

Four Pillars of a Sound PMTA Strategy

Legal, Science, Manufacturing and Marketing.

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Objectives

- + **Premarket Tobacco Application**
- + **PMTA Strategy- Pillars**
 - Legal Considerations
 - Scientific Foundations
 - Manufacturing Process
 - Marketing
- + **Strategy Tips**
- + **Integrating the Pillars- Strategy**

PMTA

Premarket Tobacco Applications

+ Regulatory Requirement

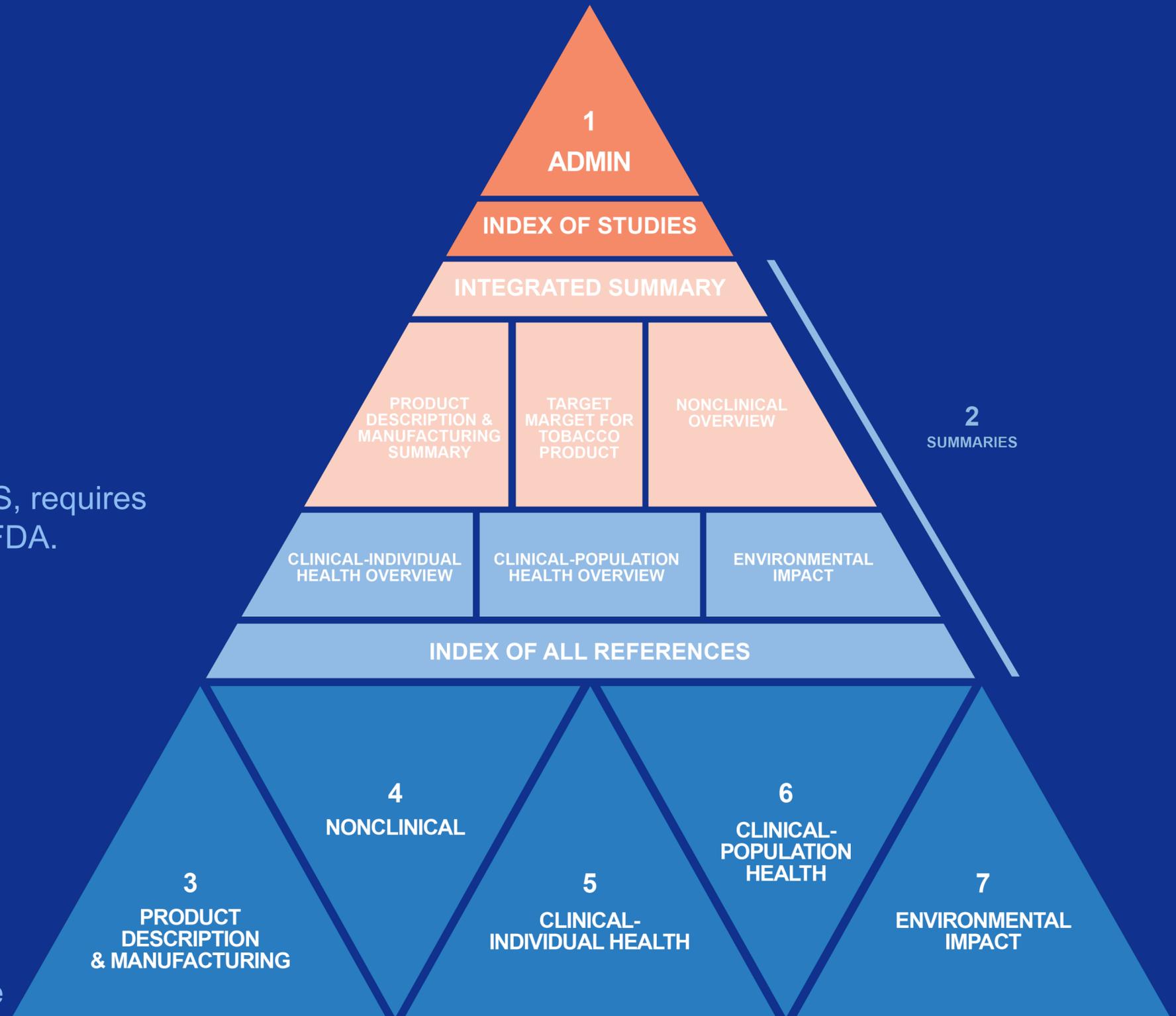
To legally market a new tobacco product in the US, requires a PMTA submission and a marketing order from FDA.

+ What Goes Into a PMTA

- Product Information,
- Product Testing Data
- Clinical Studies
- Manufacturing Controls
- Marketing Plan

+ FDA's Public Health Standard

- Determines if the product is Appropriate for the Protection of Public Health.



Importance of a Robust PMTA Strategy

- + Compliance
- + Market Access
- + Risk Management
- + Brand Reputation

PILLAR ONE:

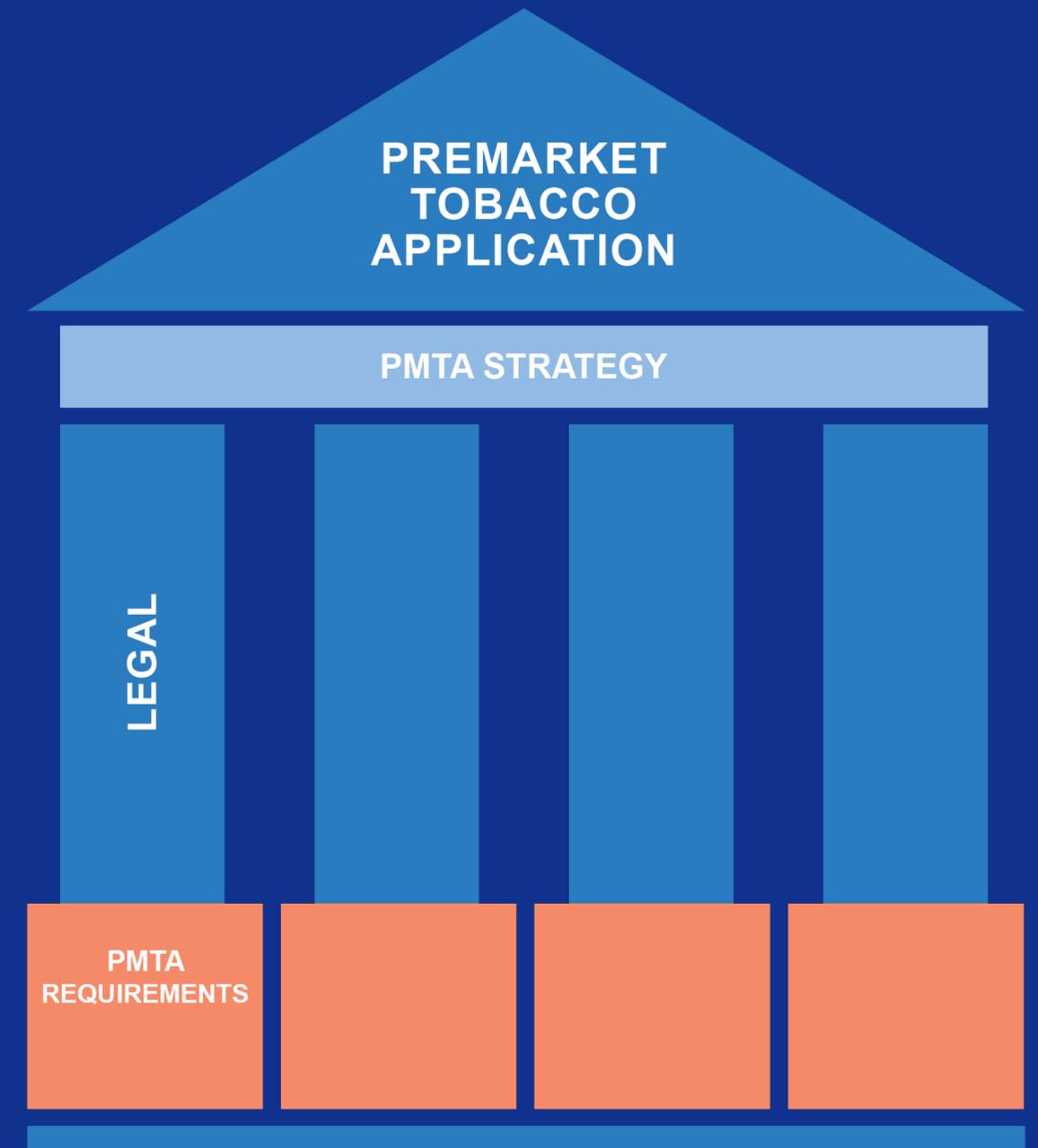
Legal Considerations

+ Regulatory Framework for PMTA

- Tobacco Control Act- Section 910
- Premarket Tobacco Application and Recordkeeping Req.

+ Responding to FDA's Decisions

+ FDA Enforcement



PILLAR TWO:

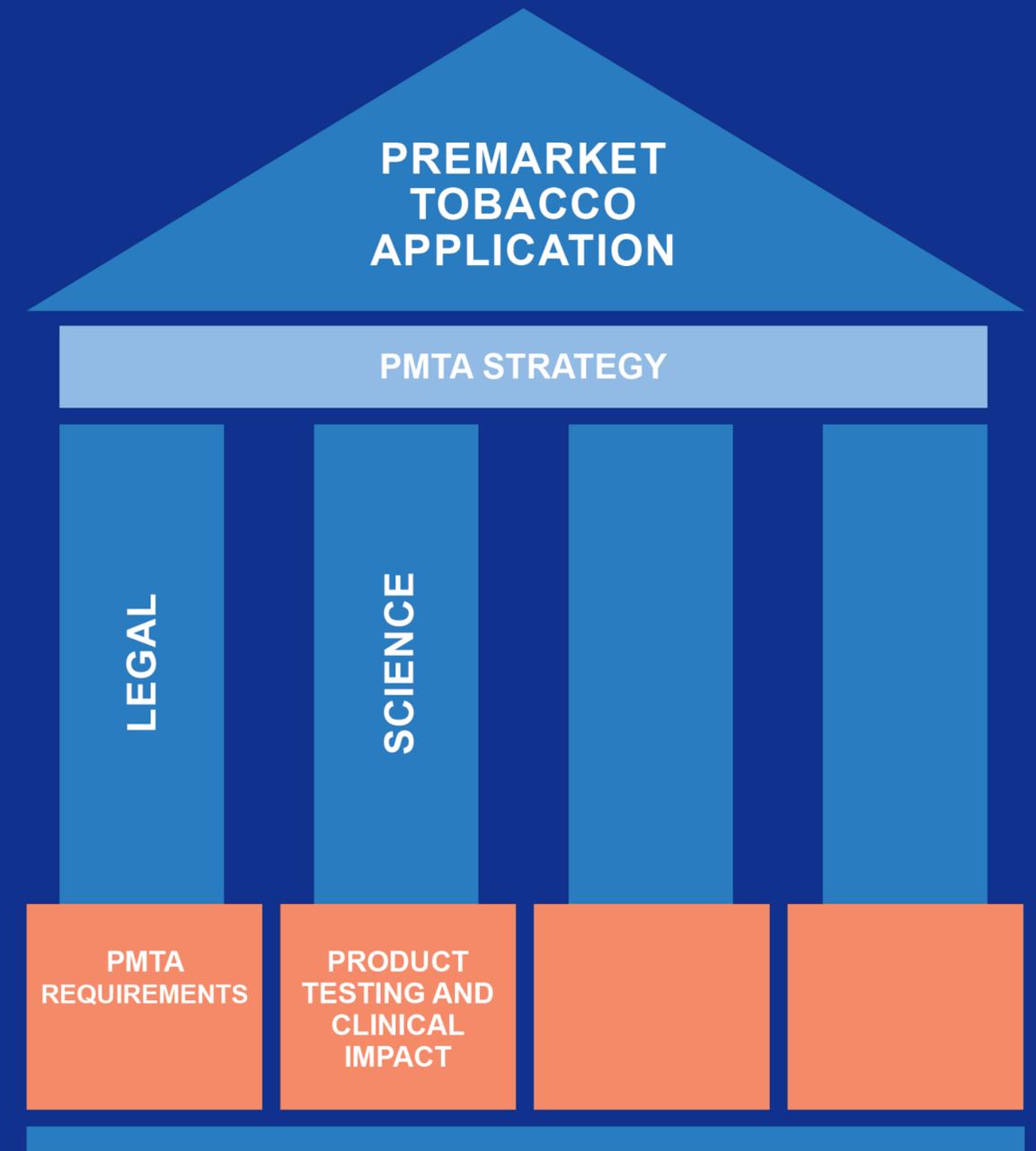
Scientific Foundations

+ Non-Clinical Testing

- Ingredients
- Safety Profile
- Extractables
- Genotoxicity & Cytotoxicity

+ Clinical Investigations

- Abuse Liability
- Actual Use
- Perception and Intention Studies
- Switching studies



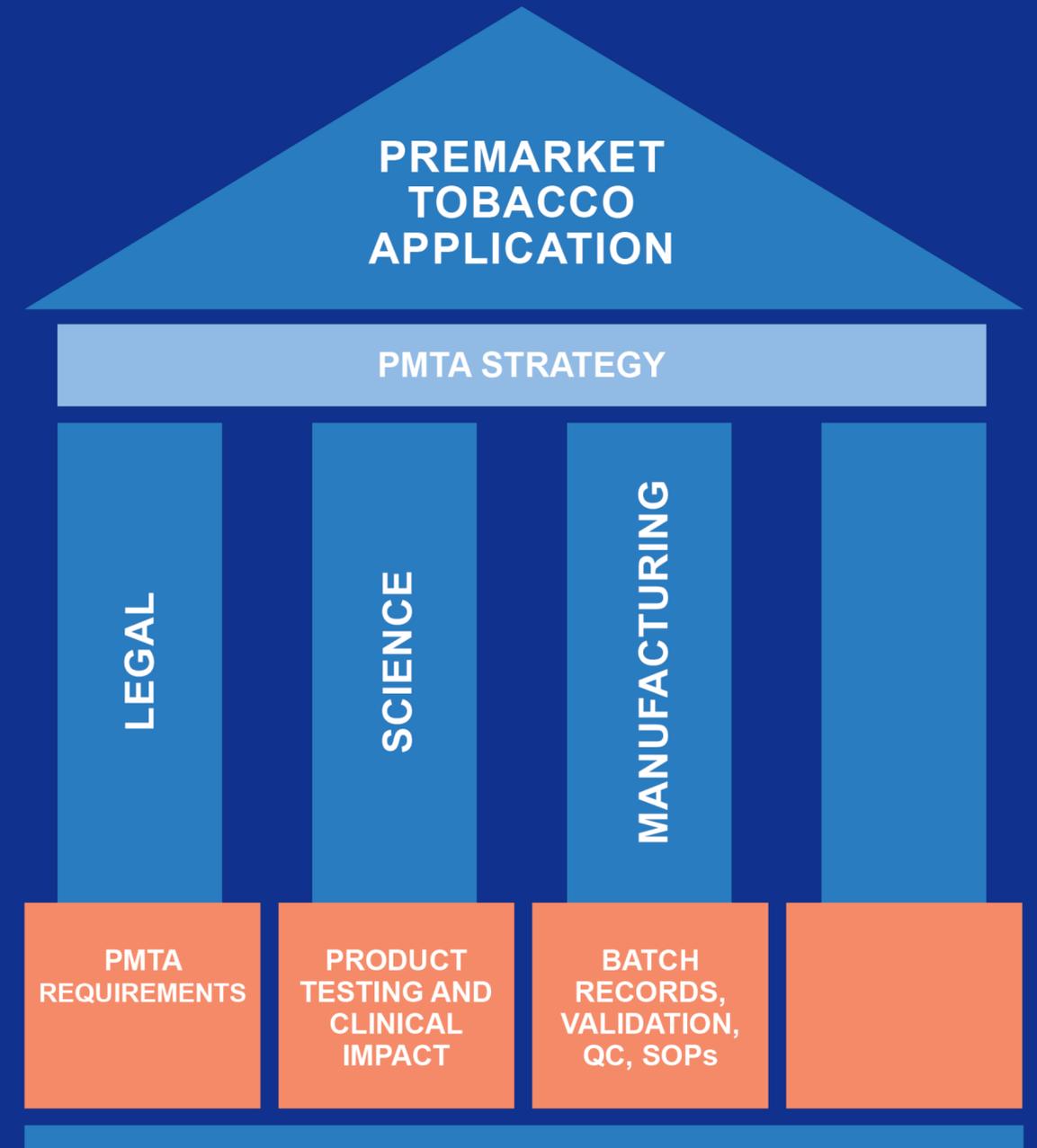
Develop a Robust Product and Clinical Testing Plan

PILLAR THREE:

Manufacturing Processes

Full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of ...

- + Consistently manufacture products
- + Validation
- + Environmental Impact
- + Documentation



Tobacco Product Manufacturing Practices

+ Who Needs to Comply with TPMP?

- Foreign & Domestic finished tobacco product manufacturers
- Foreign & Domestic bulk tobacco product manufacturers
- Specification developers
- Contract manufacturers
- Importers

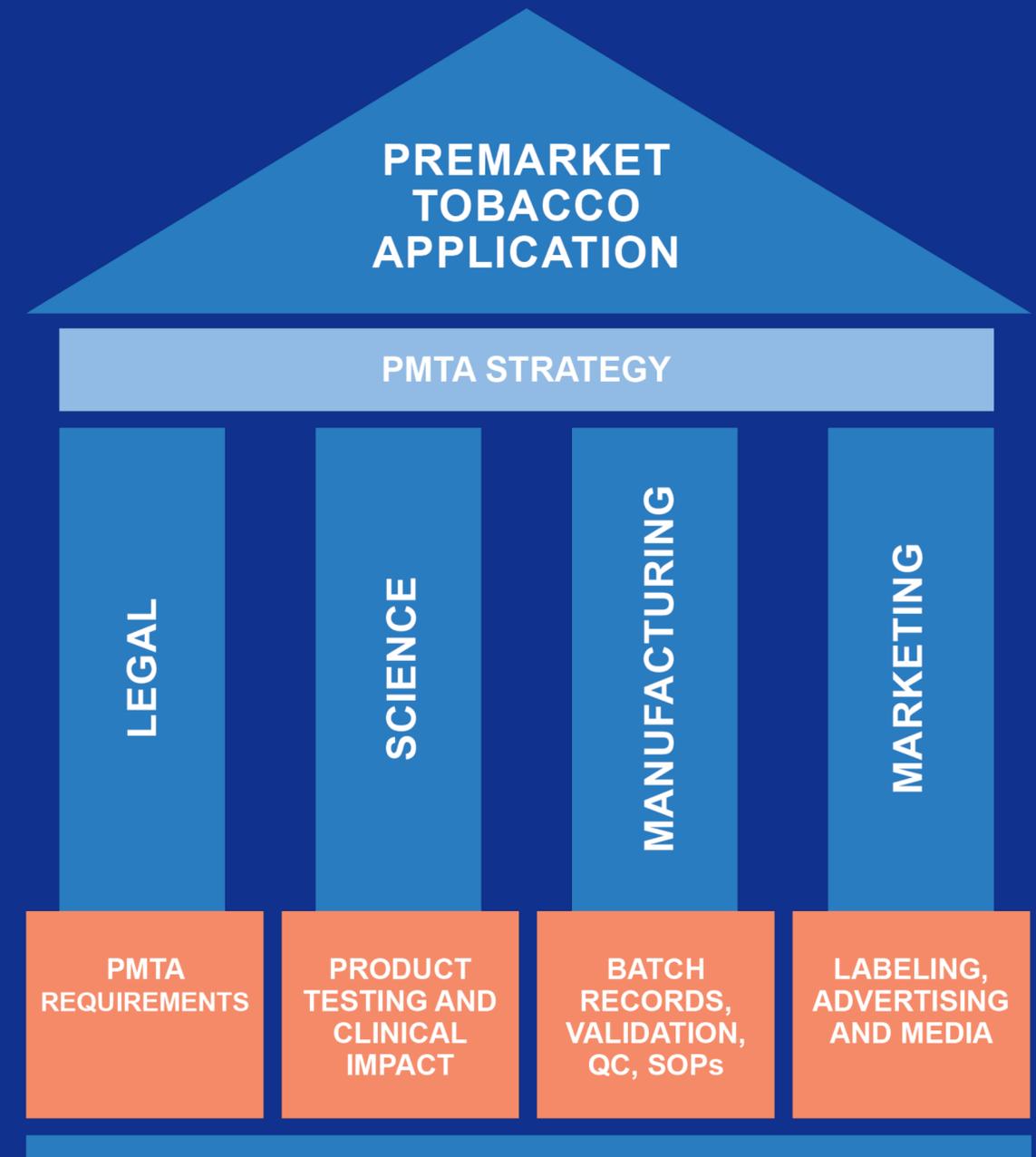
+ Who Will Be Indirectly Impacted?

- Suppliers
- Distributors
- Contract Testing Laboratories



PILLAR FOUR:
Marketing

- + Marketing Restrictions
- + Robust Marketing Plan
- + Compliant Labeling and Advertising





Integrating Strategies

PMTA Strategy Tips

- + Organizational Commitment
- + Cross-functional Collaboration
- + Risk Assessment And Mitigation
- + Engage External Experts
- + Adaptability
- + Staying Informed And Updated

Questions?

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Thank You

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