

# ***Manufacturing in China – Policy Update on the Localization of Medical Products in China***

May 8, 2025

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### Practice Areas

➤ Life Sciences and Healthcare   ➤ Compliance   ➤ M&A   ➤ Private Equity

### Professional Experience

Mr. Zhou co-chairs the firm's life sciences and healthcare practice group.

In his nearly 20 years' practice, Mr. Zhou has represented numerous domestic and foreign manufacturers of pharmaceutical products, medical devices, cosmetics and other health products, biotech and biopharma companies, CXOs, goods and services suppliers, and strategic investors and financial investors dedicated in the life sciences and healthcare sector. His key clients include Roche, BD, Pfizer, Roche, Bracco, AmerisourceBergen, Tasly, Yunnan Baoyao, Bii Bio, YZJ Pharma Group, Shanghai Pharma Group, Yiling Pharma, Huawei, Tencent and Temasek. He repeatedly receives accolades and referrals from the clients. He is recommended lawyer in the Life Sciences sector by Legal 500 for many years.

Mr. Zhou regularly participates in seminars of life sciences topics, and gives many trainings to clients on topics such as legal issues in investment and M&A in life sciences sector, anti-corruption compliance and regulatory issues in human genetic resources.



## Impact of Geopolitical Shifts and Tensions

Medical Devices	Original Tariff Rates	Current Tariff Rates
Consumables	Over 50%	175-245%
Surgical Gloves	70%	195%
Syringes	120%	245%
Medical Equipment ( CT Scanner/MRI/CDFI etc.)	45%	170%

### Exemptions???

- The ongoing trade war has huge impact on supply chain and more...
- Economic security is national security
- Acceleration of internationalization and localization

## ► America First Policies

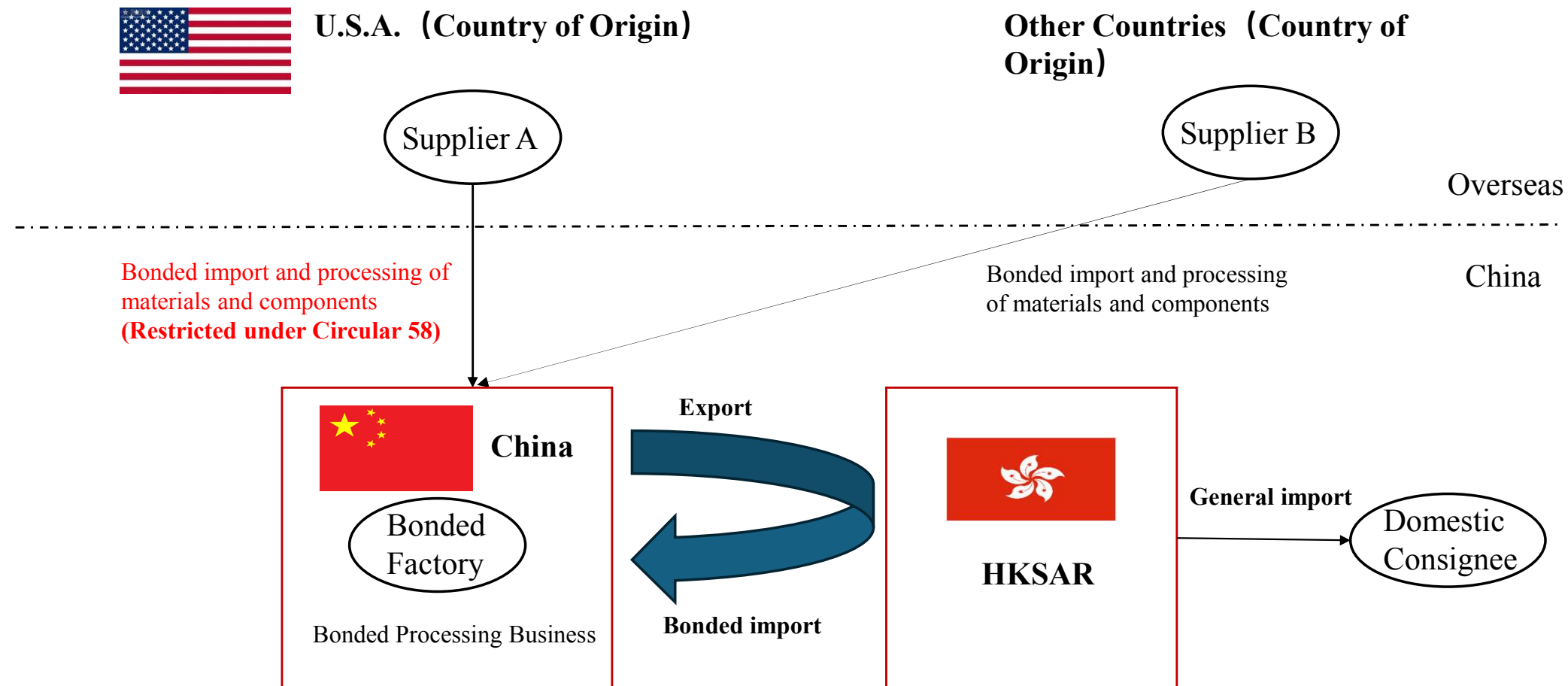
America First Trade Policy	America First Investment Policy
<b>Addressing Unfair and Imbalanced Trade Issues</b> <ul style="list-style-type: none"> <li>• trade deficit</li> <li>• anti-dumping and countervailing duties</li> <li>• Trade agreements</li> </ul>	<b>Encouraging Allies' Investment in the U.S.</b> <ul style="list-style-type: none"> <li>• Tiered treatment of foreign investors based on their relationship with adversarial countries</li> <li>• Creating "fast-track" processes for allies and partners</li> <li>• Accelerating environmental reviews for any investment exceeding \$10 billion</li> </ul>
<b>Economic and Trade Relationship with China</b> <ul style="list-style-type: none"> <li>• Economic and trade agreements</li> <li>• Section 301 investigation</li> <li>• <b>May cancel China's MFN status in 1984 US-PRC Income Tax Convention</b></li> </ul>	<b>Restricting Chinese Investment in the U.S.</b> <ul style="list-style-type: none"> <li>• Restricted investment sectors</li> <li>• Strengthening CFIUS review role</li> </ul>
<b>Other Economic Security Issues</b> <ul style="list-style-type: none"> <li>• Export control enforcement policy</li> <li>• ICTS review</li> <li>• Federal procurement plans</li> <li>• Illegal immigrants and fentanyl and other illicit drugs</li> </ul>	<b>Limiting U.S. Investment in China</b> <ul style="list-style-type: none"> <li>• Utilizing economic sanctions tools</li> <li>• <b>U.S. outbound investment restrictions (reverse CFIUS)</b></li> <li>• Using other audit, regulatory measures</li> <li>• Reviewing, suspending, or terminating tax agreements</li> </ul>

## ► China's Counter Measures

Category	Measures	Trump 1.0	Trump 2.0
<b>Tariff Measures</b>	Tariff hikes	√	√
	Retaliatory tariffs	×	√ (e.g. Circular 58 and “one day trip in HK”; soybean)
	Anti-dumping, countervailing, and safeguard measures	Not specifically implemented	√ (Targeting US medical device CT tubes for anti-dumping investigation/industry competitiveness investigation)
	Anti-circumvention measures	×	√ (Targeting US optical fibers for anti-circumvention)
<b>Non-Tariff Measures</b>	Quarantine measures	Not common	<b>More frequently used (soybeans, beef, etc.)</b>
	Export control	Gradually strengthened	<b>More frequently used (key materials, rare earths, etc.)</b>
	Anti-monopoly	×	√ (Nvidia, Google)
	Non-Reliable Entities List	Not used	More frequently used
	Services and Intellectual Property	×	Not yet implemented



## ► “One-Day Trip in Hong Kong”



## ► Market Access Policies for Local Manufacturing of Medical Devices

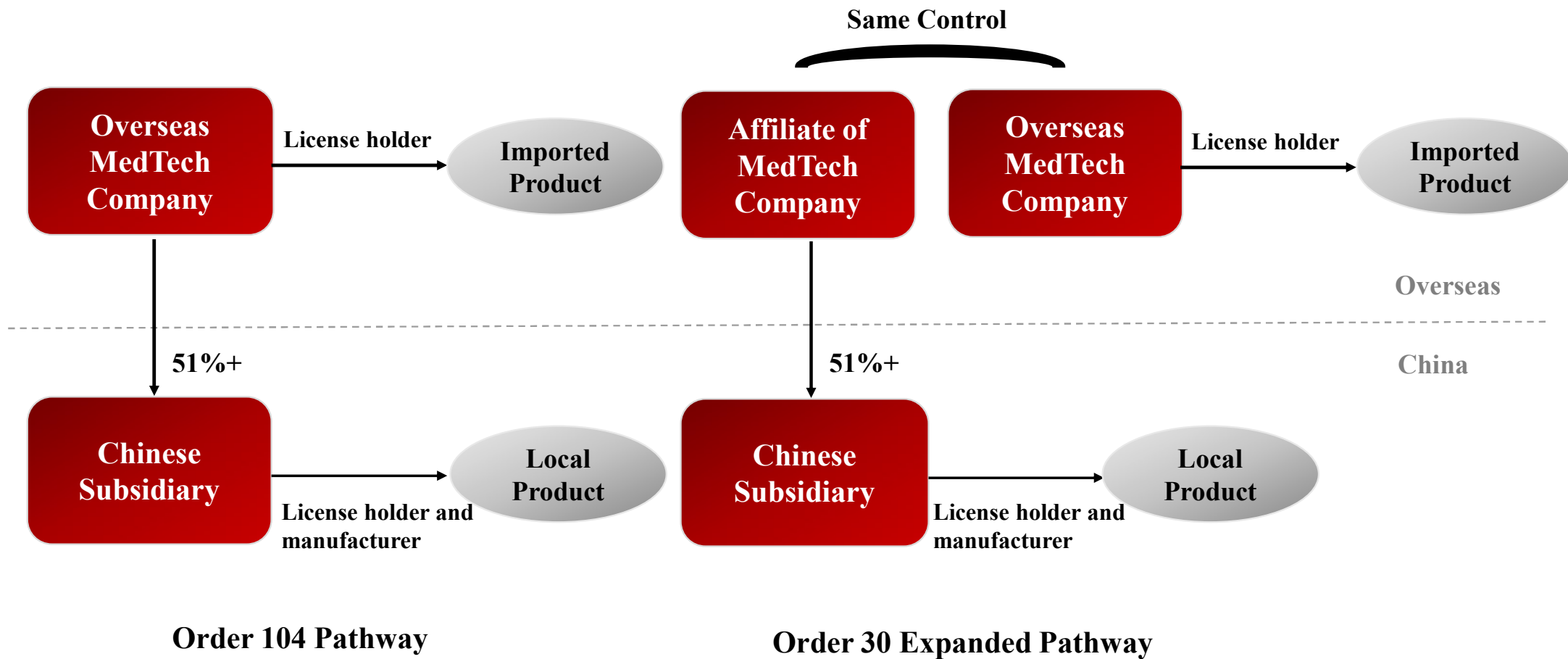
### NMPA Order 2020-104 (“Order 104”) pathway

- An abbreviated pathway for the localization of import Class II and Class III devices.
- Reduced time and cost due to simplified dossier requirements
- Key requirements under Order 104:
  - Domestic marketing authorization holder must be a subsidiary of foreign marketing authorization holder
  - Own manufacturing

### NMPA Order 2025-30 (“Order 30”) further expanded Order 104

- Eligible applicants cover both subsidiaries and affiliates
- GMP consistency only requires substantiative equivalence, rather than full equivalence
- Priority review pathway for innovative medical devices

## ► Market Access Policies for Local Manufacturing of Medical Devices



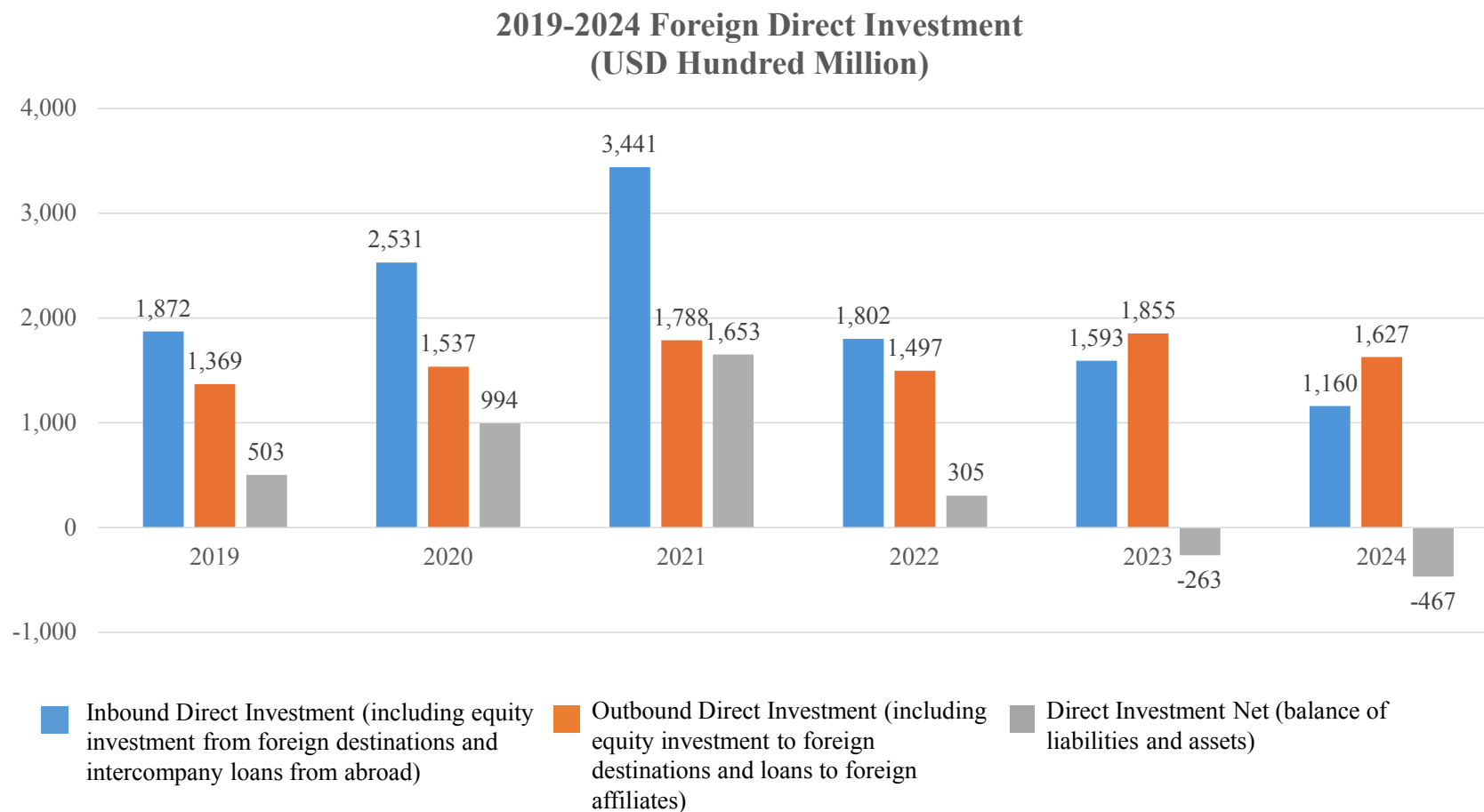


## ► Market Access Policies for Local Manufacturing of Medical Devices

### Successful Cases

Time	Applicant	Product	Notes
February 2024	Lumenis	Intense pulsed light and laser system (M22)	First localized Class III device in Shanghai
June 2023	Philips	Central monitoring software	First localized Class II device in Guangdong province
March 2021	Philips Goldway	Supersonic probe device	First localized Class II device in Shanghai

## ► Overall FDI Climate in China: Door is Wider



• \*Source: Balance of Payment Presentation issued by State Administration of Foreign Exchange and data issued by Ministry of Commerce

## ► Overall FDI Climate in China: Door is Wider

### Less Investment Restrictions

- All sectors are open except for those in the Negative List. Manufacturing sector has been fully opened up.
- The Negative List has become one of the shortest in all countries.
- Only 2 sectors related to life sciences and healthcare are in the Negative List, **with various exceptions:**
  - ✓ **Prohibited:** Development and application of human stem cell and gene diagnosis and treatment technologies
  - ✓ **Restricted:** Healthcare institutions such as hospitals are limited to joint ventures

### More De-regulations

- Unprecedented emphasis on fair competition
- Unprecedented emphasis on uniform domestic market
- **De-regulations in the life science and healthcare sector:**
  - ✓ Separation of marketing authorization and manufacturing
  - ✓ Trial use of HK/Macau commercialized medical products in Hainan Bo'ao and Greater Bay Area
  - ✓ Trial manufacturing of HK/Macau imported medical products in Greater Bay Area

## ► Public Procurement Policies and Their Role in Incentivizing Local Manufacturing



Public procurement in China prioritizes domestic products:

- Public sector must procure domestic products, unless it is necessary to procure imported products
- Procurement of imported products shall be subject to prior review and approval, unless “white listed”



Existing rules are ambiguous on the definition and interpretation of domestic products.



## ► Public Procurement Policies and Their Role in Incentivizing Local Manufacturing

**Recent draft rules by the Ministry of Finance clarify the criteria of “Domestic Products”**

### **Definition of “Domestic Products”**

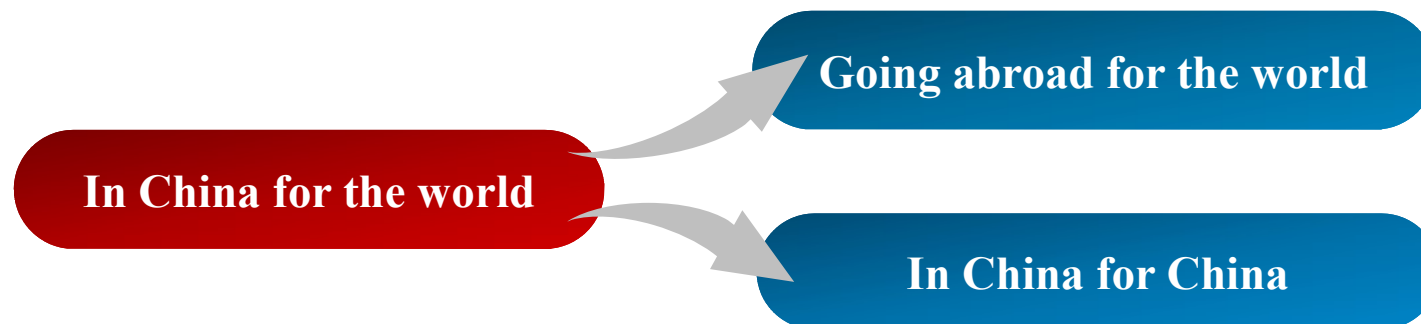
- Product is produced within the territory of China and achieves “change in characteristics”
- Domestic component cost ratio meets specified requirements
- Compliance with requirements for critical components and key processes of specific products

**Domestic products are eligible for 20% discount in price evaluation process**

### **What remains unclear**

- Where are we?
- definition of “domestic components”
- alignment with NRDL negotiation, centralized procurement and VBP policies

## ► Our Observation on Current Status and Next Steps on Localization in China



### **The drag and pull forces**

- Economic development
- Trade imbalances
- National security concerns

### **Our observations**

- Localization of manufacturing becomes more attractive for certain business and products, particularly for businesses which rely on government procurement.
- IP protection strategy becomes more and more important.
- ASEAN and China trade and investment relationship have great potential.



# Q & A



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