



BELGIAN-CHINESE  
CHAMBER OF COMMERCE  
比中经贸委员会

# Life Science Regulations and Opportunities in China

Bart Horsten  
22 February 2024

***Cisema***



**HORSTEN**  
International  
豪斯顿国际有限公司

# Life Science Regulations and Opportunities in China

## 22 February 2024

### Agenda:

**10:30-10:35:** Opening words by Mr. Bart Horsten, Board Member of the BCECC

**10:35-10:50:** Mr. Bart Horsten (HORSTEN International): “Introduction China healthcare market”

**10:50-11:40:** Ms. Victoria Caldý (CISEMA): “Developing a successful China regulatory strategy”

**11:40-11:55:** Company testimonial by Mr. Nicolas Deleye (FLEN HEALTH), Director International Business Development

**11:55-12:10:** Q&A session

**12:10-12:15:** Closing remarks



# Upcoming events

- **27 February:** Webinar “How to avoid common IP mistakes when doing business in China”
- **5 March:** Webinar “Ferdinand Verbiest and the discovery of China”
- **12 March:** Webinar “The 4th China International Consumer Products Expo (CICPE): Opportunities for your business”
- **Starting on 12 March:** Webinars “Online Business Chinese language courses”
- **26 March:** ChinaCareers Event



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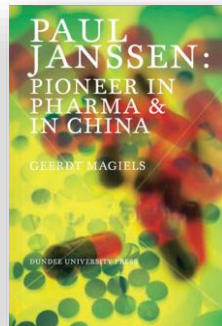
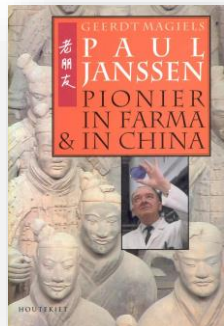
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Bart Horsten

- China Entrepreneur and Consultant since 1998, focusing on assisting European SMEs and Scale-ups in doing business in China.
- Board Member of **Belgian-Chinese Chamber of Commerce (BCECC)**
- Managing Director of **HORSTEN International**, offering China consulting services to European SMEs
- Founding Partner of **MyChinaWeb**, providing China digital marketing services
- Shareholder and Board member of several China/Hong Kong ventures
- Regular speaker at China seminars and workshops and guest lecturer at Universities and Management Schools



1979: first negotiations



Xi'an Janssen, one of the first joint ventures in China, set up in 1985



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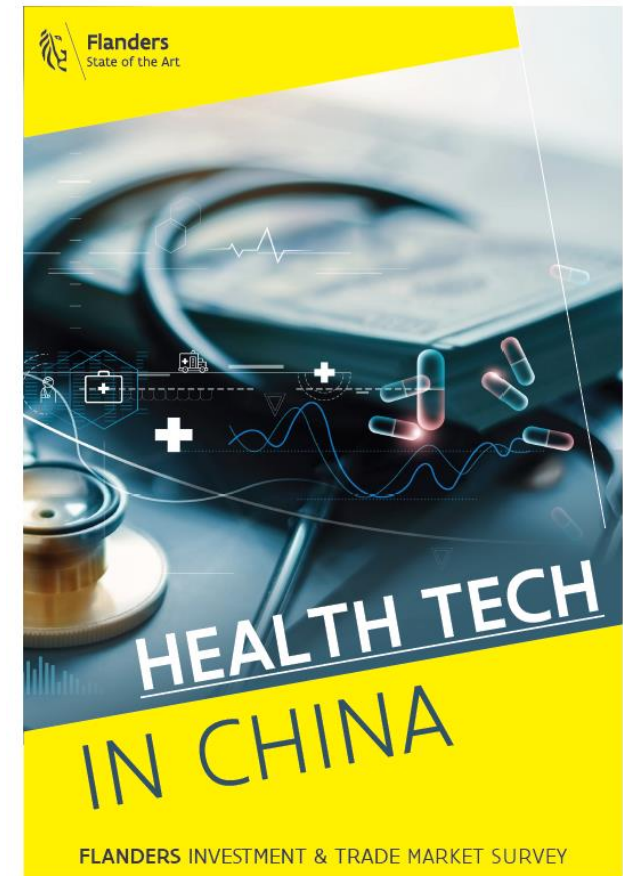
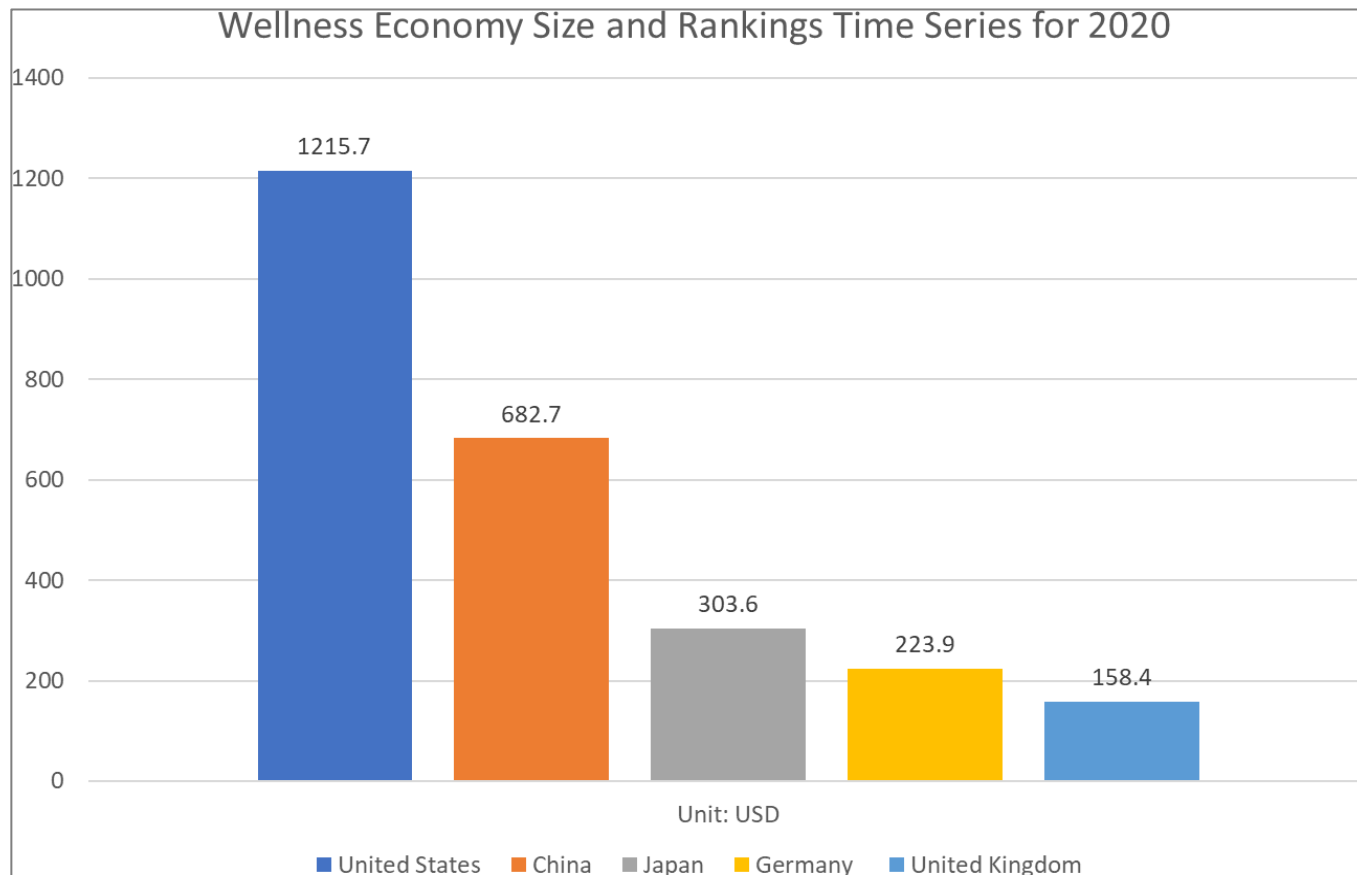
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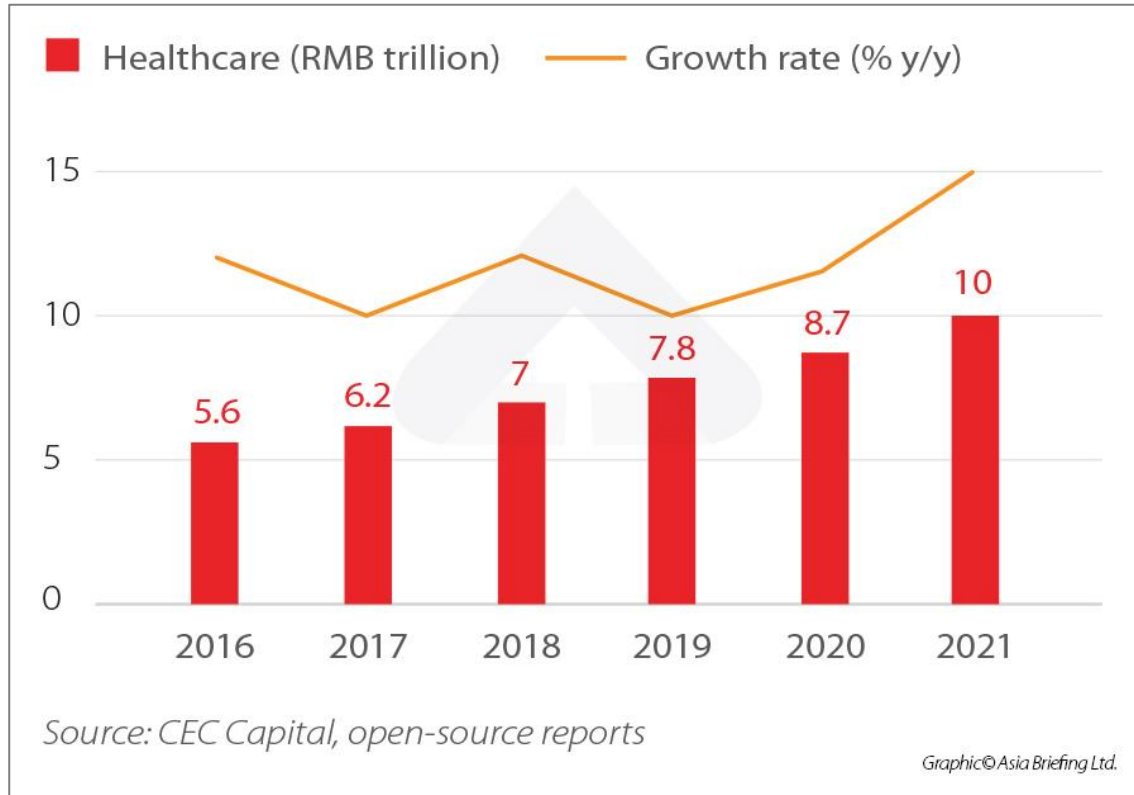
# China's Healthcare Market



# China is the second largest healthcare market in the world, half the size of the US and double the size of Japan

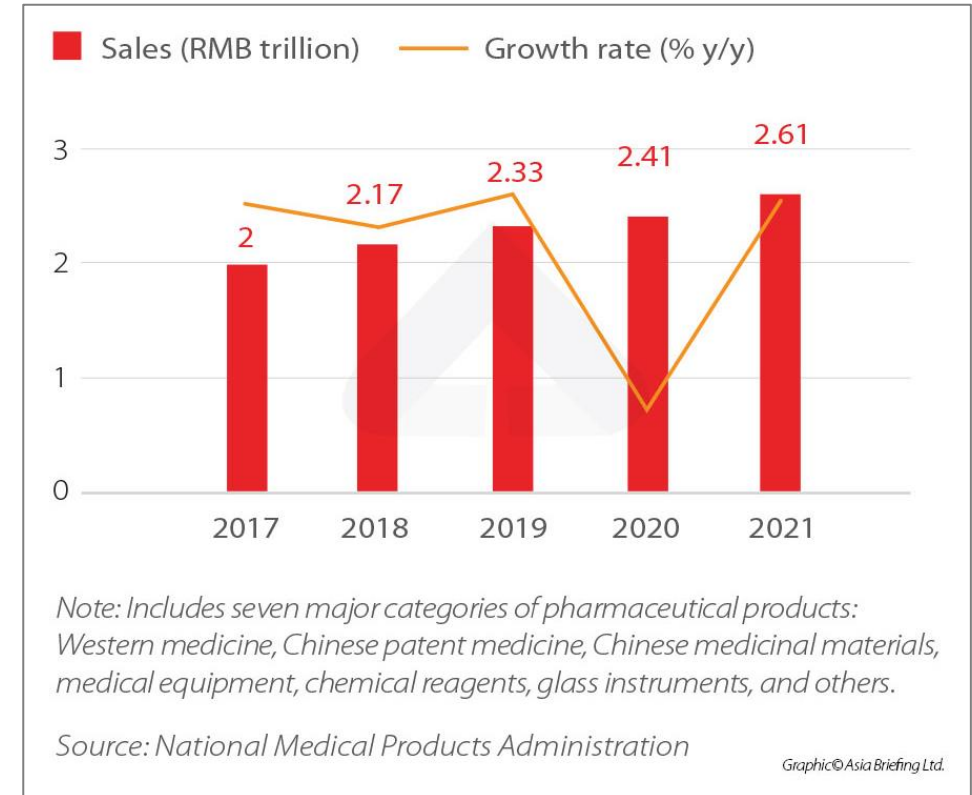


## Growth of China's healthcare market - 2016 to 2021 -



In 2021, total revenue for the healthcare market was estimated to be around RMB 10 trillion (approx. US\$1.5 trillion).

## Growth of sales of pharmaceutical products - 2017 to 2021 -



The sale of seven major categories of pharmaceutical products reached RMB 2.61 trillion (approx. US\$404.5 billion) in 2021, a realized compound annual growth rate (CAGR) of 5.4 percent since 2017.



# “Healthy China 2030” initiative

- A program launched in 2016 and re-confirmed in the midst of the Covid-19 pandemic and the 14<sup>th</sup> Five-Year plan in 2022.
- By 2030 (‘China Healthy 2030’ policy), the market value is expected to reach RMB 16 trillion (US\$ 2,4 trillion)
- Increased focus on disease prevention (incl. sports and fitness infrastructure investments).

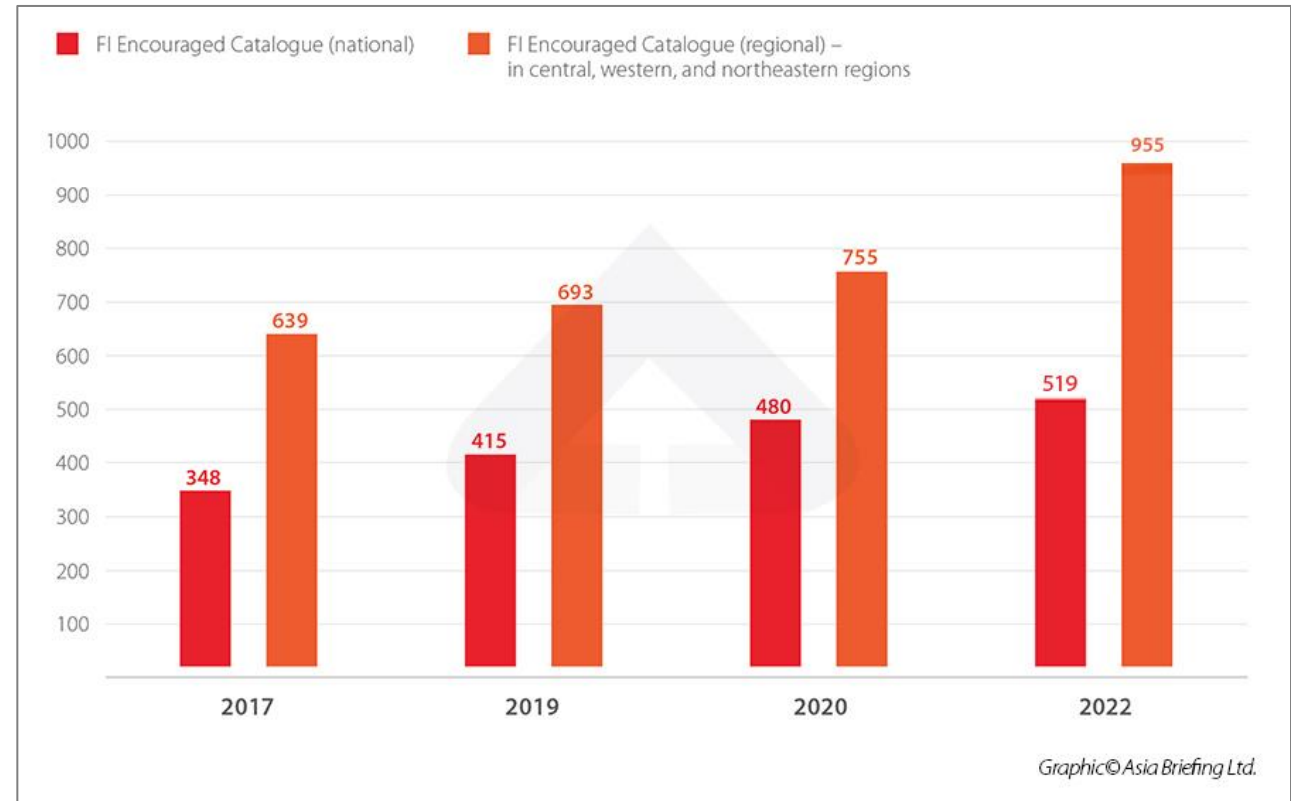
Key Healthcare Targets for China			
	2020	14th FYP target (2025)	Healthy China 2030 target (2030)
Life expectancy	77.93	Increase by one year	79
Infant mortality rate (%)	5.4	≤5.2	5
Mortality rate of children under 5 (%)	7.5	≤6.6	6
Maternal mortality rate (per 10,000)	16.9	≤14.5	12
Premature mortality rate from major chronic diseases (%)	16	≤15	30% lower than in 2015 (19.1)
Scale of healthcare service industry (trillion RMB)	8 (approx. US\$1.2 trillion)	>11.5 (approx. US\$1.7 trillion)	16 (approx. US\$2.4 trillion)
Personal health expenditure as share of total health expenditure (%)	27.7	27	25

Source: Healthy China 2030, 14th Five-Year Plan for National Health

Graphic©Asia Briefing Ltd.

# The catalogue of industries encouraged for foreign investment

- This catalogue lists industries where foreign direct investment (FDI) is welcome and treated with favorable policies in China.
- The extension of encouraged industries demonstrates that China is committed to opening up more to foreign investment in selected industries.
- And increased number of medical fields are included in the catalogue; examples:
  - ✓ Production and research and development of therapeutic medical and health textiles, artificial skin, absorbable sutures, hernia repair materials, new dialysis membrane materials, catheters for interventional therapy, and high-end functional biomedical dressings.
  - ✓ Development and production of drugs for rare diseases and special drugs for children.
  - ✓ Consumables related to pharmaceutical manufacturing industry: separation and purification media, solid phase synthesis media, chiral resolution media, consumables for drug impurities control and detection, etc.
  - ✓ Manufacturing of dental implant system for implant repair in patients with bone loss.
  - ✓ Manufacturing of closed negative pressure drainage and protect wound materials, bacterial cellulose film, and polyurethane foam dressing and other polymer material dressing manufacturing.
  - ✓ Hearing aid and cochlear implant manufacturing.
  - ✓ Postpartum maternal and child services in maternity centers
  - ✓ Rehabilitation institute for autistic children.



# China's major challenges

An aging population



Commercial health insurance is still very limited



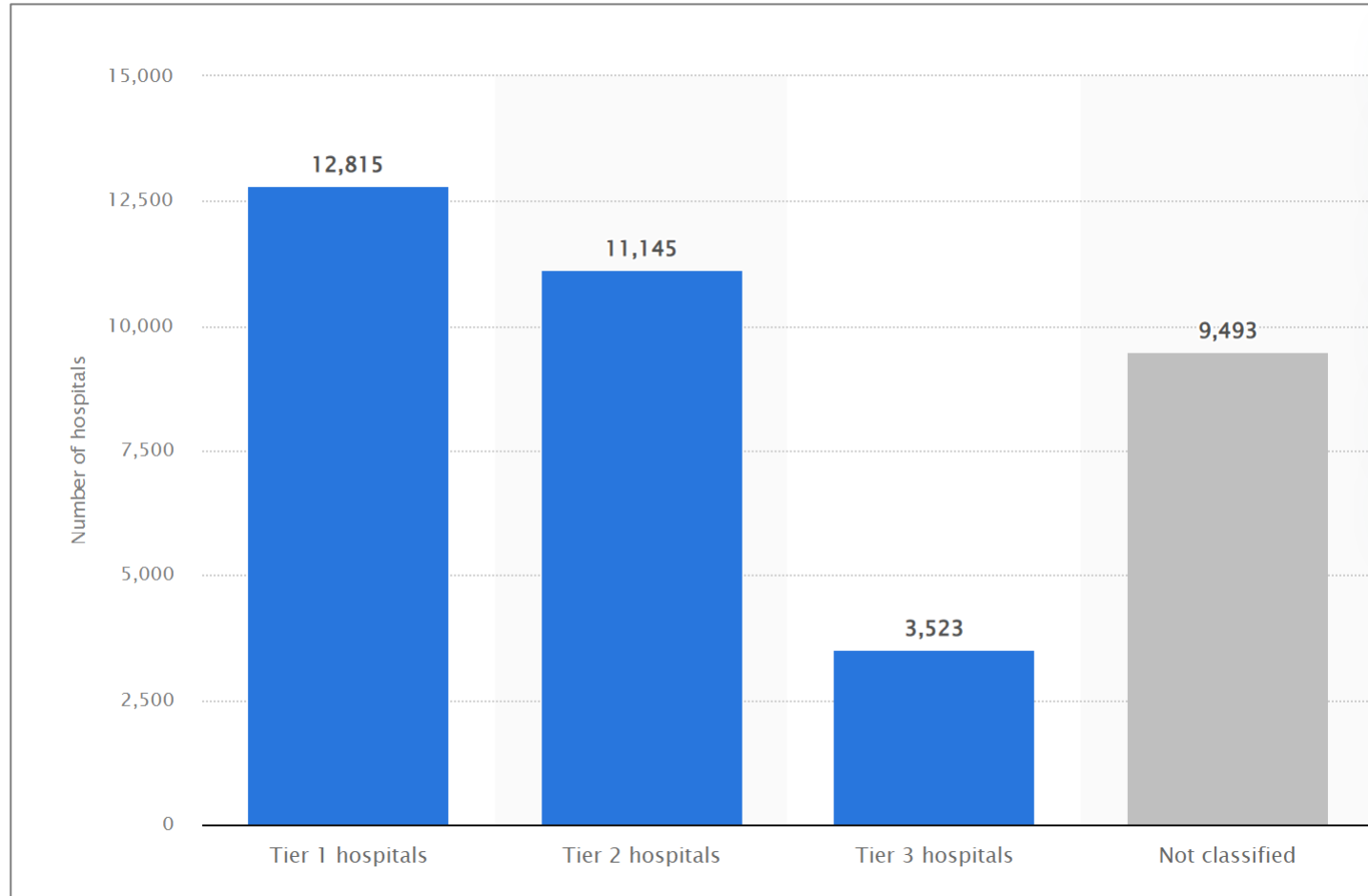
Shortage of doctors and nurses



Inbalance between urban and rural care



# An unbalanced healthcare system

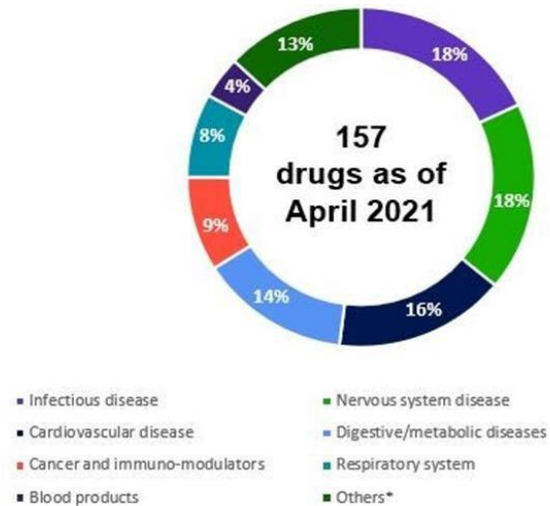


- Hospitals in China are organized according to a three-tier system
- In 2022, the healthcare system in China had 3,523 tier-three hospitals and over 11,000 tier-two hospitals.
- Tier-three hospitals are the most advanced and specialized institutions
- They are constantly overcrowded, whereas low-tier hospitals, clinics, and health centers are desperately trying to attract more patients.

Source: Statista 2024

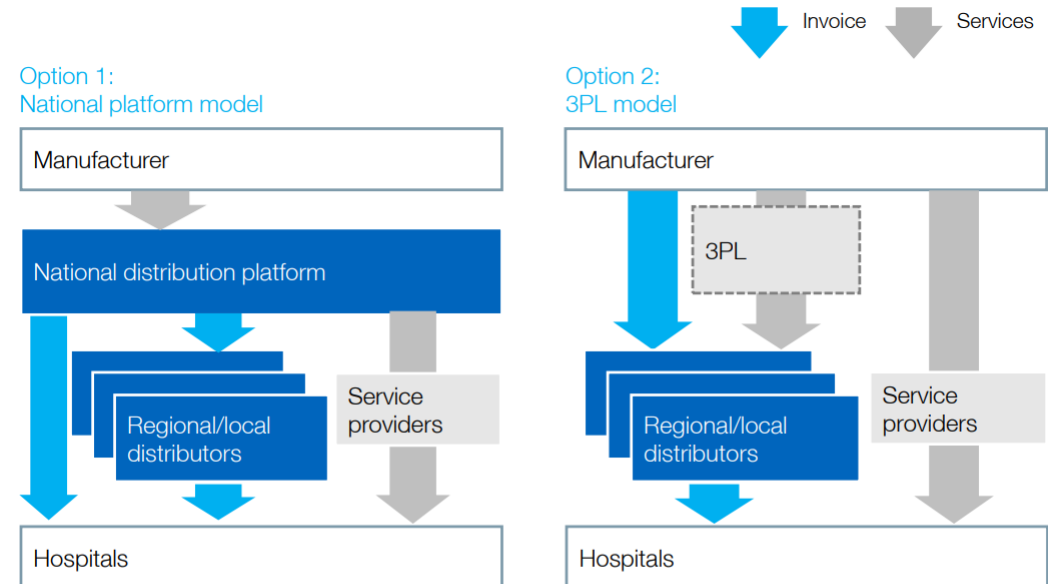
# Reforms in the government's procurement model

The **China volume-based procurement (VBP)** of drugs, equipment and consumables, resulting in major price decreases (50 to 80%!), but bigger volumes.



As of April 2021, **157 drugs** have also been procured under the volume-based procurement strategy.

The **Two-invoice system** was introduced in 2016 and is allowing only two invoices at most to be issued along the chain of pharmaceutical product procurement between manufacturers and medical institutions.



- Works if platform is issuing first invoice
- Least complex option for manufacturer
- Model gives national distributor great bargaining power
- Harder to control T2 distributors
- Third-party services can be organized by distribution platform

- Requires significant resources for distributor management
- More exposure to compliance risks
- Third-party services likely to be on manufacturer's P&L

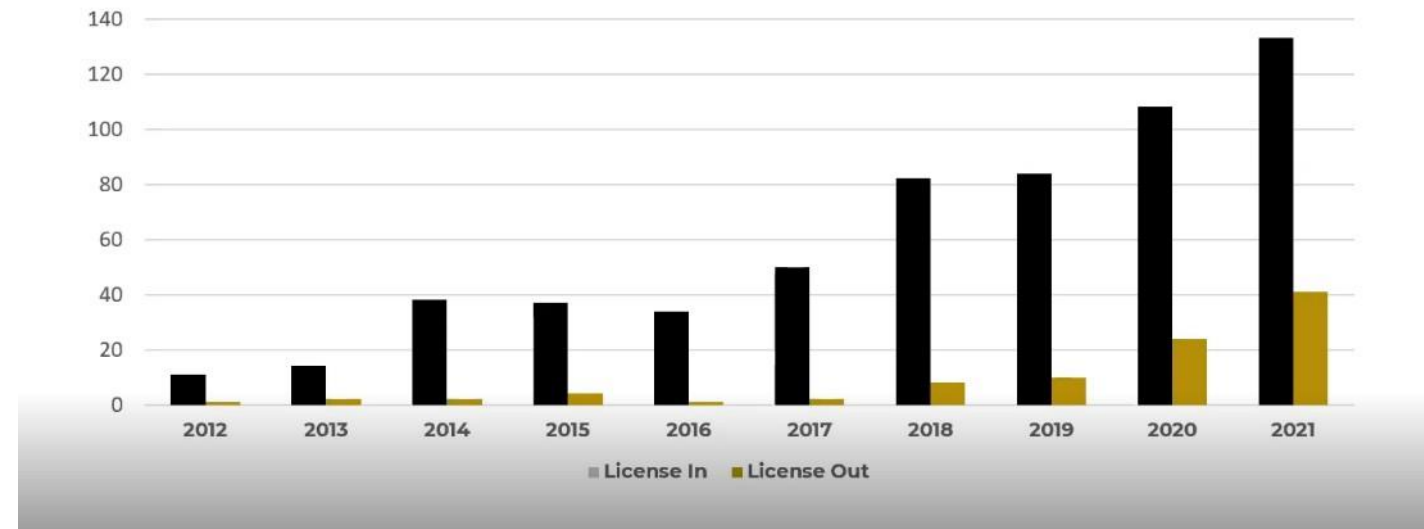


# The leading Chinese private biopharma companies are the ideal partners for biotech companies from Belgium on the China market

New biotech and biopharma companies have been grown over the last decade, of which the leading ones are actively **globalizing** and **looking for in- and out-licensing and collaboration opportunities for the Chinese market.**

This is an opportunity for Belgian companies with a **pipeline in clinical development phase** in Europe or the United States.

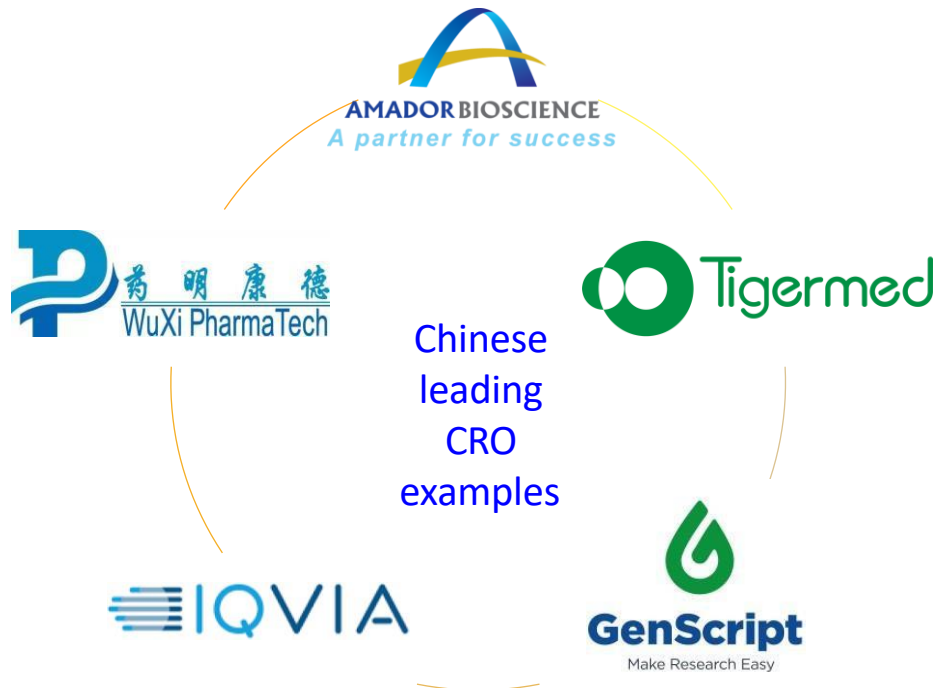
Licensing deals by Chinese **therapeutic** companies in last 10 years



Source: Agio Capital

# China's leading CROs and CDMOs are following the Chinese biopharmas into Europe

China's CRO (Contract Research Organization) industry started more than ten years later than European and American countries, but with strong growth in Life Science R&D spending in China, the growth rate of China's CRO industry is significantly higher than that of the global market.



China's CDMO or contract development and manufacturing space for biomanufacturing is relatively new but growing at over 15% year-on-year. There have been around a dozen new mAb therapeutics from domestic innovators in the last two years, and this continues to create domestic demand for biomanufacturing CDMOs.

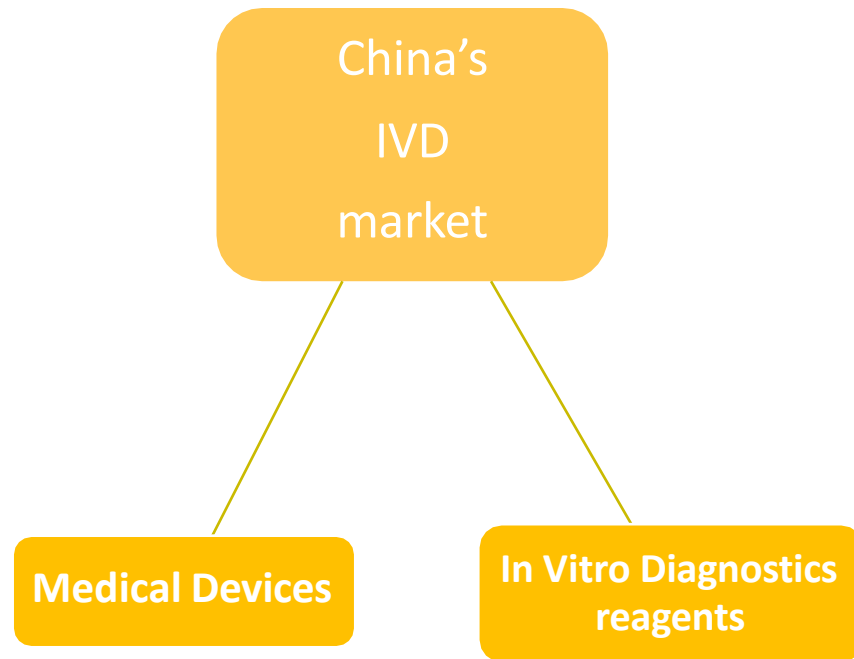


Sources:

十大CRO医药外包公司, CRO医药外包-医药外包研发排行榜-买购品牌网 (maigoo.com)  
 2022年中国十大cro公司排名 2022中国cro医药公司排名top10 - 南方财富网 (southmoney.com)  
 全面解析中国新型CRO企业TOP10|TOP10|CRO|解析|数据|研发|药物|技术|健康界 (cn-health care.com)  
 2021年中国医药CDMO重点企业对比 (baidu.com)

Report: China CRO/CDMO Sector: Big opportunities in China and abroad

# China's IVD market is growing double digit and one of the most valuable advances has been in the form of molecular diagnostic tools



Chinese leading IVD companies examples:



Chinese leading NGS (Next Generation Sequencing) companies examples:



Sources:  
[12家IVD企业荣登胡润中国500强！|IVD|胡润|荣登|企业|制药|健康界\(cn-health care.com\)](#)  
[IVD上市公司已达75家，还有12家在排队！|ivd|ipo|丽珠集团|港交所|网易订阅\(163.com\)](#)  
[国产医疗器械上市公司Top15，群雄逐鹿！|群雄逐鹿|Top15|医疗器械|骨科增长|营收|健康界 \(cn-health care.com\)](#)



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# China Medical Equipment Fair

- Largest Health and Medtech tradeshow in China
  - ✓ 200.000 visitors
  - ✓ 320.000 m<sup>2</sup>
- Several product categories in different halls:
  - ✓ medical imaging
  - ✓ electronic medical equipment
  - ✓ hospital construction, medical
  - ✓ consumables
  - ✓ orthopedics & rehabilitation
  - ✓ animal care
- FIT pavilion with companies from Flanders or their local distributors



**11-14 Apr. 2024 Shanghai**

**12-15 Oct. 2024 Shenzhen**





# 8 Conclusions & Recommendations

1. The health care market in China continues to have **high potential** as the second largest health care market in the world with double digit growth.
2. **Domestic competition** is increasingly getting stronger and with global ambitions.
3. The 'old model' of multiple layers in the sales channels is being replaced by a '**new model**' with more '**localization**' and **financial discipline**.
4. The **regulatory environment** is getting increasingly challenging, especially considering the focus on price reduction systems, such as Volume-Based Procurement and the Two-Invoice System.
5. Western companies should target the China market with **innovative products or services** that have no direct competition in China yet.
6. **Registration of trademarks and patents** is key and should be started as soon as possible.
7. The best way to enter the market today is through a **licensing or distribution agreement with a local partner** (or alternatively even as a **joint venture**). There are also possibilities to collaborate with Chinese medtech leaders in Europe.
8. Take your time to get to know the market and **see China with your own eyes!**





# Introduction Horsten International



[www.horsten.be](http://www.horsten.be)



[www.mychinaweb.com](http://www.mychinaweb.com)



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Feet on the ground in China



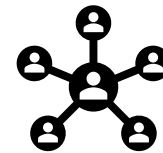
## KEY ADVANTAGES

Extensive network



关系

Unique Horsten model



Liaison



Representation



Watchdog





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