

BRANDWOOD : BIOMEDICAL

securing your compliance



China and You:

*Medical Devices & IVDs in the World's
Second Largest Economy*

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China: The Medical Device and IVD Landscape

- I want to export into China. What should I do?
- I want to import or use imported Chinese products. What do I need to know?
- I want to know about the Chinese market:
 - *How many Medical Devices and IVDs are registered in China?*
 - *What are the Market Drivers?*
 - *How Many Manufacturers?*
 - *How Many Distributors?*



China Facts

		Aust
Population:	1300M	(23M)
Number of Hospitals:	76,060	(1300)
Licensed Device Manufacturers:	13,530	(<200)
Licensed Device Distributors:	40,310	
Number of Domestic Devices Registered:	95,627	
Number of Foreign Devices Registered:	28,500	(123)

Mmmm... This represents less than 0.5% of the Chinese market...



China Facts: Price Comparison

	Australia	China
Medtronic Insync III Triple Chamber Pacemaker Model 8042	A\$12,480	A\$21,667
CYPHER Select Plus Sirolimus Eluting Coronary Stent	A\$3,450	A\$3,250
Medtronic Capsurefix Novus Model 5076 Pacing Lead	A\$1,248	A\$883



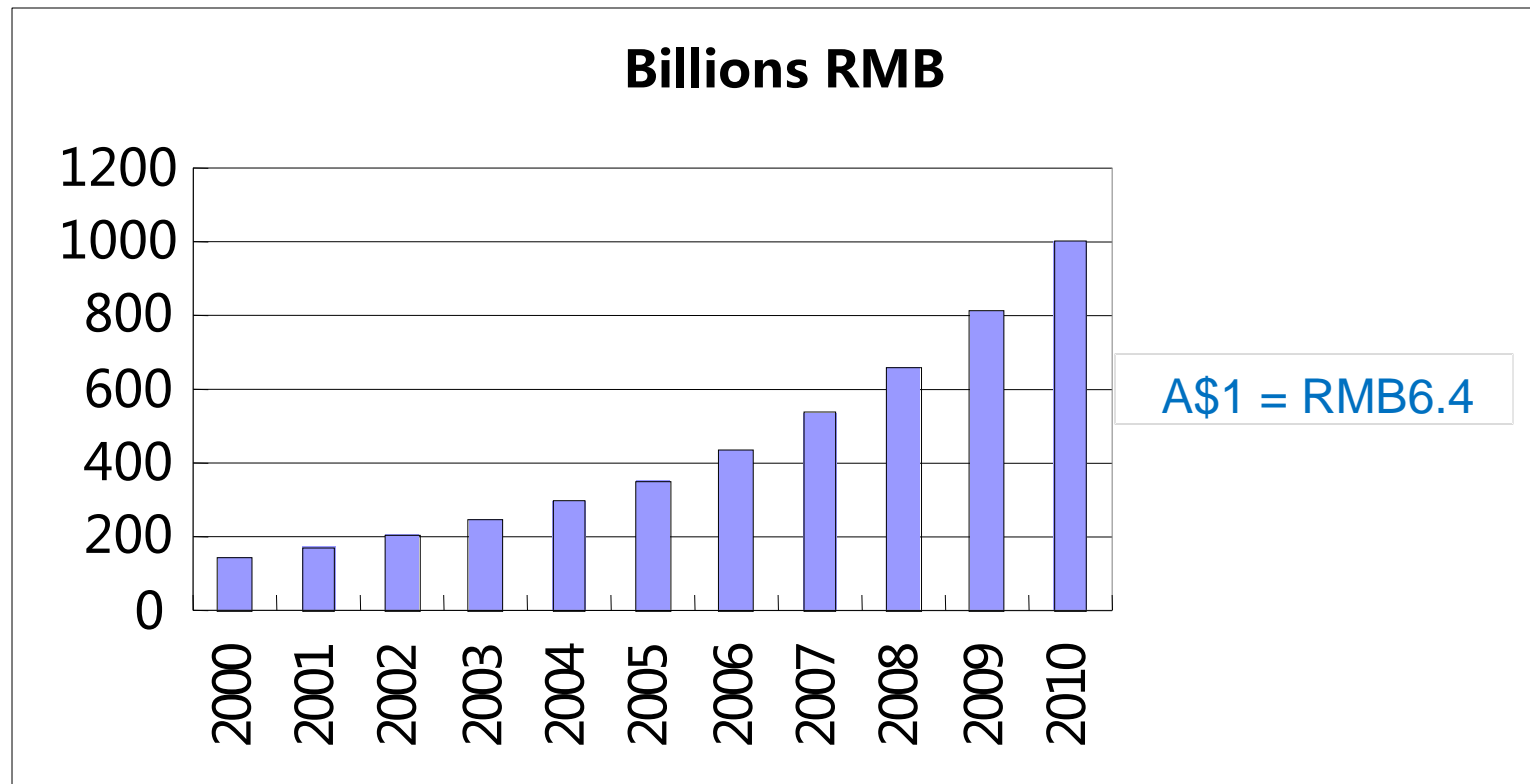
Market Size

Growth:

- 22% compound annual
- 6 times 2000 – 2009

Global Market Share

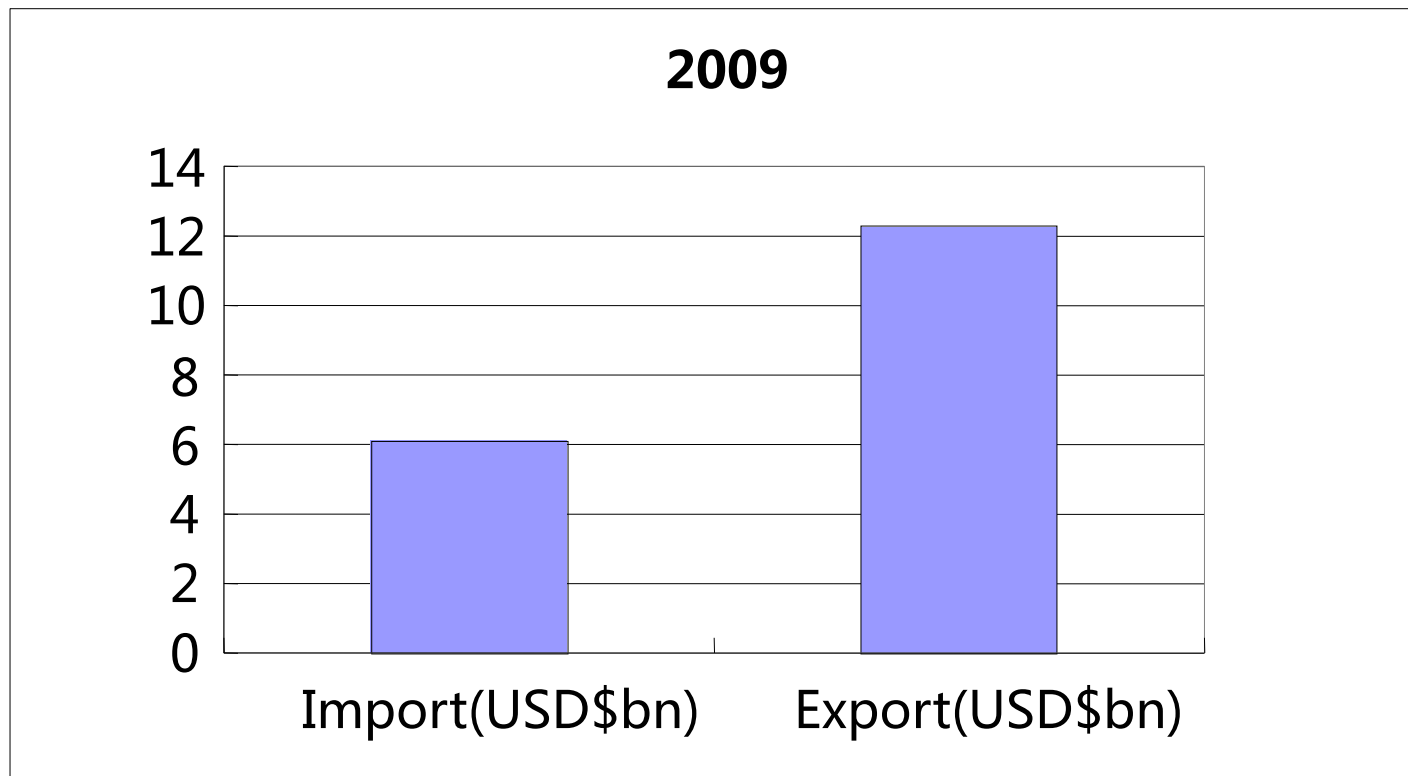
- 2009: 4%
- 2050: 25%



Import and Export of Medical Devices

Total I/E USD \$ 18.4 billion in 2009

- **Import \$6.1 billion up 17% from 2008**
- **Export \$12.3 billion up 11% from 2008**



National Healthcare Reform Plan

For Accessible and Affordable Medical Services

Additional USD123 billion government in healthcare over 3 years

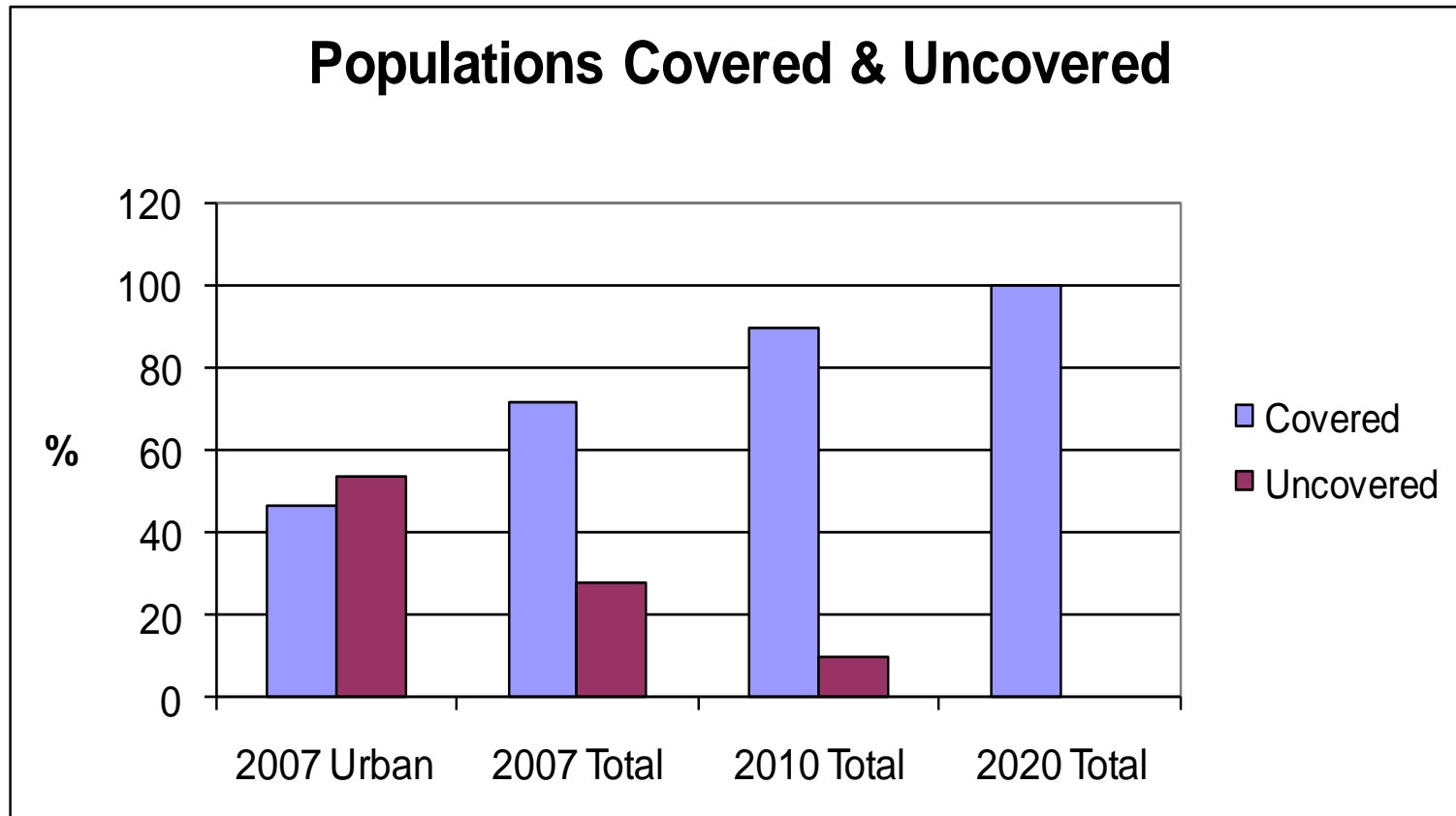
Five Goals:

1. Enhance Basic Medical Insurance coverage
2. Fund public hospitals, community healthcare centers
3. Establish National Basic Drug system, including medical device
4. Medical professionals to work in rural and community healthcare centers
5. Make public healthcare service equally available in urban and rural areas



National Healthcare Reform Plan

Medical Insurance coverage – above 90% by end 2010



National Healthcare Reform Plan

Fund public hospitals and community healthcare centers

- Increased expenditure to build infrastructure and purchase medical equipment.
- Increase of government spending on healthcare exceeds overall
- increased rate of government expenditure.

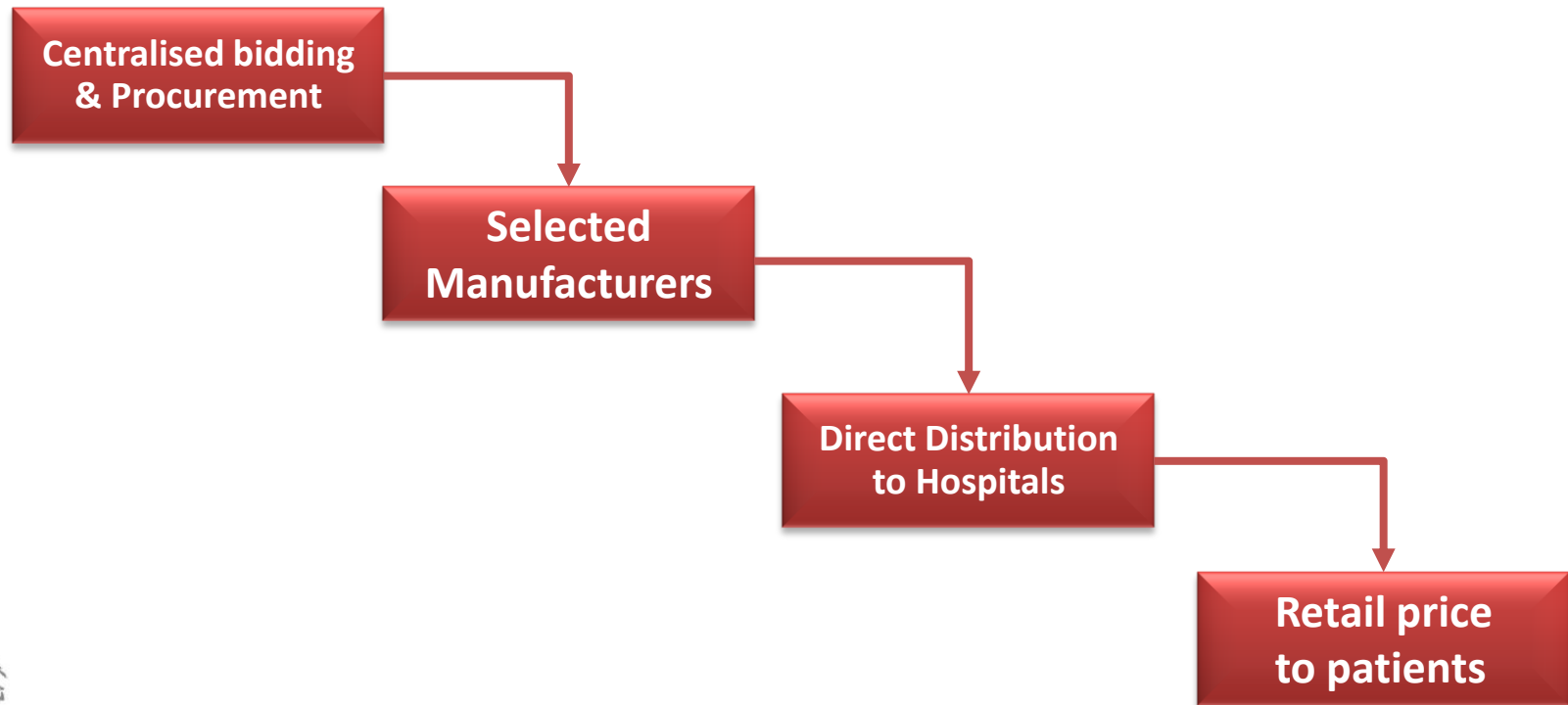
	1980	2006
Total HC Expenditure <i>(Billion RMB)</i>	14.3	984.3
Proportion from Govt Input	7.9%	5.1%

Target 22,000 Township Hospitals
300 County Hospitals
400 Chinese Traditional Medical Hospitals
950 Women & Child Hospitals



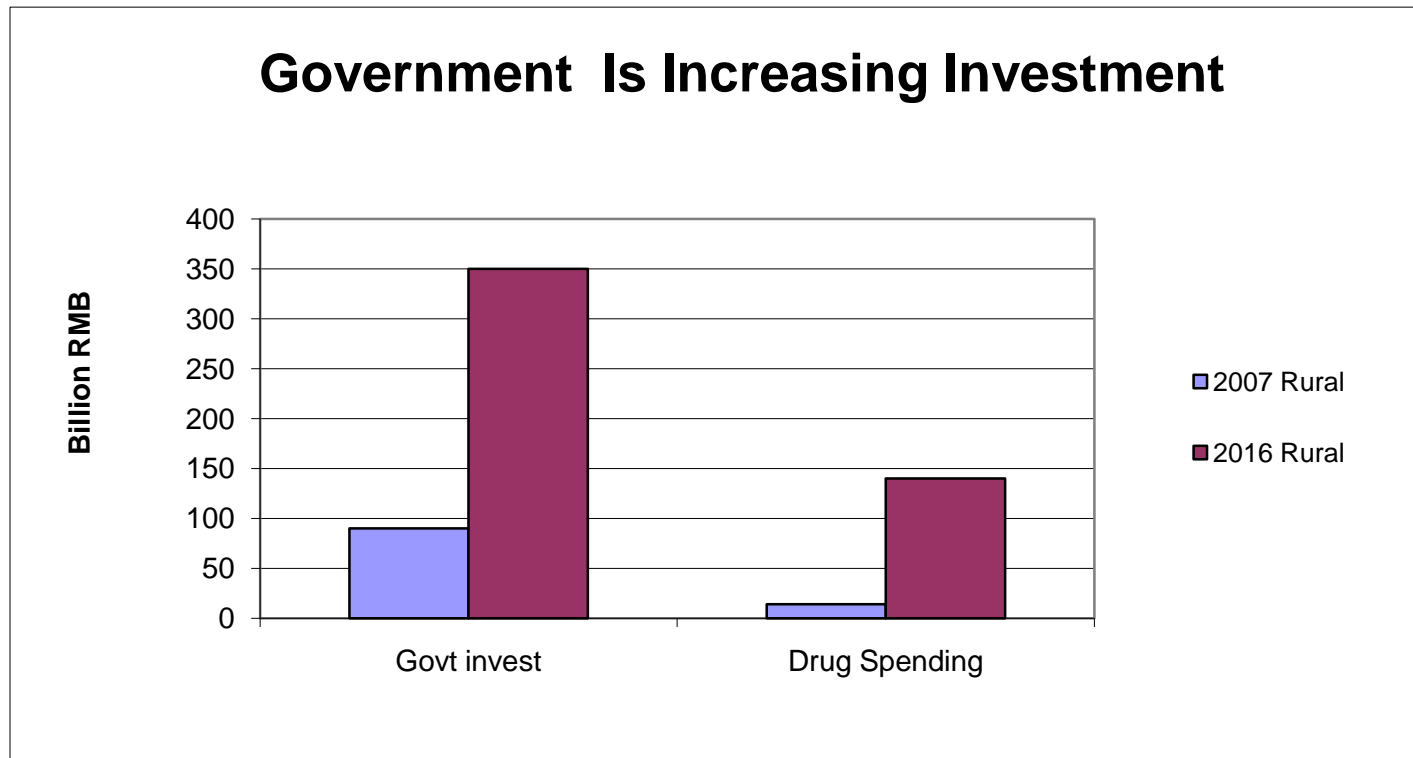
National Healthcare Reform Plan

Basic Drug and Medical Device System Covers 80% of Grass-Root Medical Institutions



National Healthcare Reform Plan

Make health care services equally available for urban and rural residents



Challenges:

- Centralized bidding, and contracted producers of basic drugs = Win Big / Lose Big
- Downwards retail price pressure
- Increased payment rates for professional services
 - e.g. fee for surgeon and nurses
- Decreased fees for automated services
 - e.g. diagnostic examination by CT scan
(Prices down, but volume up)



Healthcare Reform Plan:

Opportunities:

- Universal coverage will expand medical care demands of 1.3 billion consumers
- Achieving Reform Plan requires dramatic increase in government spending on medical products
- Encouraging private investment to build up for-profit hospitals will increase total HC expenditure

Conclusion:

Opportunities for medical device industry
far outweigh **Challenges**



Huge Market Growth Potential

- Healthcare expenditure as % GDP
 - China: 4.7%
 - Western average: 10%
- Market size as % of Global
 - 2010: 4%
 - 2050 forecast 25%
- 60+ demographic:
 - 2020 16%
 - 2050 25% (0.4 billion)
- Revenue of Medical Devices vs Pharma
 - China: 1:5.0
 - Global average 1:1.9

Economy growing fast and relatively steadily
Healthcare expenditure grows faster than economy



Pathways to Success for Australian Companies

The combination of

- **Market Size**
- **Healthcare expansion; state and private**
- **Manufacturer Base**

results in opportunities for

- **Export to China**
- **Import from China**



Pathways to Success for Australian Exporters

What are the best registration, manufacturing and distribution options ?

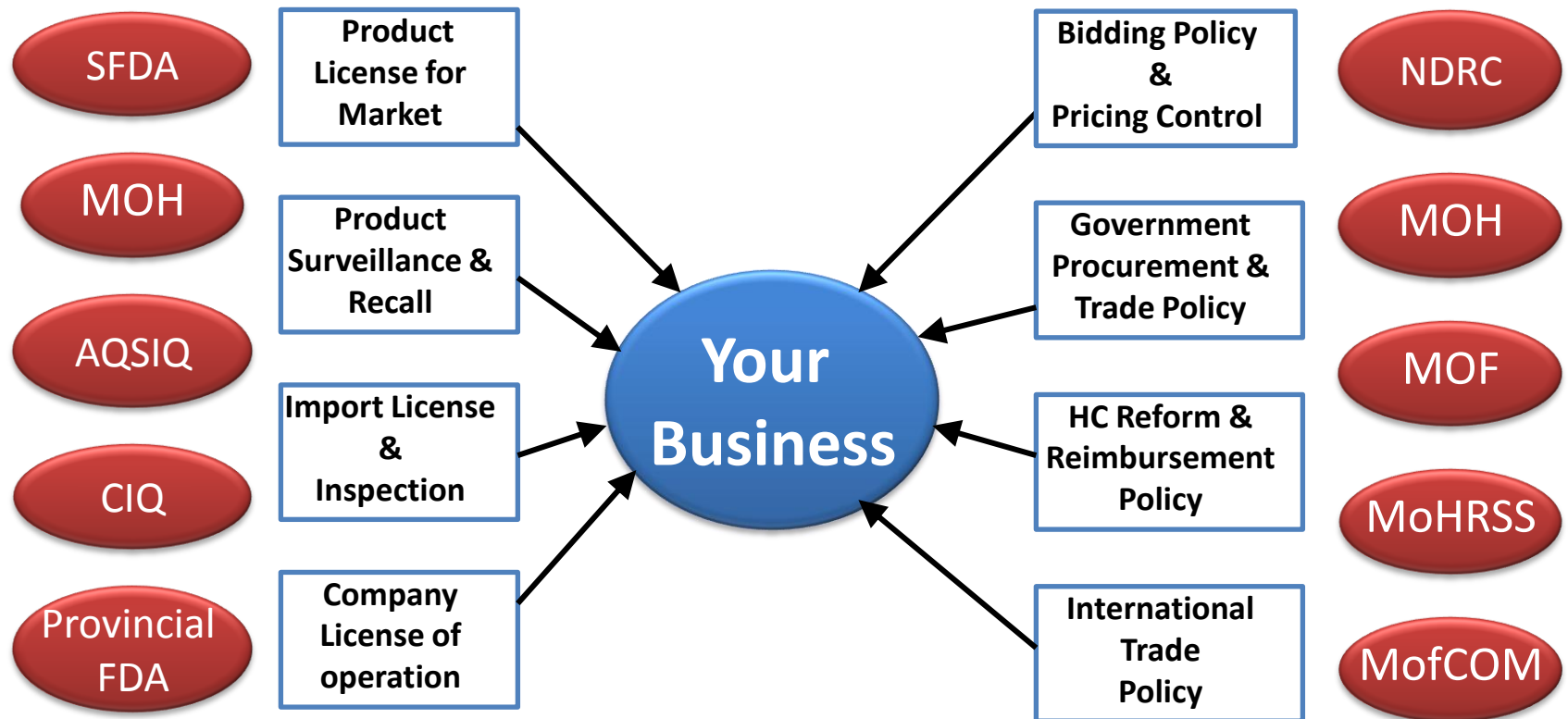
- Is it possible to succeed in China?
- Is everything cheaper in China than elsewhere?
- Should I manufacture in China?
- What is the regulatory environment?
- Is there risk to my IP?
- What is the pathway to succeed as an exporter to China?
Agent → Rep office → Joint Venture → WFOE → Direct Sales?
- What to do first?



Regulatory Environment in China

Product Regulators

Business Regulators



Medical Products strictly controlled by government
Healthcare sector is centrally administered by government



Different Type of Licenses to Do Business

Registration
Certificates of
Import
Medical
Devices

China
Compulsory
Certification

License for
Distributor of
Selling Medical
Device

License of
Purchasing
Large Med
Equipment

License of
Importation

Certificate of
Import
Inspection

Radiation
work Permit



General Process to get SFDA registration

Registration Product Standard

Type test by SFDA authorized test house

Clinical trial or evaluation

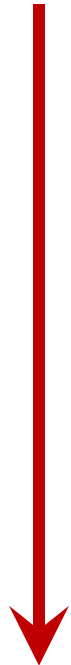
Submission to SFDA

SFDA Tech review

SFDA Admin Approval
(Validity for 4 years)

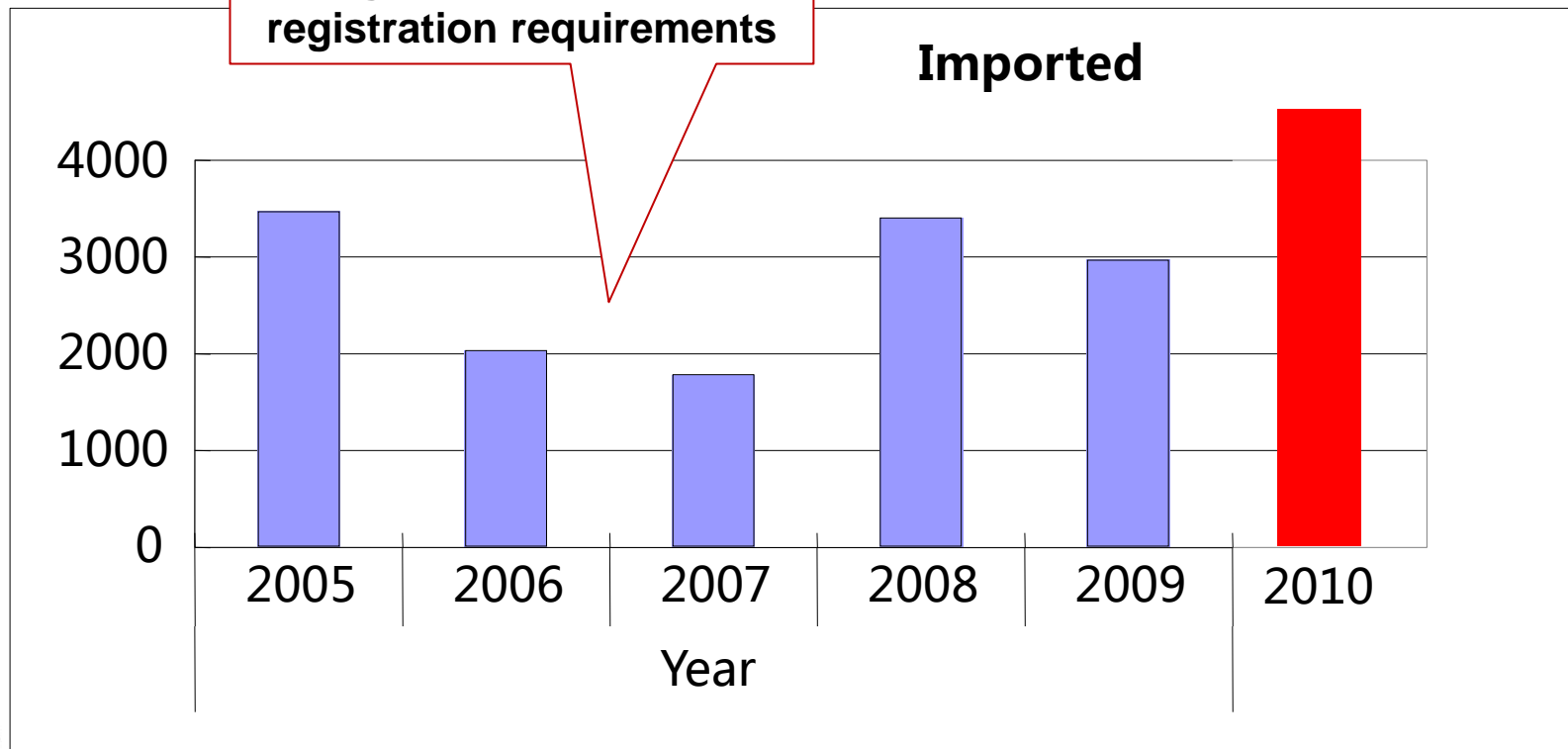
**Approx. 9
months to
finish the
process

(Can take
much longer if
not done right)**



Registrations are complex, but **achievable**

**Note: Decrease in 2006/7
caused by major delays
during introduction of new
registration requirements**



Exporting to China

Pathways to Success

Consider strategies for “Go To China”

- Export finished products?
- Local China manufacture, with opportunity for lower cost / easier registration pathway?
 - *what activities of local manufacture are sufficient to label “Made in China”?*
- The right distribution partner



Exporting to China

Pathways to Success

Finding a trustworthy Chinese Partner

- **Compliance**
- **Financial Stability**
- **Supplies on time / in full**
- **Understands my needs**



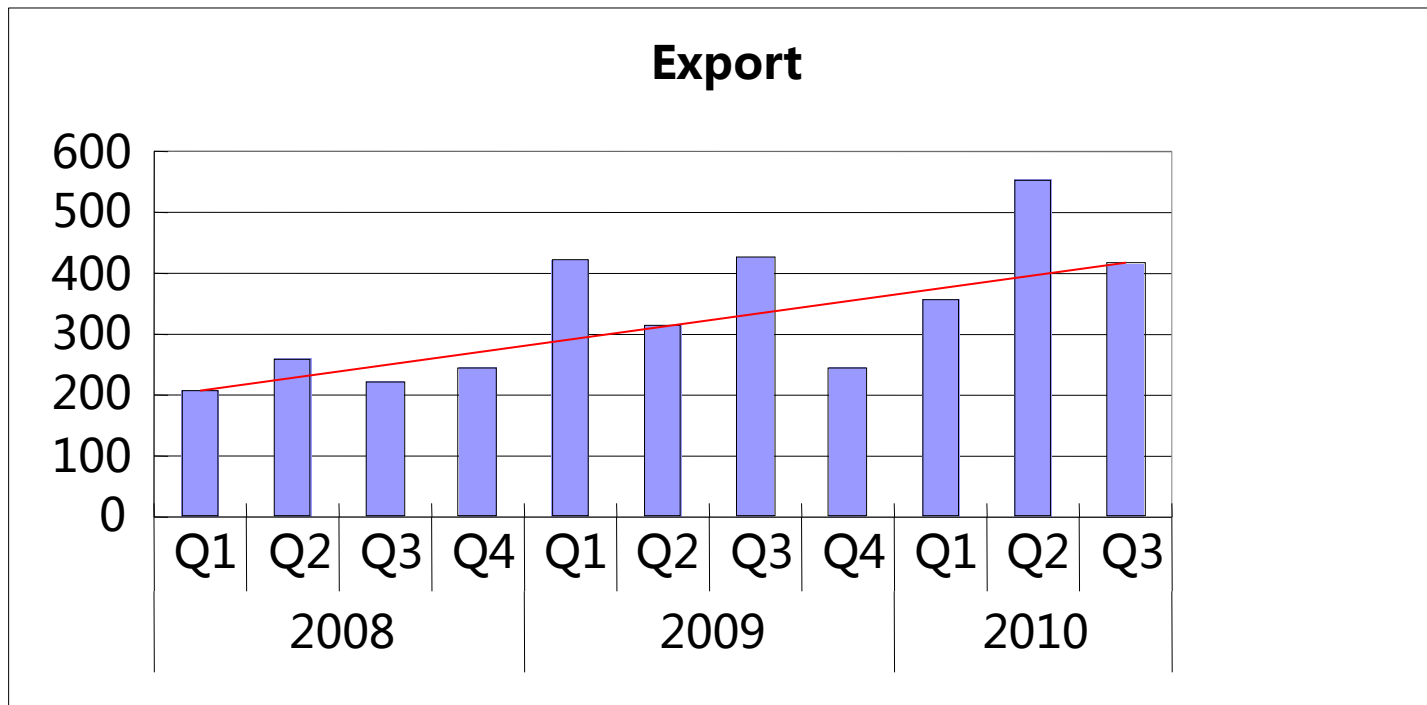
Importing from China

Pathways to Success

China Government is Encouraging Export

Strong Increase of Export Certificates Issued by China SFDA

- **14%** Increase in first 3 Quarters of 2010 vs 2009
- **92%** increase in first 3 Quaters of 2010 vs 2008



Importing from China

Pathways to Success

What questions to ask when choosing and qualifying Chinese suppliers and partners?

How to be sure that the answers are valid?



Importing from China

Pathways to Success

Leading foreign companies:

- Include China in their potential sourcing countries
- Research and consider strategies for importing from China
- Obtain expertise to identify reliable and capable vendors



Pathways to Success

Don't be scared!

You don't have to know everything about China. Instead, you need to have the right partners with:

- thorough technical knowledge of the regulatory pathways
- effective contacts with government officials
- excellent industry networks including manufacturers and distributors
- ability to integrate all of this into effective strategy
- able to execute on your behalf



Pathways to Success

Only companies with vision and expertise will maximize success with:

- Import and Export opportunities opened
- Partnerships established and nurtured
- Timely market access
- Sustainable, profitable growth

You need a partner with skills and representation in China and Australia to make this happen.



Thank You!

