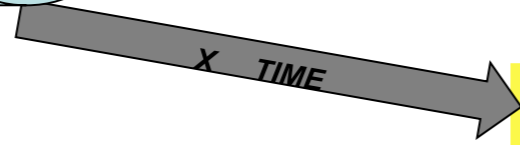
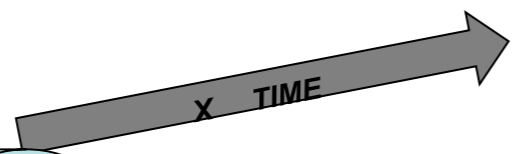
Procedure  
Request

3rd

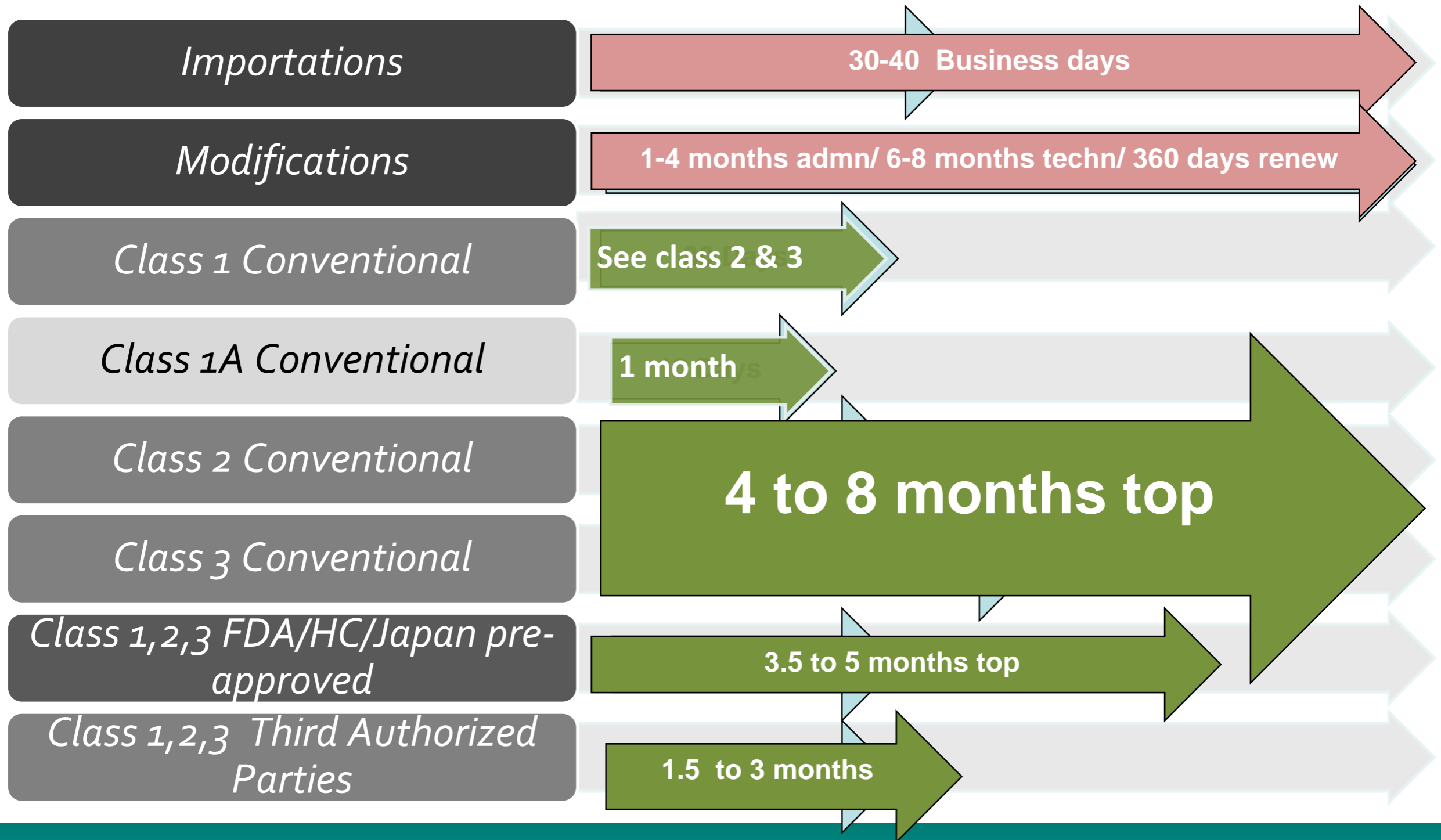
Preliminary  
Resolution



SPECIALIZED LINE



# How long?



# Questions?

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