



# MEXICO'S HEALTHCARE REGULATORY INSIGHTS

---

Unlocking the Business  
Potential in Latin America

NZTE Webinar



NEW ZEALAND  
TRADE & ENTERPRISE  
Te Taurapa Tūhono

# CARLOS ALMANZA – Beachead advisor



Food Scientist, with over 17 years of experience in:

- Food, beverages & specialized nutrition regulation & regulatory strategy.
- Public affairs & external engagement with industry associations, government & academic bodies.
- National & international standards drafting.

Conflict of interest declaration:

The speaker is a consultant on regulatory strategy and collaborates as technical advisor for food, beverages, ingredients and healthcare companies. He does not have an affiliation with, nor receives financial support from New Zealand companies.

# HEALTHCARE REGULATION & PUBLIC POLICY TOPICS

**I. EXECUTIVE SUMMARY**

**II. LEGAL & REGULATORY FRAMEWORK**

**III. GENERAL PROCESS FOR APPROVAL**

**IV. REGULATORY PROFILE FOR PRODUCT CATEGORIES**

**V. GENERAL CRITERIA FOR ASSESSMENT & APPROVAL**

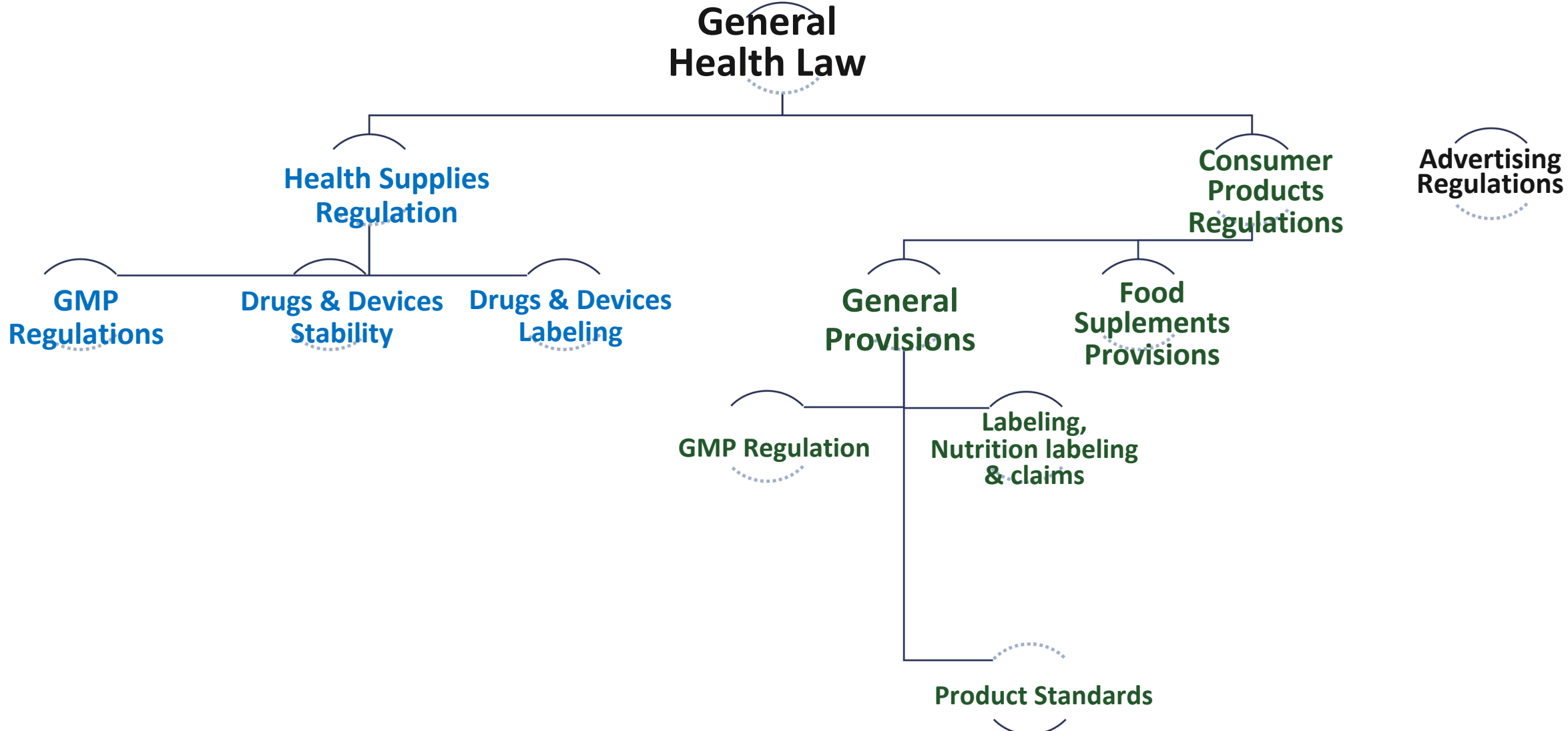
**VI. PUBLIC POLICY AFFAIRS – NUTRITIONALS, HEALTHCARE**

**VII. TAKE AWAY POINTS**

# EXECUTIVE SUMMARY

- Mexico's Healthcare Regulation framework follows a hierarchical structure based on legislation and detailed technical requirements, some of which is being harmonized with WHO and ICH Guidelines.
- Most Healthcare Regulations are currently being revised to align with recent Quality Infrastructure Law. There is increased focus on conformity assessment and consumer protection meaning compliance is key for successful registration, launch and marketing.
- Public policy engagement requires a clear understanding of public health priorities, sound initiatives that contribute to addressing those priorities, and partnering with key industry associations.
- The Mexico Healthcare market is complex yet filled with opportunities and advantages, including the geographical advantage that Mexico offers..

# LEGAL & REGULATORY FRAMEWORK



# GENERAL PROCESS FOR APPROVALS/REGISTRATION

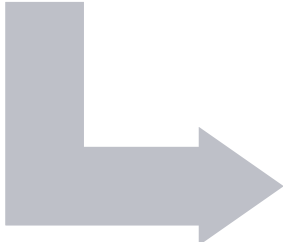
Item classification

- **Composition**
- **Indication, Uses or Benefit**
- **Other countries status**



Legal, Technical & Data requirements

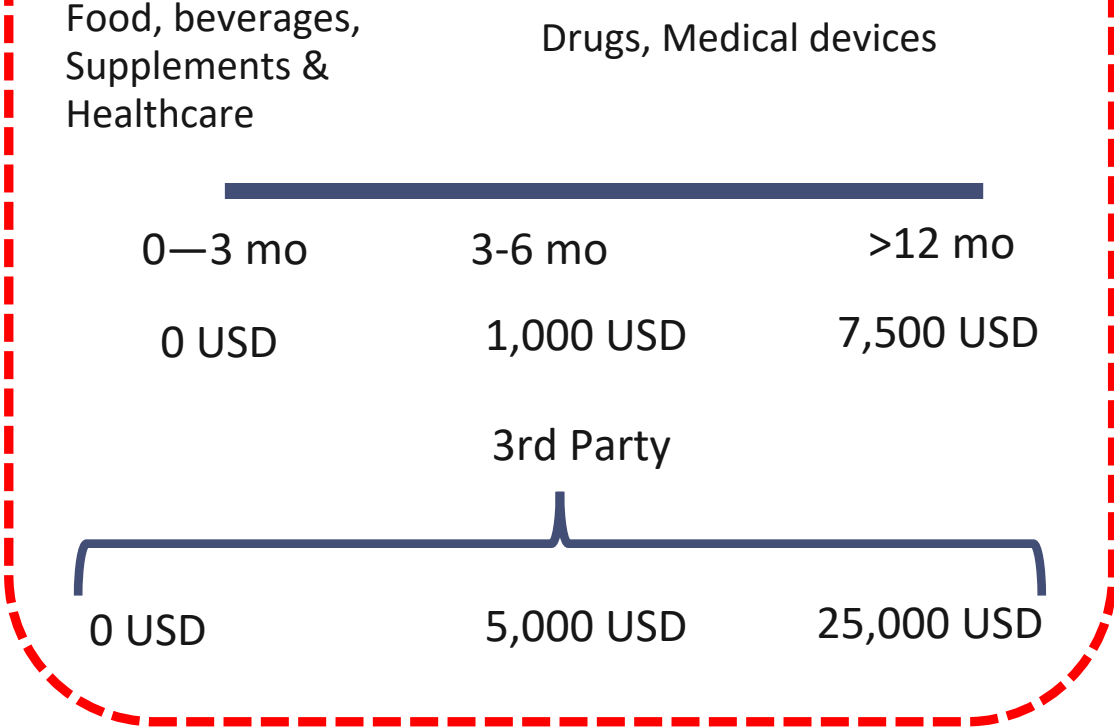
- Information & Data Consistency
- Supporting evidence



Import & Marketing

- Import License
- Country of origin & Spanish labeling

## - Timeframes & Costs



# REGULATORY PROFILE FOR PRODUCT CATEGORIES

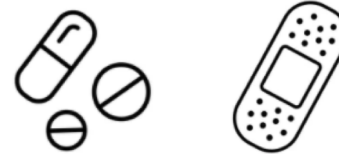
Food, Supplements & nutritionals



Healthcare & cosmetics



OTC Drugs & Class I Medical Devices



Rx Drugs & Class II & III Medical Devices



Regulation	Food/Nutrition	Food Supplement	Healthcare & Cosmetic	OTC Drugs & Medical Devices	Prescription Drugs & Medical Dev. Class II & III
Registration	NA	Approval (3 mo)	Only for hygienic products	Required	Required
Content Claims/ Health Claims / Function claims	Aligned with labeling regulations (Contains xxxx). <b>[Warning FOP labeling]</b>	Only nutrient content claims	Aligned with use. For hygienic products, aligned with registration	Aligned with therapeutic indication approved in registration.	Only for HCPs.
Health claims / Health benefits	Yes. Specific function claims need approval	NA	For hygienic products, aligned with registration		Aligned with therapeutic indication approved in registration.
Advertising	Compliant with regulation	Approval required	Approval for Hygienic		
Taxes	Excise tax 8% confectionary 0.05 USD/L added sugar drinks	VAT 16% 0.05 USD add. sugar	NA	NA	NA

# GENERAL CRITERIA FOR ASSESSMENT & APPROVAL

## RESOURCES, REFERENCES & EVIDENCE TO BE CONSIDERED FOR SUBMISSION

### Essential medicines and health products

List of Stringent Regulatory Authorities (SRAs)



CTD – ICH





# PUBLIC POLICY AFFAIRS - NUTRITIONAL, HEALTHCARE

- The political environment and ideology is challenging, however there is access to key stakeholders as long as there's alignment with public health priorities.
- The current public agenda is focused on: nutrition, overweight and obesity, diabetes, CVD, medical access, universal coverage, consumer protection.



# Take away points

- Product composition, intended use and market compliance
- Technical consistency, compliance and conformity assessment
- Stakeholders mapping



# THANK YOU

---

Carlos Almanza