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# Seizing Opportunities in China's Healthcare Industry:

*A Guide for Foreign Investors*

March 30<sup>th</sup>, 2023





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# 1. China Healthcare Market

# Policy: Healthy China 2030

- Largest population in the world & an aging demographic: increased incidences of NCDs (e.g., cancer, cardiovascular disease)
- Health spending would increase to US\$ 2.5 tn in 2035 (US\$ 543.5 bn in 2014), according to a report from the World Bank
- Imbalance between rural and urban healthcare coverage

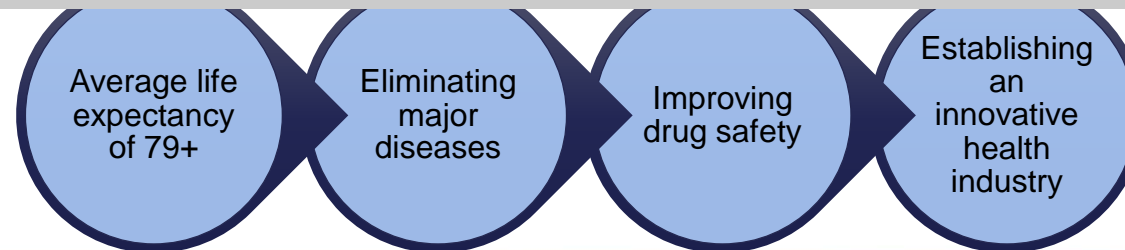
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<b>“All for Health” – the fundamental path to building a healthy China</b>		<b>“Health for All” – the ultimate purpose of the initiative</b>	
4 Core Principles			
<u>Health Priority</u>	<u>Reform and Innovation</u>	<u>Scientific Development</u>	<u>Justice and Equity</u>
Public policy implementation	Innovation is a key role, simultaneously speed up reform in key areas	The importance of both prevention and cure, focusing on prevention and control	The rural areas of the country are given special attention to promote equal access to basic public health services and to maintain public welfare

China is beginning to **re-orient** itself from economic growth to health development.

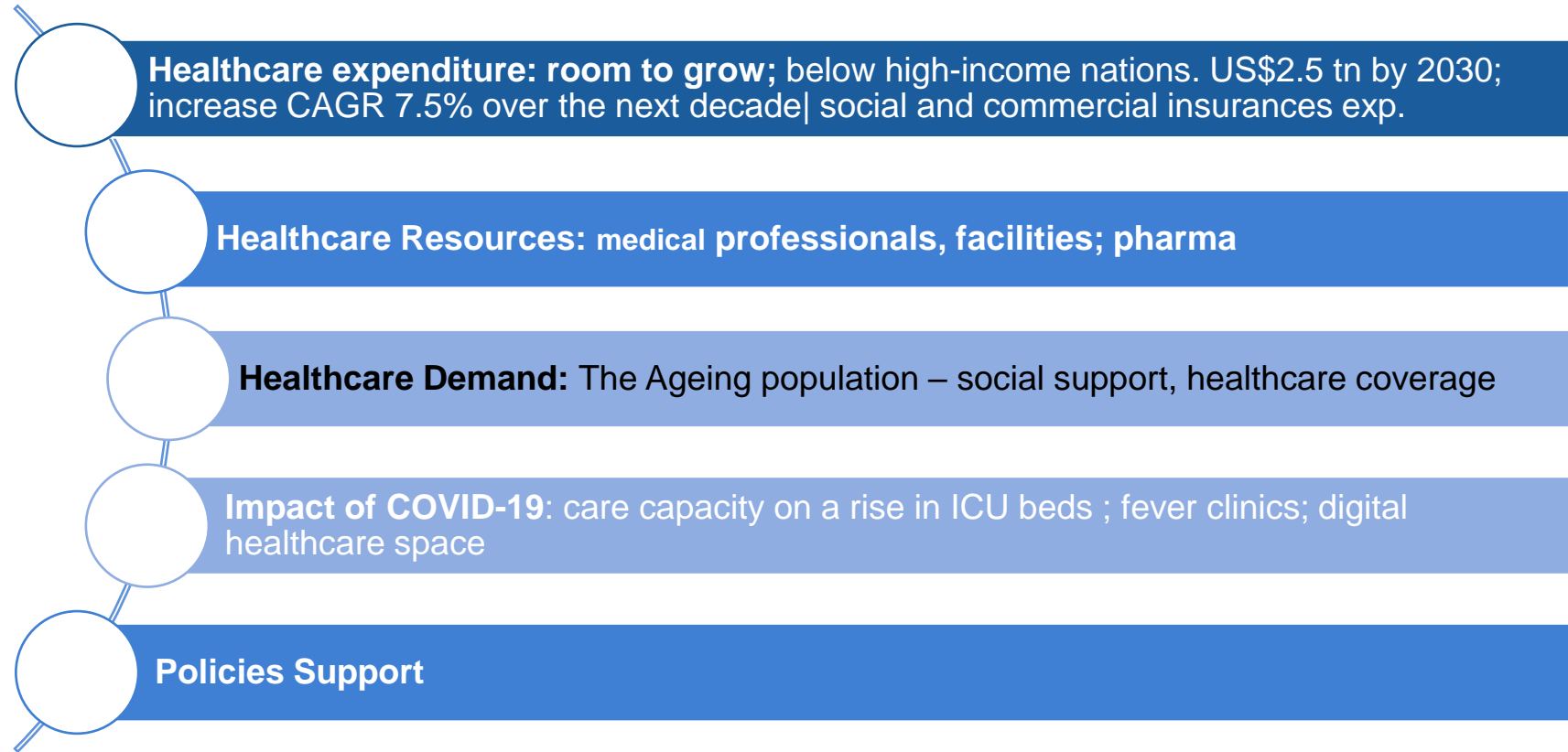
# Healthcare in China - Unprecedented Growth

- The national health investment capital will be raised to 16 trillion yuan, and three of every 100 citizens will be certified as doctors by 2030.
- To achieve the GOALS, **the Healthy China 2030 plan** has outlined 5 specific objectives:

Key Objective	Definition
1. Continuous improvement in people's health	People will enjoy much stronger health, with <u>an average life expectancy of 79 years</u> and much longer healthy life expectancy by 2030
2. Effective control of major health risks	Health literacy of the population will be significantly enhanced; healthy lifestyles will be widely adopted; people will work and live in an environment conducive to their health; <u>food and drug safety</u> will be ensured; and a host of major diseases will be eliminated
3. Increase in healthcare capacity	An excellent, efficient system of integrated healthcare and a sound system of fitness services for all will be established; medical insurance protection will be further improved; China will lead the world in health <u>technology innovation</u> ; and the overall sophistication and quality of health services will be greatly enhanced
4. Expansion of health industries	An all-rounded and well-balanced <u>matrix of health industries</u> will be developed, including a group of large corporations with strong innovation capabilities and global competitiveness, so that these industries can become pillars of China's Economy
5. Further improvement in health-promoting institutions	<u>Policies, laws and regulations</u> promoting health will be enhanced even further. The governance system and governance capacity in relation to health will be modernized



# Key Drivers: Continue to Grow



# China's largest Healthcare Segments

## Pharmaceuticals

### 7 major categories:

- Western medicine,
- Chinese patent medicine,
- Chinese medicinal materials,
- medical equipment,
- chemical reagents,
- Glass instruments, and
- Others

## Medical Devices

- Equipment (60% - 2021)
- High-value consumables
- Low-value consumables
- in-vitro diagnostics

## Healthcare Institutions

- The end of 2021, 1m institutions in China, +8013 in 2020;
- 36,570 hospitals [11,804 *public*; 24,766 *private*], + 1,176 from 2020.
- Expected to 3 for every 100K residents in 2022 & 2023
- Comprehensive hospital
- TCM\* hospitals
- Specialized hospitals
- Other

*\*Traditional Chinese Medicine*



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## 2. Trends & Opportunities



# Key Trends to Shape China's Healthcare Industry

## Effective Epidemic Surveillance and Management

- Public Health in Post COVID era
- Telemedicine
- Digital health technologies (AI, big data analytics, cloud computing)
- Government Initiatives

## Ageing-Oriented Healthcare

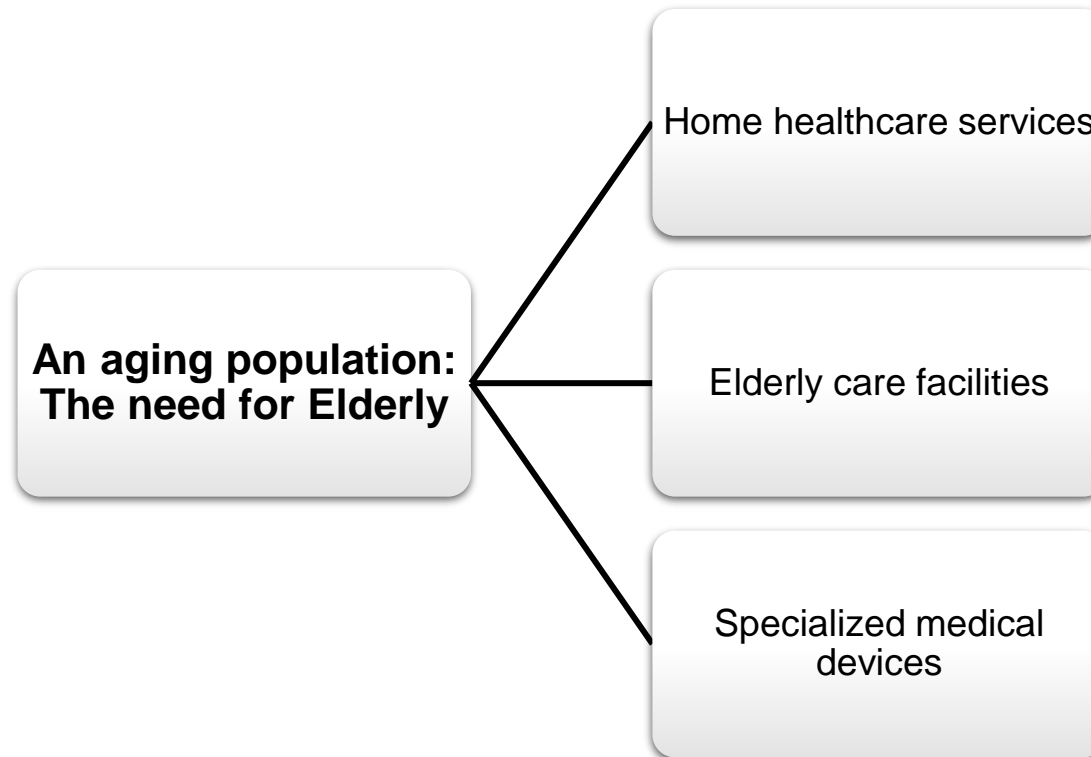
- Ageing population
- Chronic disease management
- Preventative Healthcare (products and services)
- Wearables like fitness trackers, health watches, electrocardiogram watches, blood pressure monitors

## Health Awareness in Young People

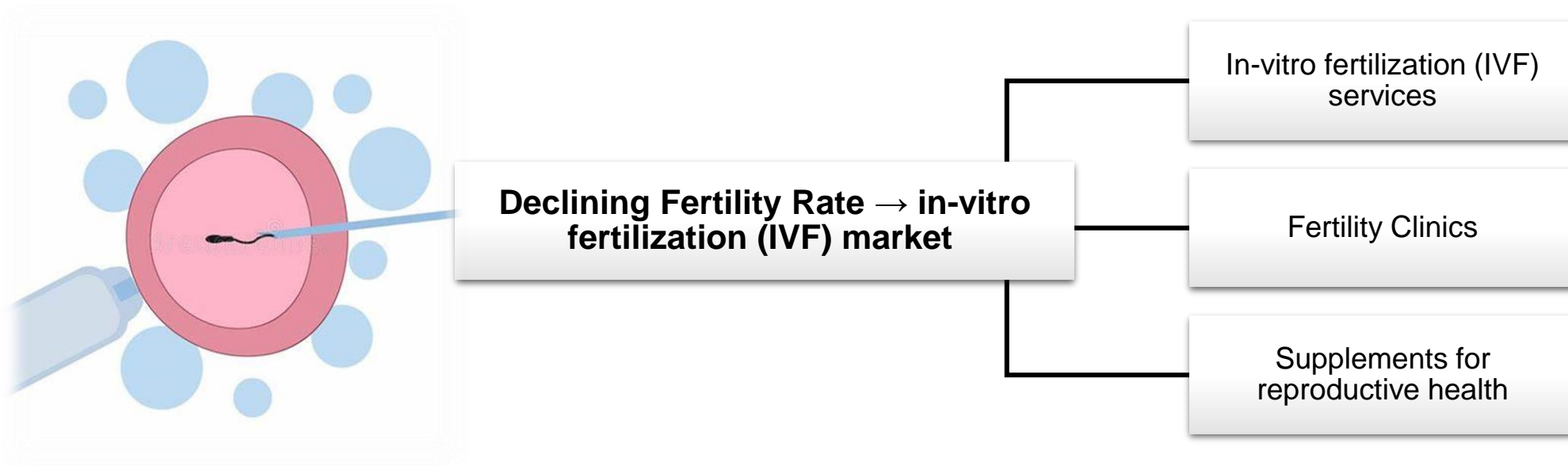
- Willing to pay more on healthy food, products and services - Healthy Lifestyle
- Health related information online and connect users with healthcare professionals
- Healthcare community
- Health Insurance as health, sport and wellness have been prioritized.

# Opportunities: Aging-Oriented Healthcare

- **An increasingly ageing population:** China is now home to the largest population of older people in the world.
- In 2019, 254 million people in China were aged 60 years or older.
- By **2040**, this number is expected to increase to **402 million**, making up around 28% of the population. the number of people aged 65 and above in China is expected to reach **487 million** by **2050**, accounting for over 1/3 of the total population.



# Opportunities: Reproductive Technology is on Rise



***China's in-vitro fertilization market is expected to be more than US\$2.8 billion by 2025.***

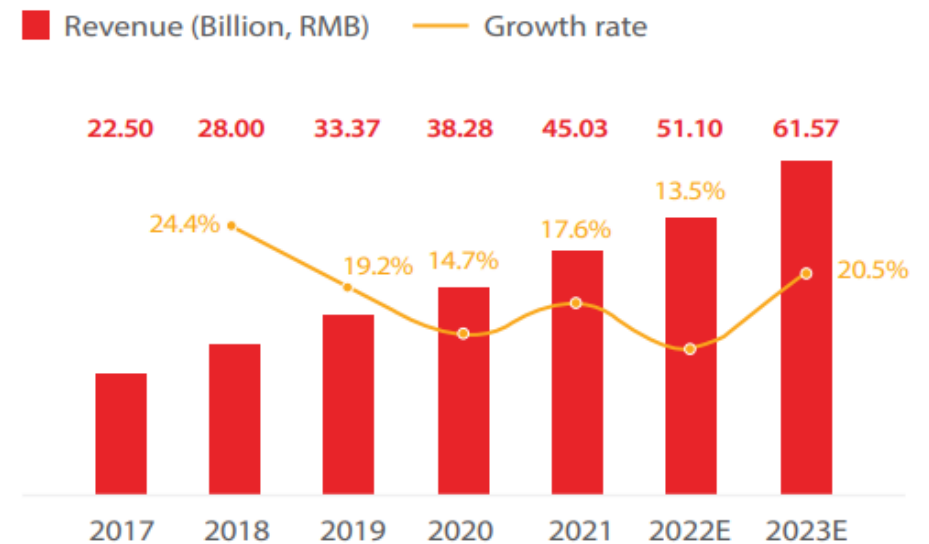
# Opportunities: Rehabilitation - A Lifeline for Many

- The rising number of rehabilitation hospitals in China
- Private hospitals make up the majority of China's rehabilitation hospital market, accounting for **77.53%**
- Policies Support

Year	Total number of rehabilitation hospitals	Private hospitals	Public hospitals
2015	453	289	164
2016	495	332	163
2017	552	400	152
2018	637	485	152
2019	706	545	161
2020	739	573	166
2021	810	<b>628</b>	<b>182</b>

A Correlations

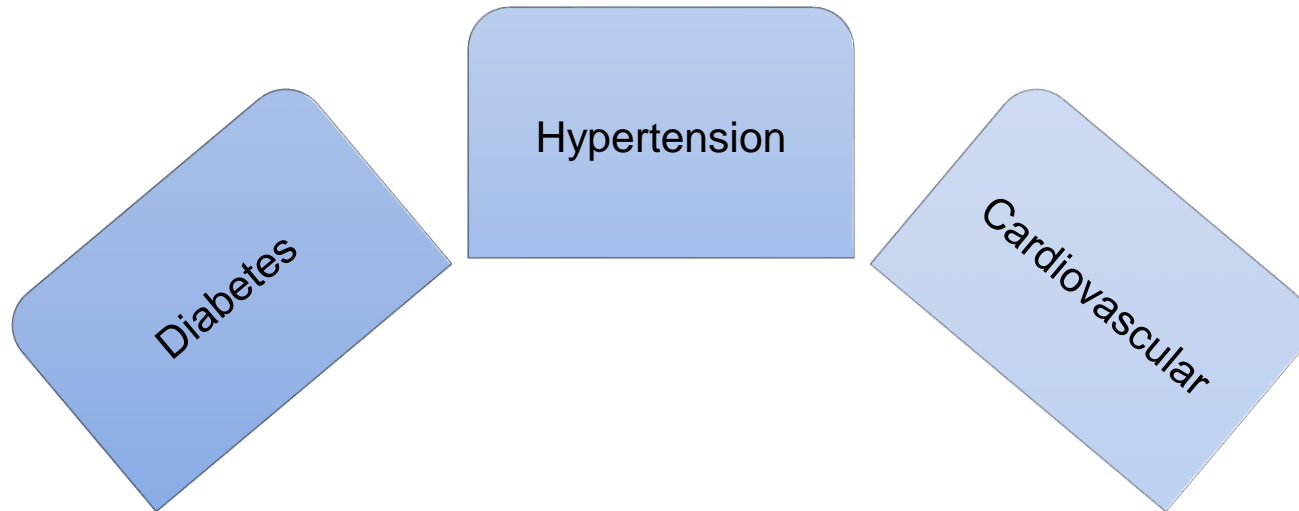
Rehabilitation medical devices



Source: China Economic and Technological Research Institute, 2022

# Opportunities: The Management of Chronic Diseases

- A growing number of people seek medical assistance for long-term illnesses.



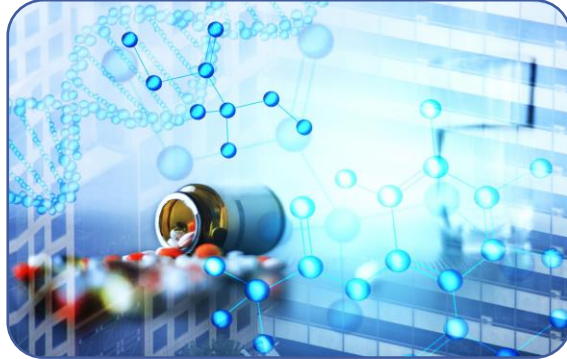
## Comprehensive management programs offered by Healthcare Providers (e.g., Hospitals)

- Regular check-ups
- Symptom monitoring
- Personalized treatment plans
- Remote patient monitor
- Telemedicine

### As a result:

- ❑ A rising demand for chronic disease management services
- ❑ For chronic diseases management service, by 2026, the market is expected to exceed RMB 1 billion (US\$) with a CAGR of 10.77% between 2021 and 2026
- ❑ For wearable devices, expected to achieve a market size of US\$4.1 billion by 2026, with a CAGR 21%
- ❑ Digital market for managing chronic condition: a CAGR 32.1% from 2016 to 2020. Targeting RMB 800 Bn in 2025 and RMB 1,808 bn in 2030; with CAGRs of 35.4% from 2020 to 2025 and 17.7% from 2025 to 2023.

# Opportunities in Niche Market



## Biotech and biopharmaceuticals

- A focus on new drugs, therapies, and medical devices **targeting specific diseases and patient populations**
- *Government policies* to support in areas of R&D, tax incentives for biotech companies, streamlining the regulatory approval process
- Collaborations with international biotech companies



## Digital healthcare market

- The COVID-19 pandemic has served as a catalyst - Virtual Doctor from apps or computers
- Internet hospitals & Online drugs: increase significantly, yoy 44% and 52%, reaching approx. RMB 223 bn and RMB 36.8 bn.
- Digital health platform: partnering with technology companies, e.g., JD pharmacy, Alibaba Health.



## AI healthcare

- **Medical imaging:** AI algorithms can analyze medical images, such as X-rays, CT scan, MRI scan to helping doctors make more accurate diagnoses and treatment plans.
- **AI-powered Drug Discovery:** using AI to analyze vast amounts of data on **molecular structures**, chemical compounds, and biological interactions, researchers can identify potential drug candidates much faster and more accurately than traditional methods

# Regional Healthcare Markets Highlights

## Hainan Medical Zone & Bo'ao Le-cheng International Tourism Pilot Zone with the \*IIR Plan

- Cooperation agreements with healthcare providers from countries, such as the United States, Germany, and Singapore.
- Promoting minimalist approvals, examination of key medical devices and drugs, and the free and convenient flow of trade, investment, and funds.
- Facilitating the suspension and residence of foreign personnel

## The Yangtze River Delta (YRD) region

- One of the most dynamic and economically *prosperous regions*
- 220 million people, a GDP of over US\$2.5 trillion
- Shanghai, Suzhou, Hangzhou, Taizhou etc.
- Biomedical and biopharmaceutical industry
- Developed infrastructure, talent acquisitions, supportive policies
- R&D of new drugs and technologies

## The Greater Bay Area (GBA)

- A major hub for Pharmaceutical and medical device industry
- Industrial agglomeration advantages
- A complete upstream and downstream industrial chain
- In 2021, medical device industry reached RMB 125.48 billion – 16.67% of the national total – **1<sup>st</sup> rank** in China.
- Growth potential on biological drugs. (e.g., investment from AstraZeneca, Beigene etc.)

\*IIR stands for Integration and Innovation Reform Plan



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## 3. Key Considerations for Market Entry



# Foreign Investment Access

- **First question to check whether your specific sector is on:** Negative List; or Catalogue of Encouraged Industries for Foreign Investment
- **The 2022 FI Encouraged Catalogue adds multiple new items for the healthcare sector. Some areas where foreign investment is encouraged are:**
  - 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.
- **Certain sectors that remain off-limits or restricted to foreign investment:**
  - Medical institutions: limited to a joint venture structure; unless special approval; Mainland & HK CEPA
  - Human stem cells and genetic technology: Restricted. **BUT → High-throughput sequencing (HTS) is ALLOWED**
  - Foreign investors are also generally **NOT restricted** from engaging in the import and export, production, sales, and research and development of genetic testing equipment.

# Approval and Licensing (Pharmaceutical)

## Pharmaceutical R&D

- Good Laboratory Practices for Nonclinical Drug Research (GLP) **certificate** issued by NMPA\*
- A record-filing with local health bureau
- An **approval** from local department of science and technology
- A Radiation Safety **Permit** from local environmental protection bureau if the drug R&D process involving radiative materials
- Import-export related licensing and approvals

## Pharmaceutical Manufacturing

- A Drug Manufacturing **License** from provincial NMPA
- Comply with the Good Manufacturing Practices (GMP) standards
- A Work Safety **License** for the production activities
- Relevant import-export **licenses** if needed

## Drug supplying and trading

- A Drug Trading **License**
- comply with the pharmaceutical Good Supply Practice (GSP) standards.

*\*NMPA: National Medical Products Administration*

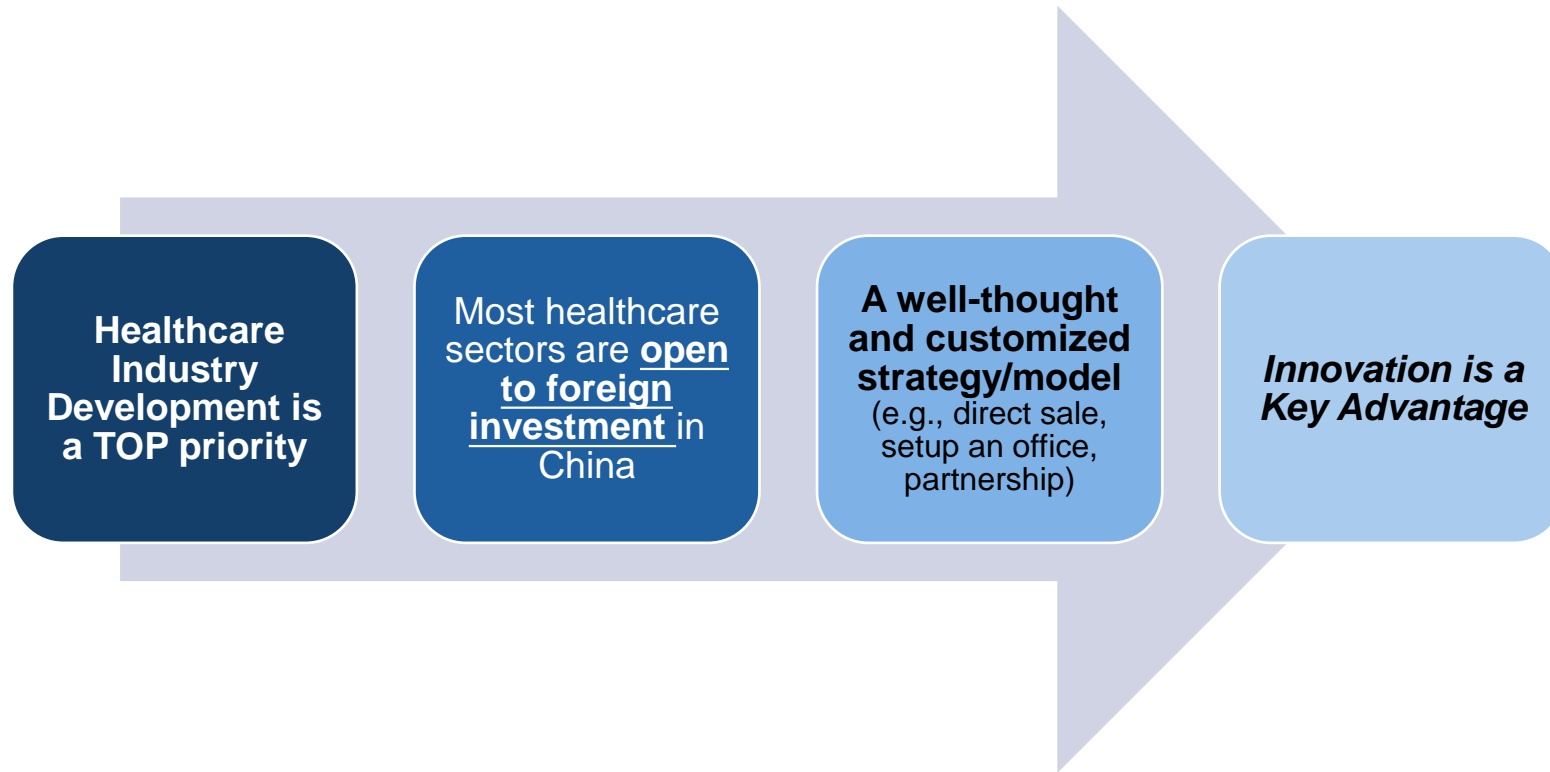
# Medical Devices & Real-World Evidence (RWD)

Classified Management:		
Class	Risk level & Description	Requirements
Class I	Low-risk Device; such as bandages and exam gloves	Record-filing management - comparatively easier; clinical trial is not required.
Class II	Mediate-risk devices; requires strict control, such as suture needle and electrocardiograph	A Medical Device Registration Certificate (clinical trial shall be conducted) file a record with local NMPAs for trading Class II
Class III	High-Risk Device; require special strict control, such as implantable pacemaker and intravascular	A Medical Device Registration Certificate (clinical trial shall be conducted); an approval for trading Class III medical devices

- **One of a step for Class II & III is Clinical Evaluation Report (CER) will be needed for a China device approval. **A clinical Trial may be needed.** [Article 20 Clinical evaluation of medical devices refers to the process that the applicant or filing entity validates whether the products under registration can meet their intended use and indications based on the information of clinical literature, clinical experience data and clinical trials.]**
- Local clinical trial takes 1-1.5 years and expensive
- June of 2021, **NMPA** issued a new set of regulation for **innovative medical device** for the treatment of urgent public health emergencies and rare diseases – exempted from clinical trials in China if certain conditions met.
- Real-world Data (RWD) is **still in early stage** in China – challenges in data quality, data accessibility and data sharing, demanding collaborations from government bodies etc.
- Hainan Boao - Lecheng Pilot Zone** is a unique opportunity for **innovative medical device** to gain accelerated approval in China
- Glaucoma drainage tube—the first medical device approved using domestic RWE in China.

# Takeaways on Market Entry Strategies

Stay focused on the core mission of improving and saving lives of patients in China and around the world!





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