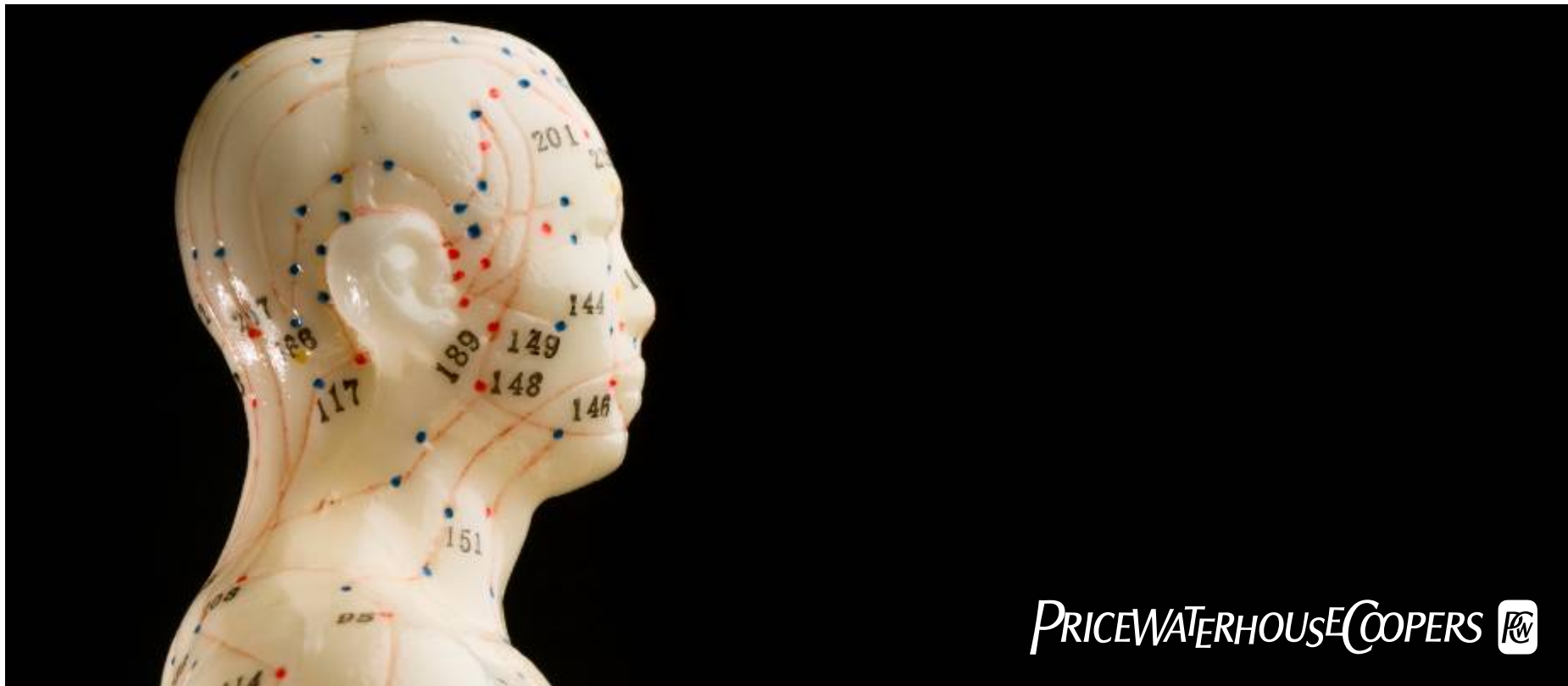


Industries  
Pharmaceutical

# Investing in China's Pharmaceutical Industry – 2nd Edition



# Executive Summary

## Introduction

The topics discussed in this edition:

- Traditional Chinese medicine
- OTC market
- Medical devices
- Contract research organizations (CRO)
- Contract manufacturing organizations (CMO)
- R&D
- Tax incentives
- Sales and marketing
- Drug prices
- Distribution system
- Intellectual property protection
- Mergers & Acquisitions
- Capital markets and financial reporting

Under the backdrop of continuous Chinese healthcare reform plan, the topics today will likely have another spin in the years to come.

# Traditional Chinese Medicine, The Origin of Modern Medicine

## The market

- In value terms, 2007 sales revenue for TCM products accounting for 40% of the total China pharmaceutical market, reaching at US\$21 billion
- By volume, TCM 2/3 of total China drug sales
- In forecast, TCM sales will reach US\$28 billion by 2010
- The top 10 formulated TCM companies represents 14% of the total market
- Chinese patients tend to opt for TCM unless they are certain of the causes of ailment and are seeking quick relief

## The trend

- Set as a strategic priority by the government, export potential has been underscored
  - Introduction of patent right
  - Modern application of TCM-related products

## The Challenges

- Inconsistencies in the manufacturing process → GMP reinforcement in 2007 → Jan 2008 only 300+ (one-third) manufacturers met the revised GMP guidelines
- Potential exhaustion of herbal or animal resources
- Lack of product innovation
- Low Intellectual Property Protection awareness

# East Meets West In the OTC Market

## The market

- Valued at US\$7.45 billion in 2007, it accounts for 22% of the China's overall pharmaceutical market (excl. TCM)
- It is forecast to reach US\$21.49 billion by 2012

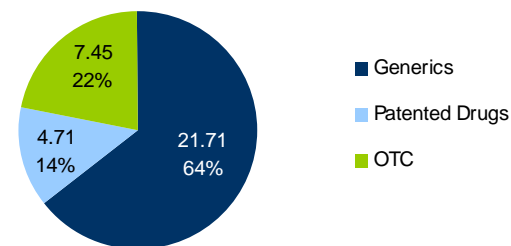
## The trend

- More fierce competition posed by global players breaking into the market
- Continuous expansion plan of larger players through mergers and acquisitions

## The challenge

- Low profitability, for smaller manufacturers in particular
- Fragmented distribution channel

China's Pharmaceutical Market (excl. TCM), 2007  
(in US\$ billion)



Source: Business Monitor International

# Medical Devices – A Market of Opportunities

## The Market

- A double-digit growth
- Both multinationals and domestic companies
- Well established major multinationals (i.e. Siemens and GE) in the China market dominate the high-tech segments
- Highly fragmented
- Lacking in major domestic players resulted in strong growth in imported medical devices at a CAGR of 18.4% from 2000 to 2007, reaching US\$4.3 billion

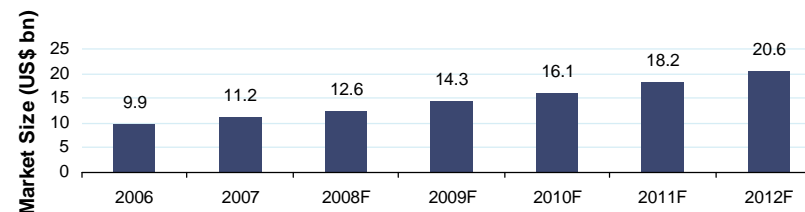
## The trend

- Growing attempts to reinforce the regulations on quality standards and pricing
- Domestic players beginning to catch up in the high-tech sector
- Export continues to grow with an increasing number of domestic companies (including MNCs' China-based subsidiaries) manufacturing for overseas markets
- Old devices to be replaced by new ones (75% currently used were made prior to 1980)

## The Challenges

- Intellectual property infringement
- Quality and safety control
- Regulatory instability

China Medical Devices Market Size (US\$ bn)



Source: Business Monitor International

# Contract Research Organizations – Benefit From Pharma Moving Up the Value Chain

## Today at a glance

- 298 registered Chinese-based clinical trials in 2007, a year-on-year growth of 41%
- Rapid development in biotech capability
- Movement towards genomics and gene therapy
- Increasing ability to meet western standards in drug quality and safety

## An outsourced destination in the future

- Despite the proportionally small base of 1% of the total global CRO revenue, China's attractiveness attributable to:
  - Cost and time savings, suggestively 50%
  - Talent pool
  - Patient pool
  - Animal resources
  - Rapid economic development

# Contract Research Organizations – Benefit from Pharma Moving Up the Value Chain (con't)

## The Challenges

- The lack of enforcement of IP laws
- The difficulties in recruiting experienced talent for project management as well as in retaining them
- Largely fragmented

## The Trend

- Emergence of one-stop service provider, offering services from drug discovery to registration and marketing
- Expansion via mergers, acquisitions or strategic partnerships with other domestic peers and international players
- Growing number of IPOs
- Establishment of foothold in China by multinationals

# Contract Manufacturing Organizations – Going Strong

## The Market

- In 2007, the export value of Chinese pharmaceutical contract manufacturers reached US\$453 million, with an annual growth rate of 23%
- Reinforced GMP regulations, the development of which is based on concepts similar to US GMP, with an ongoing effort to increase inspections on already-certified sites

## The Trend

- The authority continues its efforts in lifting the GMP standards to encourage multinationals
- Chinese CMOs are expecting an increasing number of orders from large pharmaceutical companies who are incentivised by China's appealing cost advantage, market opportunity, ever improving GMP standards, and tighter control on IP laws

## The Challenges

- Intellectual property protection

# An Innovation-Oriented Country Through R&D

## The Market

- Ranked #3 in 2006 worldwide on R&D expenditure, trailing US and Japan
- Between 2000 and 2007, China's R&D expenditure grew at an annual rate of 26.5%
- The ratio of R&D/GDP increased to 1.49% in 2007 (2.66% in US), a 66% increase over that in 2000
- A growing number of multinationals setting up and/or relocating their R&D centres in China

## The Trend

- Greater importance attached to R&D by domestic companies
- Multinationals continue to pump investment in its R&D establishment, incentivised by a number of key advantages China offers:
  - Cost advantage
  - Talent resources
  - Patient pool
  - Pharmaceutical and biotech clusters: biotech zones
  - Government incentive programmes

# Tax Incentives for Building a World R&D Base

Shifting China from world's factory to a world R&D base, a series of incentive programmes are issued to encourage R&D activities:

- High/New Technology Enterprise (HNTE) incentive
  - For qualified HNTEs, reduced CIT rate of 15%
  - For newly established HNTEs in the Five Special Economic Zones and Shanghai's Pudong New Area, tax holiday of 2 years' full exemption followed by 3 years of 50% reduction in CIT
- CIT super-deduction of 50% extra for eligible R&D costs
- Income tax exemption for the transfer of technology

# Navigating the Risks of Bribery and Corruption in Sales & Marketing

In line with the global intensified grip, China has made some efforts

- Clearly defined anti-bribery and corruption legislation

Despite the regulatory efforts, risks are still persistent in the M&A domain

- Associated risks of assuming liability for the target company's illegal practices
- Sales via improper methods may affect the value of legitimate sales and alter the post-acquisition landscape

Some critical measures for maintaining compliance

- Adequate design and maintenance function in the anti-bribery and corruption control framework
- Good documentation and record-keeping practices
- Adequate staff training
- Inspection of distributors, sales representatives and investment

# Cutting Drug Prices: Whom Does it Help?

Progressive imposing cuts on drug prices, to cap the retail selling price of 2,400 types of drugs

However drug prices still not under control, as:

- Distribution system being congested with middlemen
- Heavy reliant on drug sales as a result of inadequate government funding on hospitals
- Hospitals' intention of purchasing more expensive drugs incentivised by 15% mark up policy

Consequences of the price cut policies

- Hospitals and retailers switching to alternatives
- Conflicts among various stakeholders

In response, government's further attempts in the near term

- Price ceiling on all prescription drugs throughout the distribution channel, piloting in Guangdong
- "Fixed-price increase" so that the hospitals will earn a fixed and independent service fee for each prescription
- Discussions on eliminating the preferential pricing for "innovative drug"

# Risks and Challenges of a Complex Distribution System

## The current situation

- US\$44 billion distribution market, 20% of which are dominated by the top 3 distributors
- Highly competitive with 7,000+ distributors, 80% of which are small scale operators
- A declining net profit of 0.5% on average for distributors

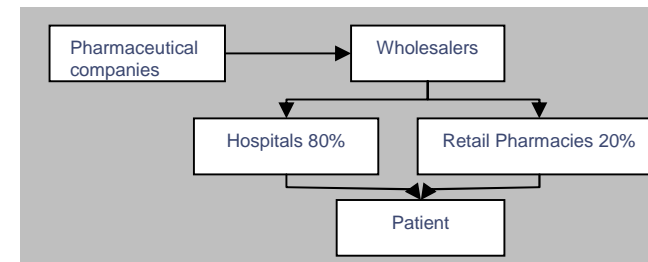
## The challenges

- Lack of scalability among small distributors
- Lack in key infrastructure and logistical expertise
- Lack of comprehensive product tracking and monitoring system
- Vulnerability to counterfeit products
- Risk of interruption of the cold chain due to the multi-layer system

## Regulatory attempts

- GSP standards issuance since 2001
- Urge for consolidation resulting in the reduction in number of distributors in half
- Open policy in 2003 for foreign distributors to operate in China by forming JV

China Distribution Channels Overview



Source: Business Monitor International

# Intellectual Property Protection: Is It Getting Better?

The answer is “Yes” – encouraging signs

- Increasing number of domestic companies filed for law suits against both domestic and foreign infringers, outnumbering US since 2005
- Chinese Patent Law underwent 3<sup>rd</sup> amendment and will be put into force 1<sup>st</sup> Oct. 2009. The major amendments are:
  - “*First-to-file*” to be replaced by “*absolute novelty*”
  - Monetary penalties increased from *three times* the lost profits of the patent holder or three times the benefit gained by the infringer to *four times*
  - In the absence of clear definition of the loss, a default threshold increased from *RMB500,000* to *RMB1 million*
- The efforts were acknowledged by half of the multinationals as “quite optimistic” and by some “very optimistic”

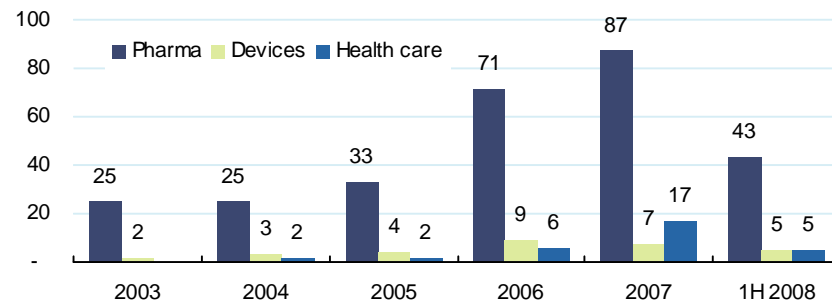
# The Pharma Sector: A Front Runner in Consolidation

## Attractiveness of China's pharma sector to mergers and acquisitions

- Increasing demand for medicines and healthcare services as a result of the healthcare reform initiation on rural areas of 600 million in population
- The 11<sup>th</sup> Five-Year plan encourages investment from both foreign and private investors to the state-dominated sector
- Stricter enforcement of certifications and IP rights have made those that are unable to meet the requirement easy targets
- Drug pricing policy has made some medium-small companies financially inadequate therefore vulnerable to mergers and acquisitions

Pharmaceutical sector remains the largest for M&A deals over medical devices and healthcare

China M&A Deal Volume by Segment



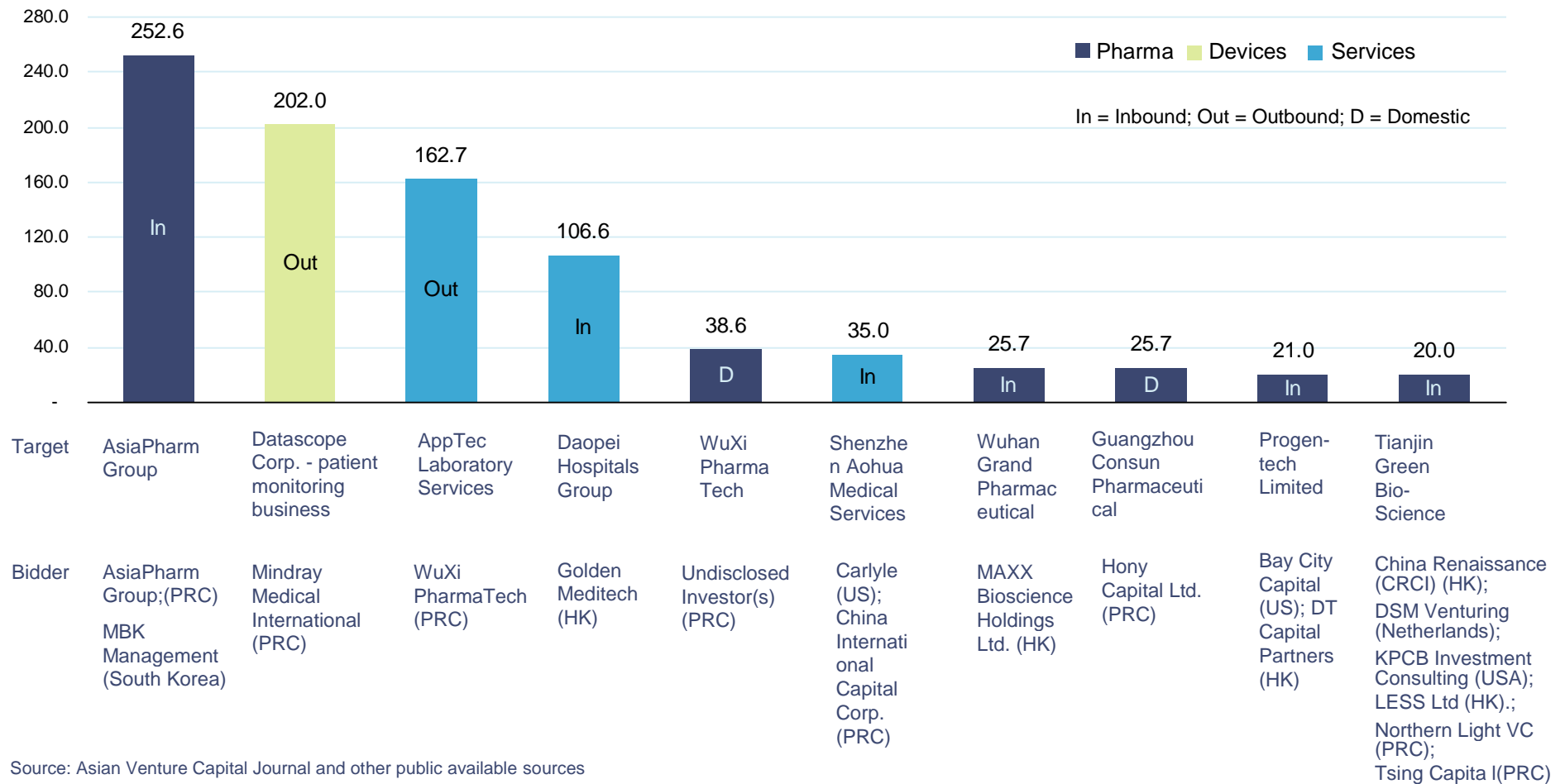
US\$1.5 billion value of deals was recorded in the pharmaceutical sector in 2007

Source: Asian Venture Capital

# The Pharma Sector: A Front Runner in Consolidation (con't)

## Top Ten Deals in 2008

\$ million

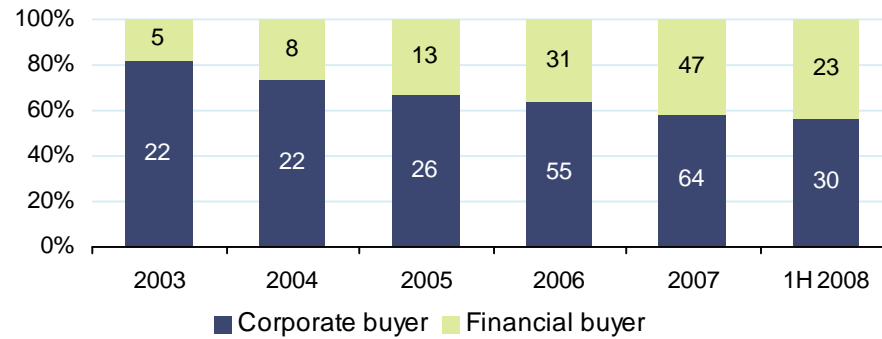


Source: Asian Venture Capital Journal and other public available sources

# The Pharma Sector: A Front Runner in Consolidation (con't)

Private equity and venture capital companies are the major funding sources

China M&A Deal Volume by Investor



Source: Asian Venture Capital

# Capital Markets and Financial Reporting: What to Consider?

Most private companies in China:

- Keep their accounting records on a cash basis for tax purposes
- Many transactions are unrecorded and undisclosed

Implications to consider by the investors

- Ongoing monitoring of the performance and prospects of the investment
- Accounting for the investment
- Planning for the ultimate exit strategy

# Looking Forward

China's healthcare reform will change the current landscape

- Expanding the basic medical insurance programmes to enroll more than 90% of the urban and rural residents
- Establishing a national drug system for essential drug selection, production and supply, clinical applications and medical insurance reimbursement
- Building a competent primary care service infrastructure
- Enhancing equal access to basic public health services by urban and rural residents
- Moving public hospital reform forward, which includes the reform of the funding of hospitals

Despite the challenges, the rewards of cost benefits and a double-digit growth thriving market are continuous and consistent drivers for investment in China's pharmaceutical industry

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# Questions & Answers

# Thank you!