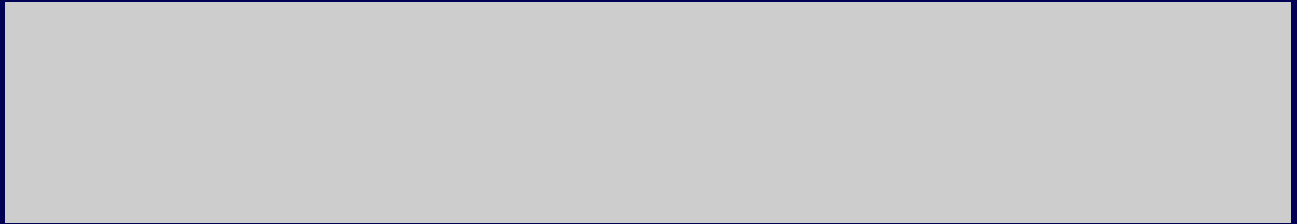




18 May 2011

Supply Chain Trends in Emerging Markets

MEDICAL DEVICE SUPPLY CHAIN COUNCIL



PRTM

*Management
Consultants*

Where Innovation Operates

Emerging Markets Growing in Importance

Mature markets are becoming more challenging

- Growth is slowing
- Reimbursement pressure is growing

Medical device companies are increasingly turning to emerging markets to accelerate growth

Five-year medical device CAGR in mature markets is estimated to be 7.5% vs. an emerging markets rate of 15%*

BRIC five-year CAGR is forecasted to be 20%

What supply chain trends and operational challenges result from this increased focus on emerging markets?

Supply Chain Priorities in Emerging Markets

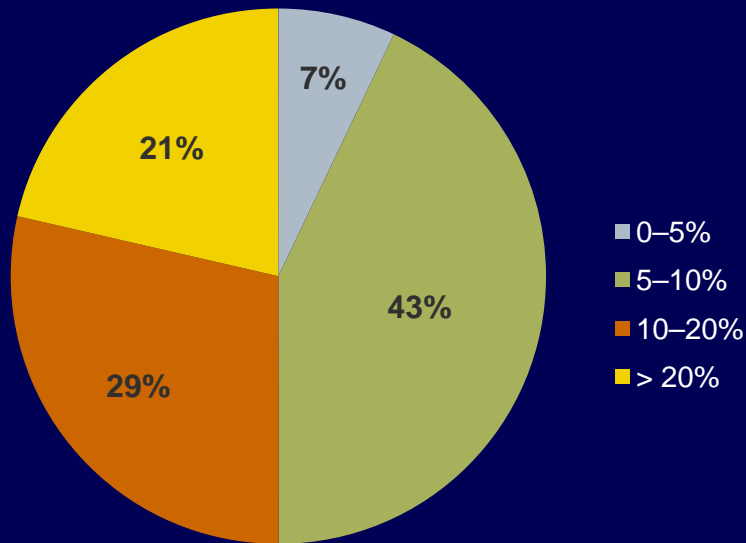
PRTM MDD Emerging Markets Study set out to explore the implications of emerging market expansion on supply chains

- How important is emerging market growth for medical device companies?
- How are companies managing emerging market supply chains?
- Which countries/regions are the highest priorities?
- What are the current operating models deployed (distributors, JVs, mfg/label in country/region, etc.) and what changes are being considered in key emerging markets?
- What are the primary risks, concerns in each market?

Strong Growth Expected in Emerging Markets

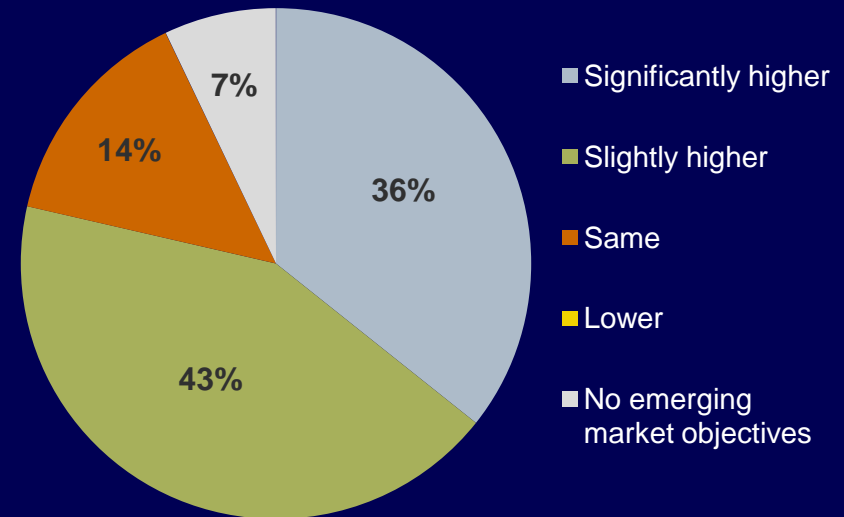
While emerging markets represent ~8% of median revenue today...this is expected to change

What is your forecasted 2011 % sales growth for emerging markets?



50% report forecasted 2011 growth of 10% or higher in emerging markets

How do emerging market sales growth plans compare to overall company growth plans?

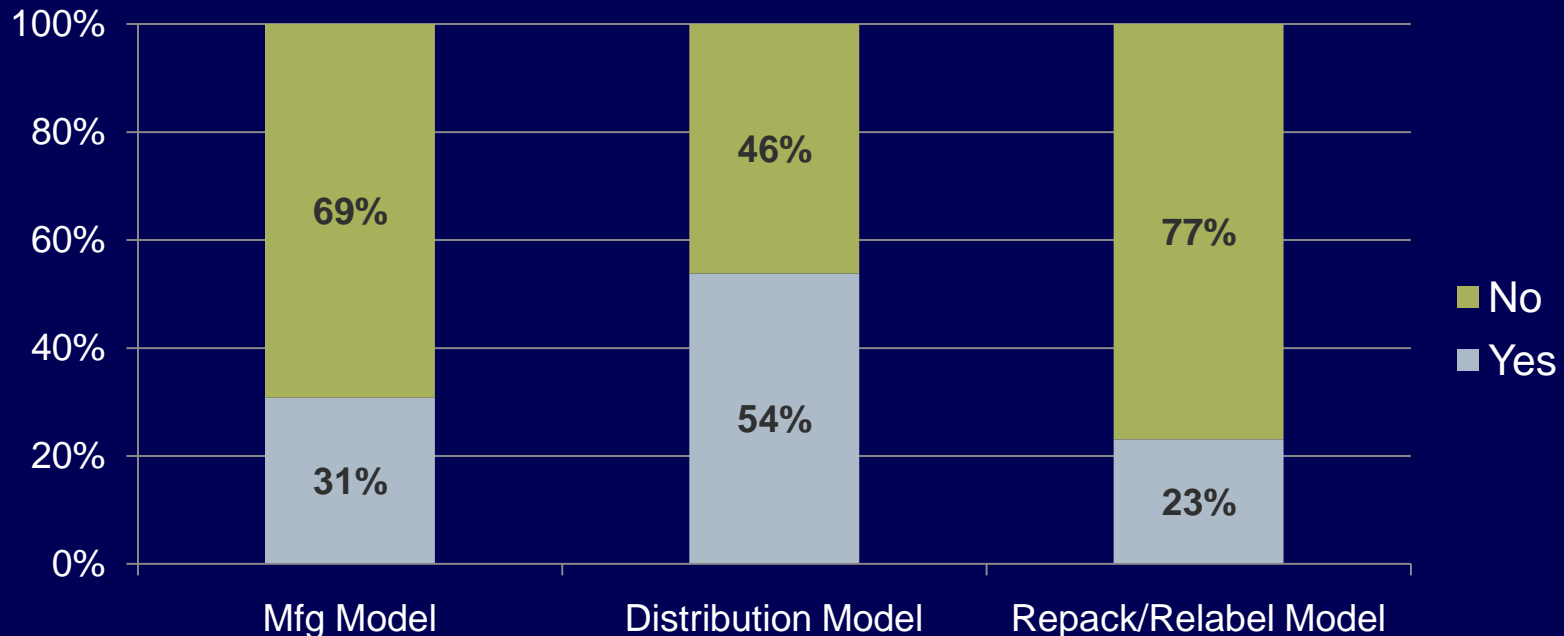


Over 80% indicate three-year growth projections in these markets are slightly or significantly higher than overall company growth projections

Implications for Emerging Market Supply Chains

Over 50% of respondents are considering changes to emerging market distribution models and 30% are considering changes to manufacturing models

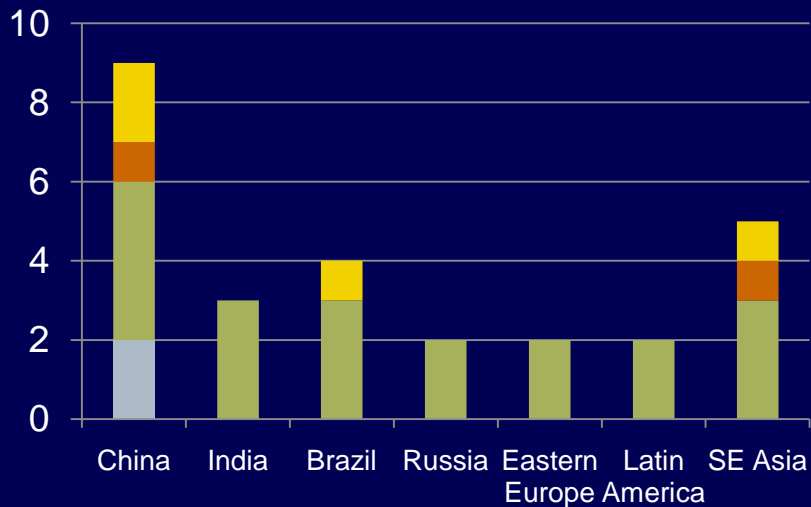
Are you considering changing your operations, distribution or repack/re-label models in any emerging markets?



Changing Strategy to Enhance Market Access

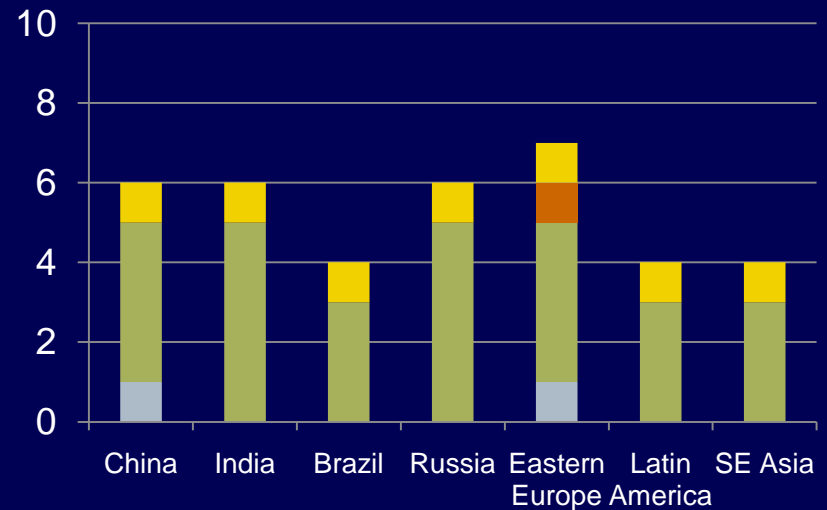
Market access is the most often cited driver of potential changes to operations and distribution models in key markets

Which of the following factors is influencing potential emerging markets operations strategy change?



- Cost Reduction
- Market Access/Sales Growth
- Tax Optimization
- Risk Mitigation

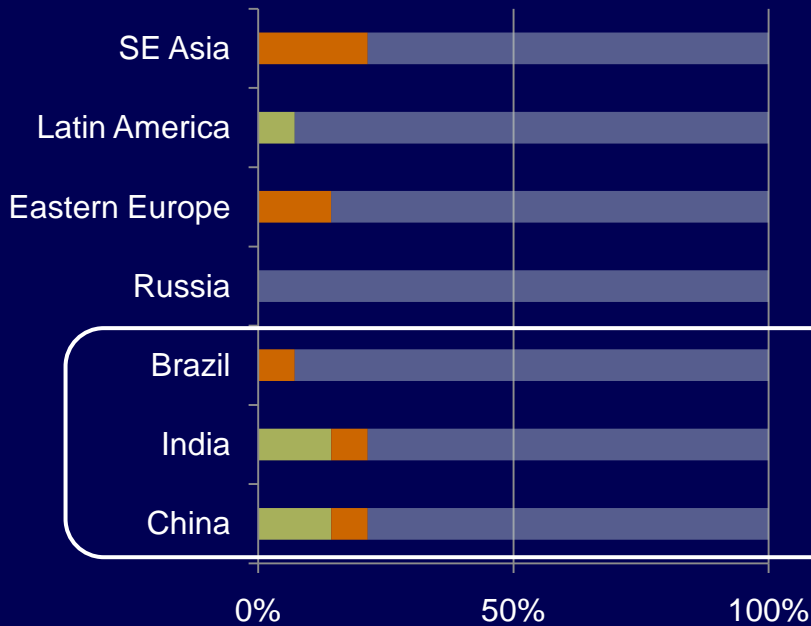
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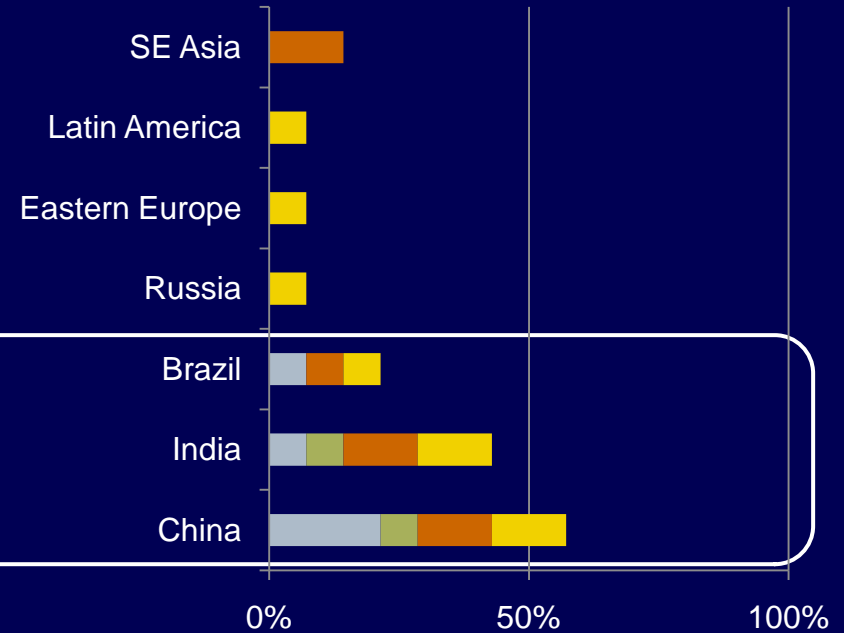
- Cost Reduction
- Market Access/Sales Growth
- Tax Optimization
- Risk Mitigation

Evolving Manufacturing Operations Models

Which option best describes your current manufacturing operations model in each country/region?



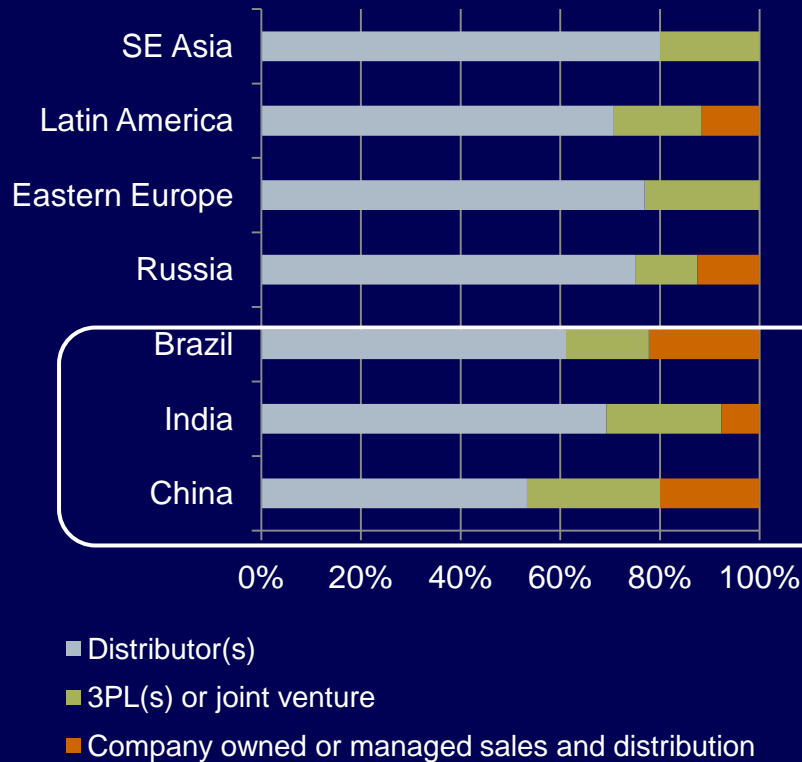
If you are planning to change models, which manufacturing models are you considering?



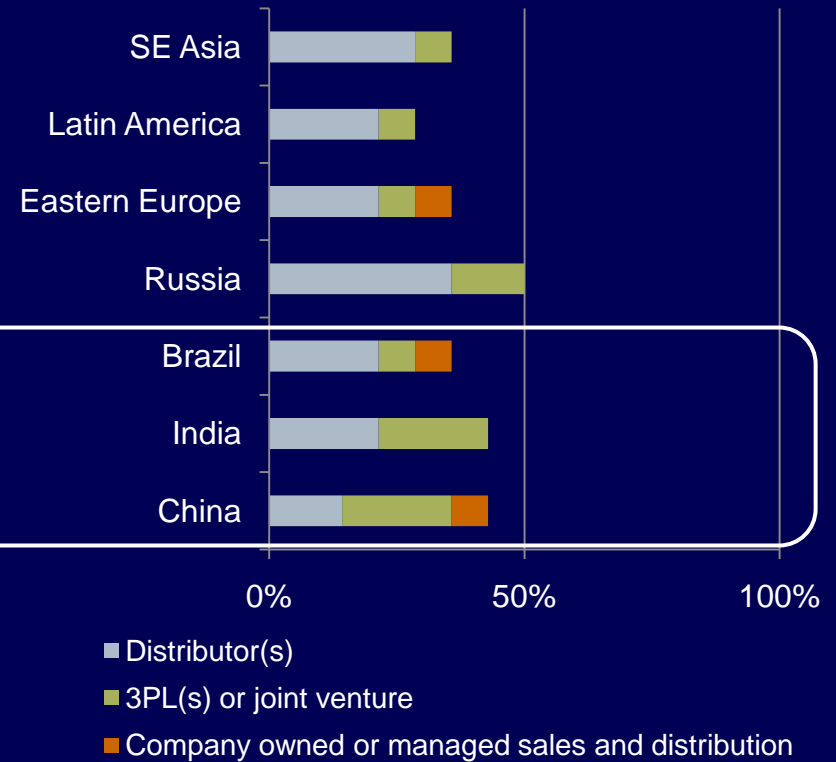
Limited emerging market manufacturing today, but models for leveraging local manufacturing are being considered—particularly in China and India

Evolving Distribution Models

Which option best describes your current distribution model in each country/region?



If you are planning to change models, which distribution models are you considering?



Distributors are most common supply chain strategy in emerging markets but increasing interest in employing 3PLs in some key markets

Source: PRTM Medical Device Supply Chain Priorities in Emerging Markets Survey, April 2011

PRTM MDSCC Presentation—18 May 2011 | © 2011 PRTM Proprietary

Risks and Challenges Vary by Market

What areas represent the greatest risks and challenges in each emerging market?

	China	India	Brazil	Latin America	Russia	SE Asia	Eastern Europe
Limited internal knowledge of market		●			●		
IP risk	●						
Level of local competition			●				
Regulatory/reimbursement uncertainty	●		●			●	●
Level of supply chain infrastructure					●		●
Availability of qualified local partners (JV, 3PL, etc.)		●			●	●	
Availability (and turnover) of qualified resources in market							

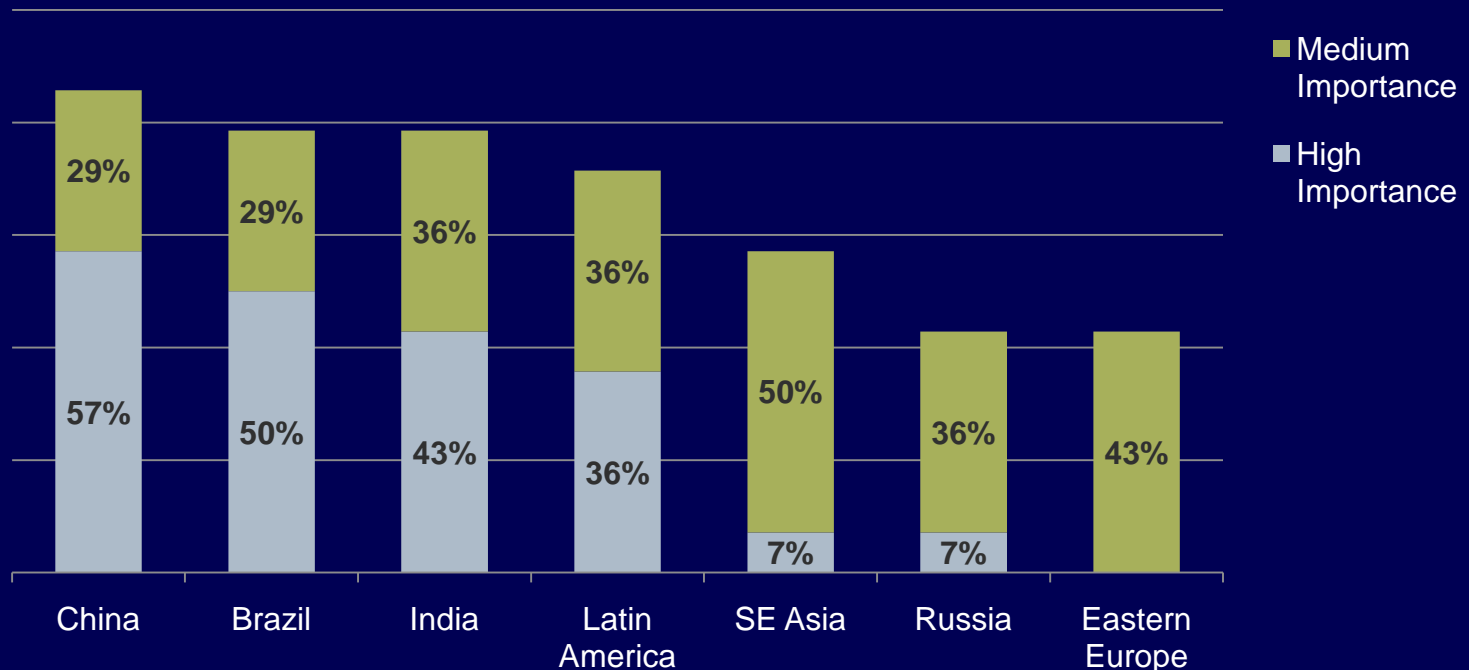
● High Risk/Challenge

Each emerging market presents its own unique characteristics and challenges

China, Brazil, and India—Most Important Markets

Respondents reported China, Brazil, and India as being the most significant markets in their emerging markets strategy

What countries or regions are of most significance in your emerging market strategy?



Market Dynamics Vary in Three Priority Markets



- 13.6% projected five-year CAGR for medical devices
- Three-year \$124B government investment in health care reform—will primarily benefit mass market equipment and consumables
- Reform provision to “Buy China” gives preference to domestic suppliers
- MNCs dominate high-end market but domestic companies are increasing investment
- Slow registration process and China-specific standards protocols



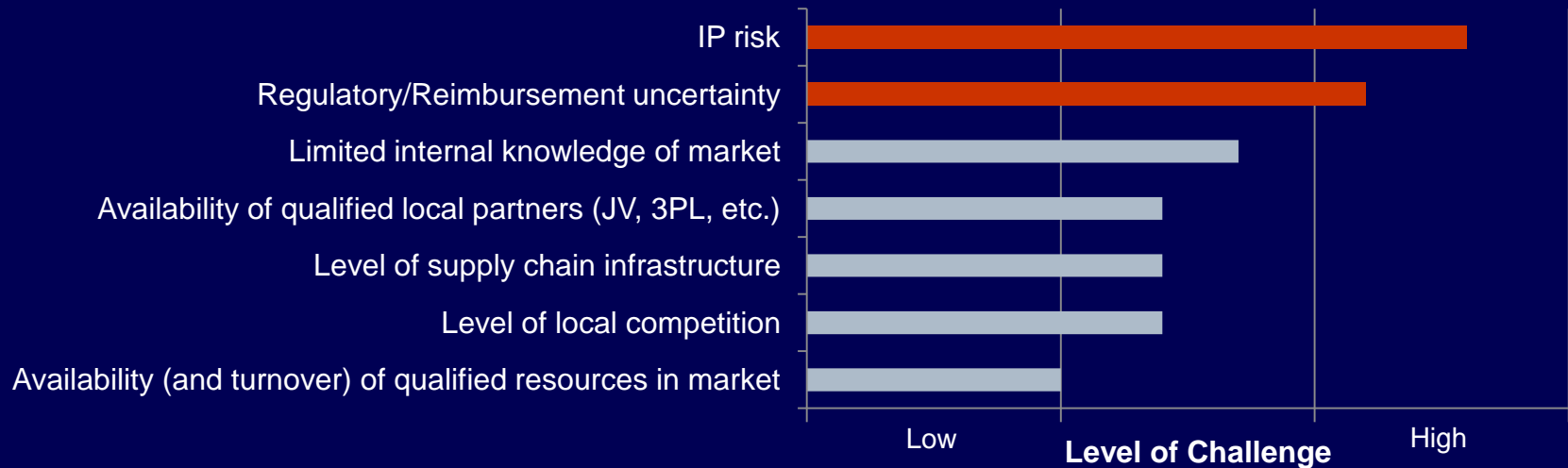
- 6.1% projected five-year CAGR for medical devices (significant slowdown from 27% CAGR in previous five years)
- Strong domestic production from MNCs and local competitors geared toward the local market, limited exports
- Distribution infrastructure struggling to keep pace with increasing access to health care outside of major cities
- Highly complex and changing regulatory environment (ANVISA)



- 15.6% projected five-year CAGR for medical devices
- Domestic production growth is surging to fulfill domestic demand—growing at 17% CAGR
- Infrastructure for manufacturing and R&D facilities is still in the early stages of implementation
- Uncertain, evolving regulatory environment
- Local distributors/agents play significant role as hospitals do not purchase direct from manufacturers

China Risks, Challenges, and Trends

IP risk and regulatory/reimbursement uncertainty present the greatest challenges in China



IP Risk

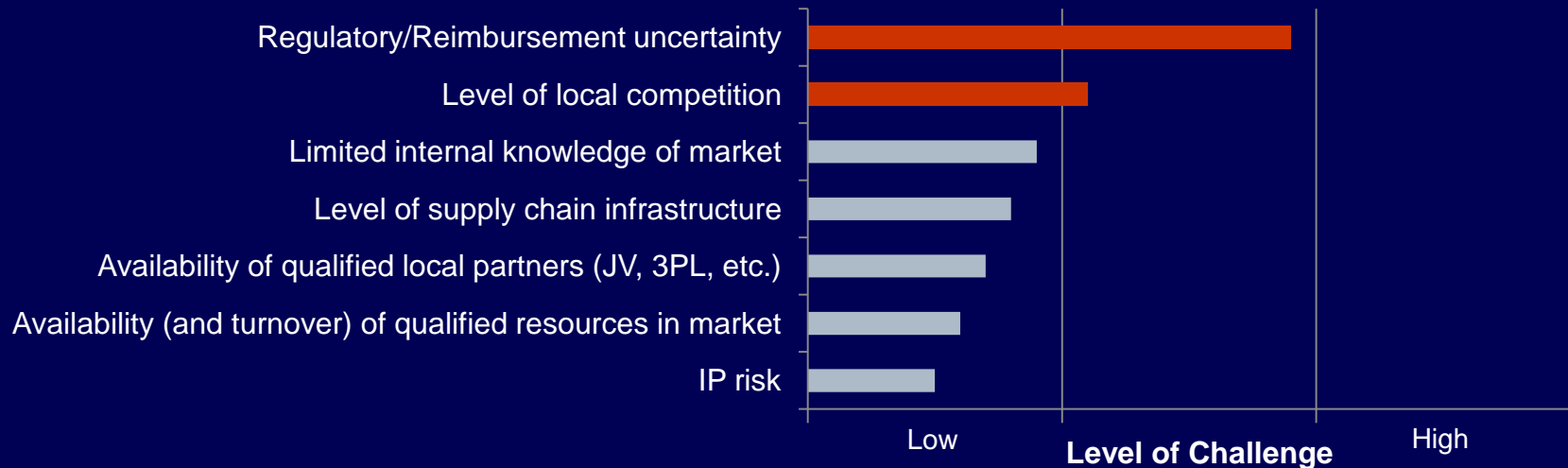
- Joining the WTO in 2001 led to initial improvements in supporting intellectual property rights
- Progress has been inconsistent and varies from region to region
- Securing government tenders will increasingly require IP development in China, not just manufacturing
- Recent changes to patent law will make patent litigation tougher to enforce

Regulatory/Reimbursement Uncertainty

- Inefficient regulation and registration processes create significant market entry barriers
- Opaque and complex tendering processes often raise suppliers' selling expense and cycle time
- Local suppliers can have significant influence on technical panel experts and decision makers in tendering process
- Pricing controls under consideration would negatively impact profitability of imported products

Brazil Risks, Challenges, and Trends

Regulatory/reimbursement uncertainty and local competition present the greatest challenges in Brazil



Regulatory/Reimbursement Uncertainty

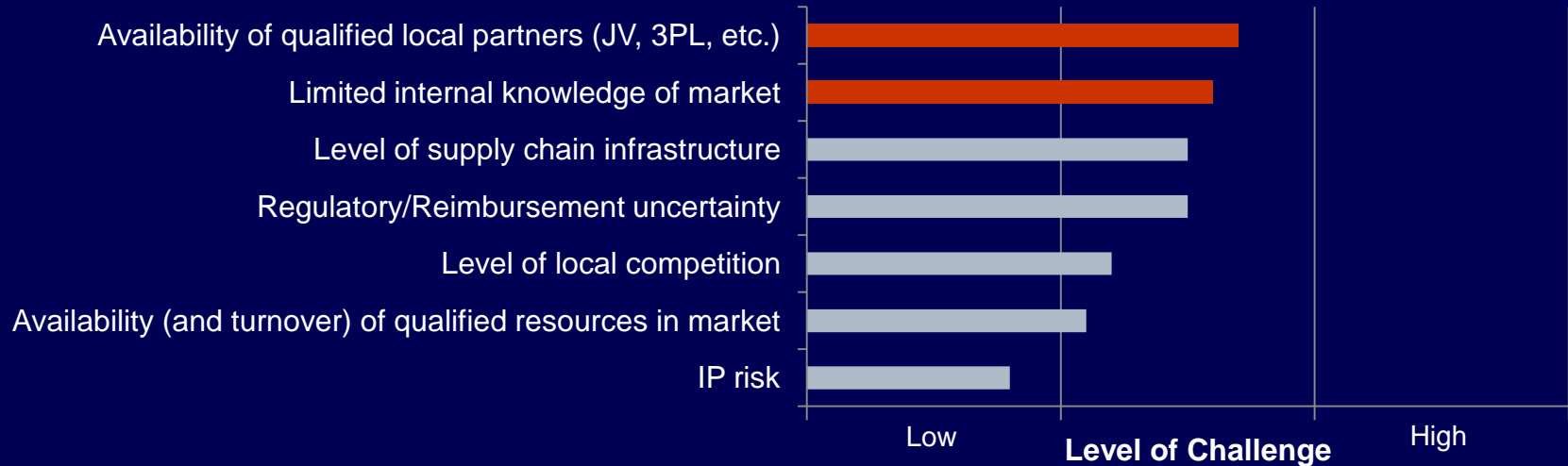
- MD companies doing business in Brazil must necessarily be well acquainted with ANVISA, Brazil's health surveillance agency
- Regulated medical devices must undergo a lengthy, and highly variable, registration and licensing process
- ANVISA known to implement disruptive regulatory change

Level of Local Competition

- Imports make up relatively low share of total MD market as compared to other emerging markets
- Strong local competitors, particularly in low-tech products (low cost, adequate quality, relationships)
- Challenging regulatory process for medical device importation
- Relatively high import tariffs and cumbersome customs system

India Risks, Challenges, and Trends

Availability of partners and S/C infrastructure present the greatest challenges in India



Availability of Qualified Local Partners

- Many major global device firms operate fully owned subsidiaries due to few local partnership options
- Some are choosing to create joint ventures with similarly large local players (GE/Wipro)
- Complexity of market often requires multiple distributor partners; most distributors lack full market reach
- Physician community perception of local companies is “low-cost and low-quality” products

Limited Internal Knowledge of Market

- Complex landscape with significant regional variations, 24 major languages, and multi-tier health care system
- Local expertise is essential to navigate changing registration, regulatory, tax environments, and also to find and manage local partners and distributors
- Hospital consolidation is on the rise but 80%+ hospitals are small (<30 beds), which challenges marketing, sales, and distribution

Conclusions

Emerging markets are an important growth area for medical device companies

- China, Brazil, and India are the primary areas of focus

The primary risks and challenges vary from market to market and present a complex playing field for supply chain executives

- Companies that lack a well-thought-out, proactive emerging market supply chain strategy are at risk of ending up with a sub-optimal supply chain that limits growth and profitability