

# China Pharmaceutical Market Study

## Independent Market Research Report

Date : \_\_\_\_\_

For and on behalf of  
Frost & Sullivan Limited



Name: Terry Tse  
Title: Consulting Director

Confidential For



Frost & Sullivan  
June. 2025

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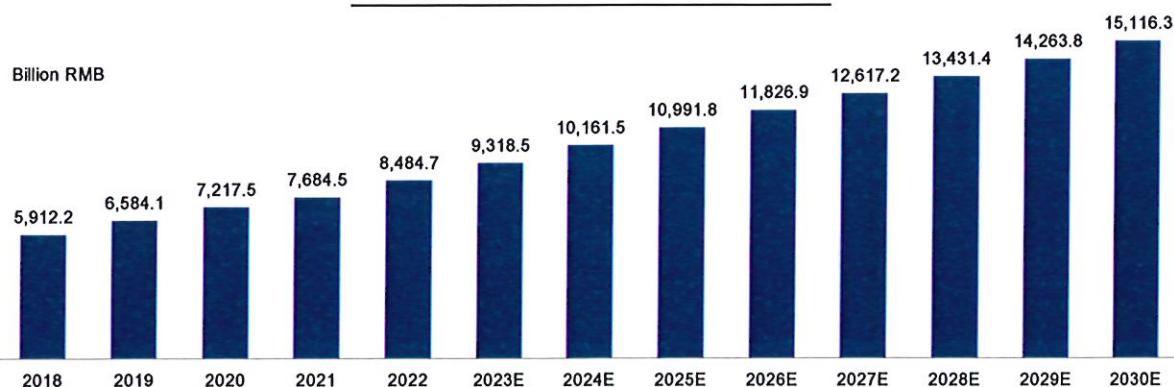
## China Healthcare Expenditure, 2018-2030E



- The total healthcare expenditure of China has experienced steady growth. From 2018 to 2022, the total healthcare expenditure of China has increased from RMB 5,912.2 billion to RMB 8,484.7 billion, representing a CAGR of 9.5%. Furthermore, the rapid increasing trend in China's healthcare expenditures will continue in the near future. The total healthcare expenditure of China is forecasted to reach to RMB 11,826.9 billion, RMB 15,116.3 billion by 2026, 2030 respectively, which represents a CAGR of 8.7% from 2022 to 2026 a CAGR of 6.3% from 2026 to 2030.

China Healthcare Expenditure, 2018-2030E

Period	CAGR
2018-2022	9.5%
2022-2026E	8.7%
2026E-2030E	6.3%





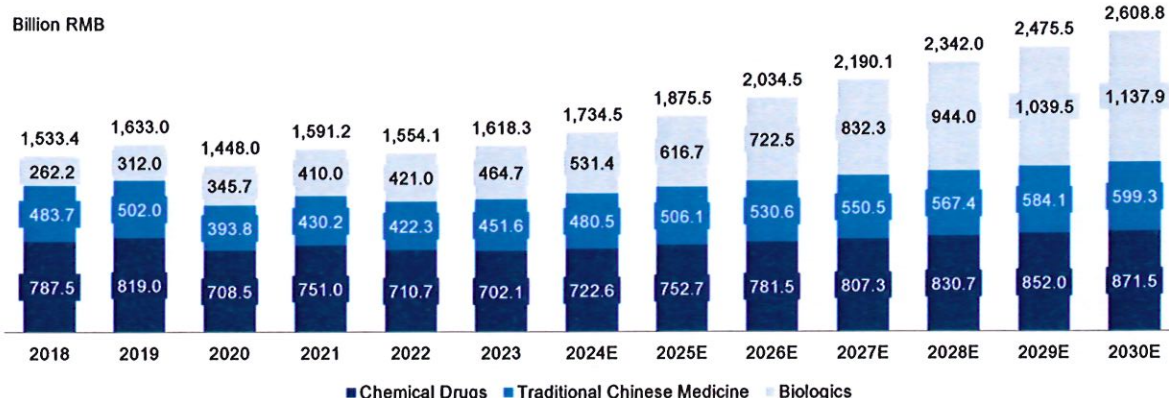
## China Pharmaceutical Market, 2018-2030E



- China pharmaceutical market, accompanying with the growth of economy and healthcare demand, increased from RMB 1,533.4 billion in 2018 to RMB1,618.3 billion in 2023 with CAGR of 1.1%. China pharmaceutical market will further increase to RMB2,608.8 billion in 2030, with CAGR of 7.1%.

China Pharmaceutical Market, 2018-2030E

Period	CAGR			Total
	Chemical	TCM	Biologics	
2018-2023	-2.3%	-1.4%	12.1%	1.1%
2023-2030E	3.1%	4.1%	13.6%	7.1%



Source: Annual Reports of Listed Medical Companies, NMPA, CDE, NRDL, MOHRSS, Frost & Sullivan Analysis

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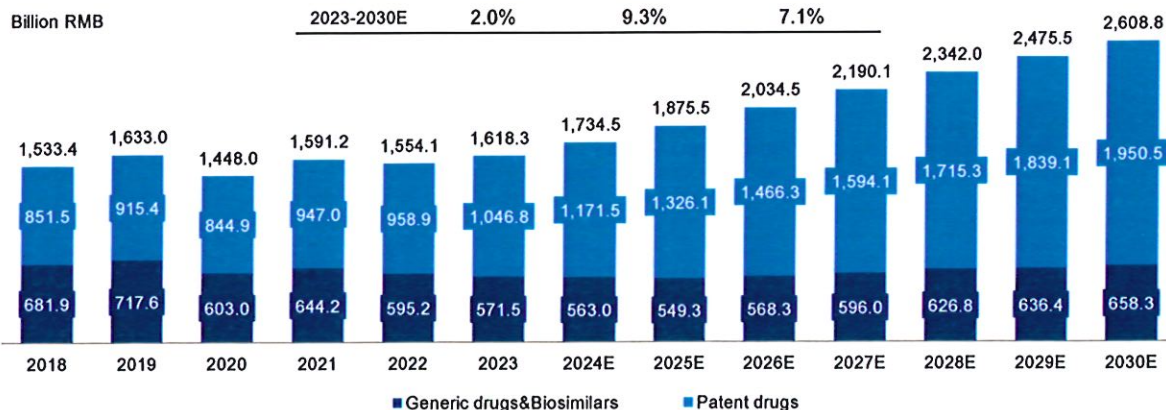
## China Pharmaceutical Market, 2018-2030E



- In the Chinese pharmaceutical market, the size of patented drugs grew at a CAGR of 4.2% from 2018 to 2023. It is expected to increase to 9.3% from 2023 to 2030, with the market size increasing to 1,950.5 billion RMB. The generics market is relatively more stable.
- China pharmaceutical market will further increase to 2,608.8 billion RMB in 2030. Patented drugs and generics will reach 1,950.5 billion RMB and 658.3 billion RMB, respectively.

China Pharmaceutical Market, 2018-2030E

Period	CAGR		Total
	Generic drugs & Biosimilars	Patent drugs	
2018-2023	-3.5%	4.2%	1.1%
2023-2030E	2.0%	9.3%	7.1%

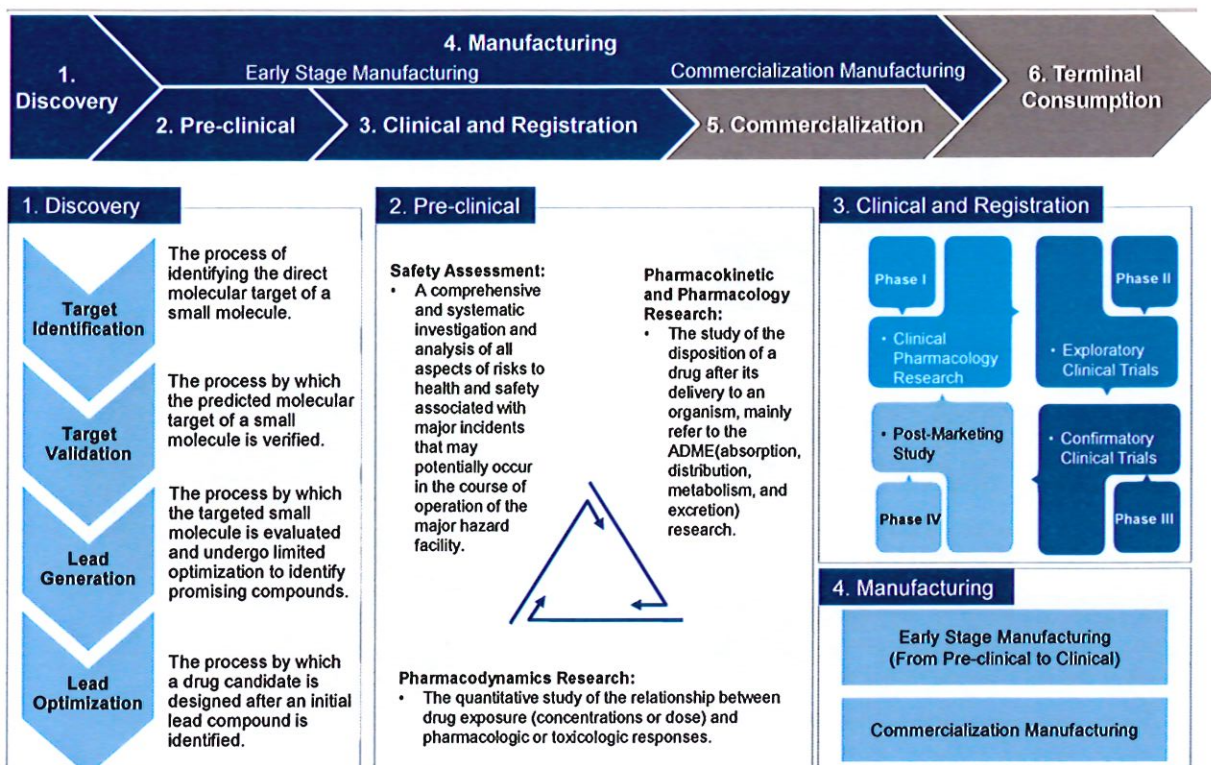


Source: Frost & Sullivan Analysis

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## Drug Research and Development Processes(1/2)

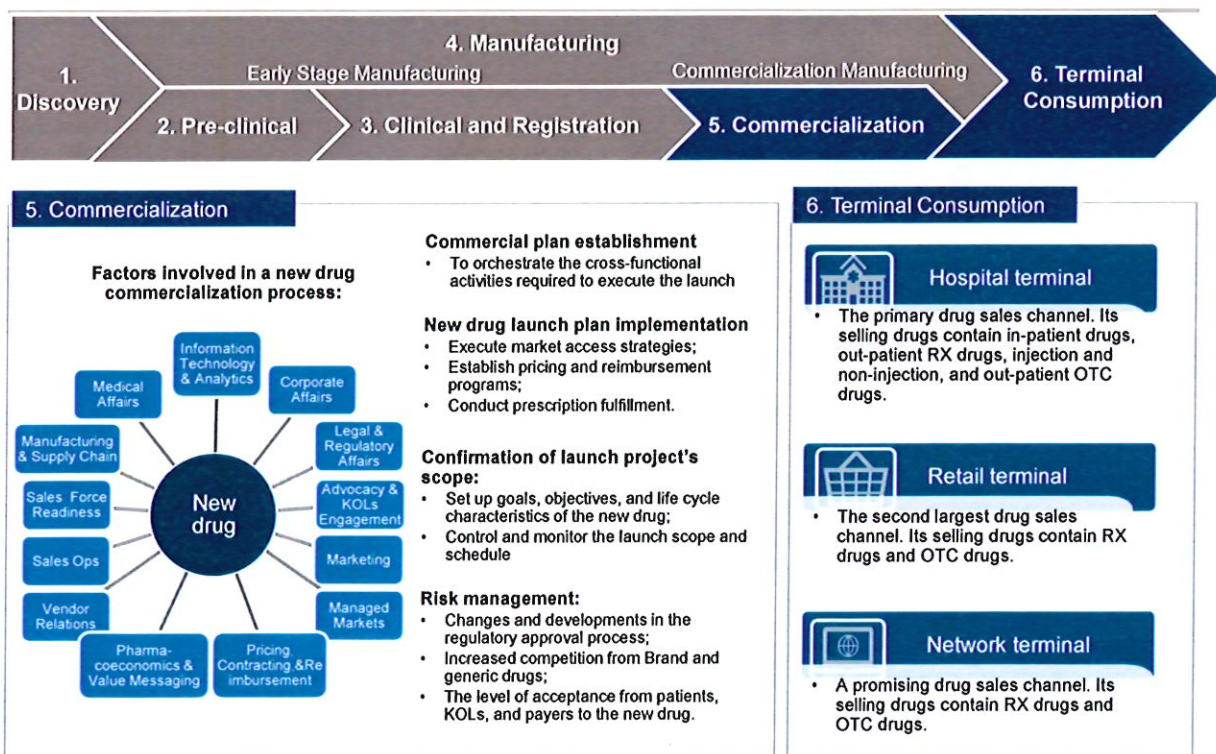


Source: Frost & Sullivan analysis

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## Drug Research and Development Processes(2/2)



Source: Frost & Sullivan analysis

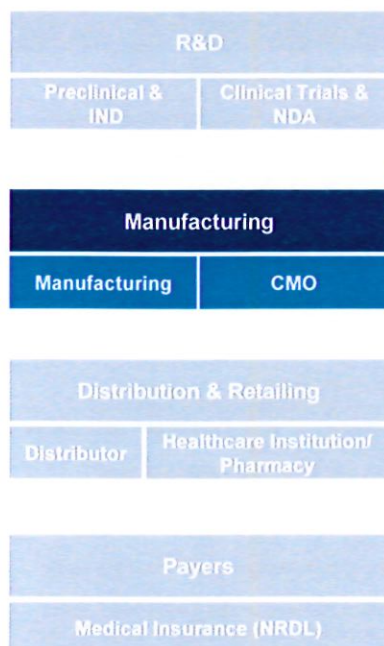
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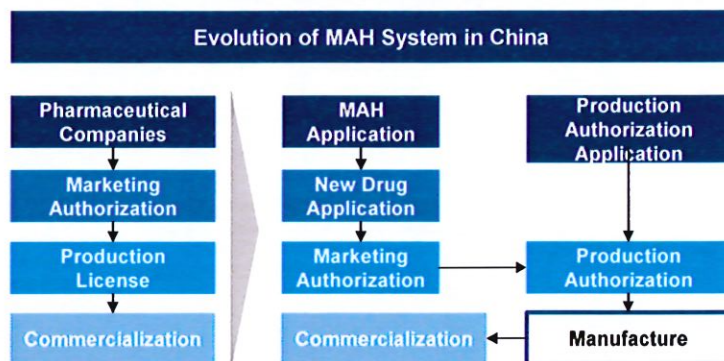


# Analysis of China Pharmaceutical Industry

## Marketing Authorization Holder (MAH)



**Marketing Authorization Holder (MAH)**  
《国务院办公厅关于印发药品上市许可持有人制度试点方案的通知》



- MAH system enables the R&D organizations or personnel to apply for and obtain drug marketing authorizations and drug approval license, and the MAHs can entrust the CMOs to manufacture drugs instead of obtaining production license themselves, so that they can focus on R&D rather than allocate the manpower and investment on manufacturing.
- MAH system helps to promote R&D innovation, accelerate industrial restructuring and optimize resource allocation.

Source: Government Website, Frost & Sullivan Analysis

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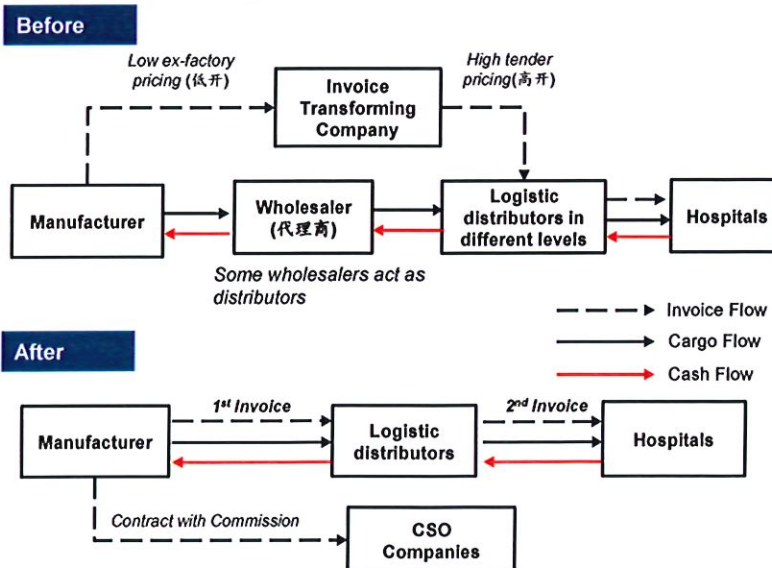
# Analysis of China Pharmaceutical Industry

## Two-Invoice System



### Two-Invoice System

《关于在公立医疗机构药品采购中推行“两票制”的实施意见（试行）的通知》



- The two-invoice system, aiming to improve transparency in drug prices and eliminate excessive profit margins associated with multi-tier distribution models, has important implications for pharma companies, distribution companies as well as CSOs.

Source: Government Website, Frost & Sullivan Analysis

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## Favorable Government Policy of Pharmaceutical Industry

### Review of Clinical Trial and New Drug Application

Release Date	Issuing Authority	Policies	Comments
Sep, 2019	NHC, NHSA, NMPA	<i>Notice for the Publication of the Health China_ Implementation Plan for Cancer Prevention (2019-2022 edition)</i> 《关于印发健康中国行动——癌症防治实施方案（2019—2022年）的通知》	<ul style="list-style-type: none"> <li>Establish a comprehensive clinical evaluation system for anticancer drugs.</li> <li>Speed up the approval of new anticancer drugs at home and abroad.</li> </ul>
Nov, 2019	NMPA	<i>Notice on Soliciting Opinions on the Working Procedures of Breakthrough Therapeutics and the Priority Review and Approval Process</i> 《关于突破性治疗药物工作程序和优先审评审批工作程序征求意见的通知》	<ul style="list-style-type: none"> <li>For innovative drugs or improved new drugs that are used to prevent or treat severely life-threatening diseases, and that have no effective prevention measures or have sufficient evidence to show obvious clinical advantages compared with existing therapies, they can apply for Breakthrough Treatment Drugs.</li> <li>Breakthrough Treatment Drugs can be reviewed and approved first.</li> </ul>
Mar, 2020	NMPA, NHC	<i>Announcement on the Release of Administrative Regulations on Extended Clinical Trials of Medical Devices (Trial)</i> 《关于发布医疗器械拓展性临床试验管理规定（试行）的公告》	<ul style="list-style-type: none"> <li>Meet the public clinical needs and support clinical experimental on medical instruments as soon as possible.</li> <li>Standardize the development of extended clinical trials and the collection of safety data for medical devices.</li> <li>Safeguard the rights and interests of subjects.</li> </ul>
Apr, 2020	NMPA, NHC	<i>Announcement on the Release of Quality Management Practices for Drug Clinical Trials</i> 《关于发布药物临床试验质量管理规范的公告》	<ul style="list-style-type: none"> <li>Deepen the reform of drug evaluation and approval system and encourage innovation.</li> <li>Further promote standardized research and improve the quality of drug clinical trials in China.</li> </ul>
Dec, 2020	NMPA	<i>Guidelines for Statistical Design of Antitumor Drug Clinical Trials (Trial)</i> 《抗肿瘤药物临床试验统计学设计指导原则（试行）》	<ul style="list-style-type: none"> <li>The statistical methods for the commonly used efficacy endpoints are proposed in the guidelines, and the statistical design requirements are put forward from the perspectives of exploratory and confirmatory trials.</li> </ul>
Jul, 2024	NMPA	<i>Pilot Work Plan for Optimizing the Review and Approval of Clinical Trials of Innovative Drugs</i> 《优化创新药临床试验审评审批试点工作方案》	<ul style="list-style-type: none"> <li>Improve the risk identification and management capabilities of drug clinical trial stakeholders, complete the review and approval of innovative drug clinical trial applications within 30 working days, and shorten the time required to start drug clinical trials.</li> </ul>

Source: Government Website, Frost & Sullivan Analysis

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## Favorable Government Policy of Pharmaceutical Industry

### Review of Innovation Encouragement

Release Date	Issuing Authority	Policies	Comments
Mar, 2016	State Council	<i>Guiding Opinions of Promoting the Healthy Development of the Pharmaceutical Industry</i> 《国务院办公厅关于促进医药产业健康发展的指导意见》	<ul style="list-style-type: none"> <li>Accelerating the development of innovative drugs and biological products with major clinical needs;</li> <li>Speeding up the promotion of green and intelligent pharmaceutical production technologies;</li> <li>Strengthening scientific and efficient supervision;</li> <li>Promoting the development of industrial internationalization.</li> </ul>
Mar, 2016	CFDA	<i>Plan of the System of the Holders of Drug Marketing Licenses</i> 《药品上市许可持有人制度试点方案》	<ul style="list-style-type: none"> <li>Drug research and development institutions or scientific research personnel in the pilot administrative areas may serve as drug applicants for registration, and submit applications for drugs clinical trials and marketing.</li> </ul>
Oct, 2016	State Council	<i>Healthy China 2030</i> 《“健康中国2030”规划纲要》	<ul style="list-style-type: none"> <li>Strengthening technical innovation by forming a Government-Industry-University-Research Cooperation efficient system;</li> <li>Improving the quality control system of drug and medical devices. By 2030, quality standards for drugs and medical devices would be fully integrated with international standards.</li> </ul>
Dec, 2016	State Council	<i>13th Five-Year Plan for National Strategic Emerging Industry Development</i> 《“十三五”国家战略性新兴产业发展规划》	<ul style="list-style-type: none"> <li>Accelerating the innovation and industrialization of new drugs.</li> <li>Promoting the development of high-tech biosimilar drugs such as monoclonal antibodies, long-acting recombinant proteins, and third-generation insulin, and increasing the accessibility of drugs to patients.</li> </ul>
May, 2017	CFDA	<i>Policies of Encouraging Drug Medical Equipment Innovation to Implement Drug Medical Equipment Life Cycle Management</i> 《关于鼓励药品医疗器械创新实施药品医疗器械全生命周期管理的相关政策（征求意见稿）》	<ul style="list-style-type: none"> <li>Accelerating the informationization of review and approval system.</li> <li>Formulating the technical requirements for the electronic submission of drug and medical device registration.</li> <li>Improving the general electronic documentation system.</li> </ul>

Source: Government Website, Frost & Sullivan Analysis

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## Favorable Government Policy of Pharmaceutical Industry

### Review of Innovation Encouragement

Release Date	Issuing Authority	Policies	Comments
Jul, 2020	NMPA	<i>Announcement on the Release of Three Documents such as the Work Procedure for the Evaluation of Breakthrough Therapy Drugs (trial)</i> 《关于发布《突破性治疗药物审评工作程序（试行）》等三个文件的公告》	<ul style="list-style-type: none"> <li>To cooperate with the implementation of Drug Registration Administration Measures, these work procedures are developed:               <ul style="list-style-type: none"> <li>(i) Review and Evaluation Procedures for Breakthrough Therapy Drugs (Trial)</li> <li>(ii) Review and Approval Procedures for conditionally approved marketing application of drugs (Trial)</li> <li>(iii) Procedure for Priority Evaluation and Approval of Drug Marketing Authorization (Trial)</li> </ul> </li> </ul>
Sep, 2020	MoF	<i>Announcement on the Release of the Second Batch on Anticancer Drugs and Orphan Drugs Applicable to the VAT Policy</i> 《关于发布第二批适用增值税政策的抗癌药品和罕见病药品清单的公告》	<ul style="list-style-type: none"> <li>In order to encourage the development of pharmaceutical industry, and reduce the cost of drugs for patients, the second list includes 39 pharmaceutical products, 6 active pharmaceutical ingredients of anticancer drugs and 14 pharmaceutical products of orphan drugs. VAT general taxpayers who produce, wholesale and retail those drugs can pay VAT at a 3% levy rate according to the simple method, starting from Oct 1, 2020.</li> </ul>
Dec. 2020	NHSA	<i>Announcement on the "Internet + healthcare" "five one" service action</i> 《关于深入推进“互联网+医疗健康”“五个一”服务行动的通知》	<ul style="list-style-type: none"> <li>Support the pharmaceutical industry by making the payment process quicker and easier, simplifying the healthcare services and applying digitalization methods.</li> </ul>
Sep. 2021	NHSA, NMPA	<i>The "14th Five-Year Plan" National Drug Safety and High-quality Development Plan Promotion</i> 《“十四五”国家药品安全及促进高质量发展规划印发》	<ul style="list-style-type: none"> <li>Support high-quality industrial development of the regulatory environment and system reform.</li> <li>Approving many innovative drugs in urgent clinical need.</li> <li>Accelerate the listing of innovative drugs with clinical value and innovative medical devices as soon as possible in the domestic market.</li> <li>Formulate and revise 2650 standards and 480 new guidelines on drugs, medical devices, and cosmetics.</li> </ul>

Source: Government Website, Frost & Sullivan Analysis

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## Favorable Government Policy of Pharmaceutical Industry

### Review of Innovation Encouragement

Release Date	Issuing Authority	Policies	Comments
Dec. 2021	NHSA	<i>Guidance from the National Health Insurance Administration and the State Administration of Traditional Chinese Medicine on Medical Insurance Support for the Development of Traditional Chinese Medicine Inheritance and Innovation</i> 《国家医疗保障局和国家中医药管理局关于医保支持中医药传承创新发展的指导意见》	<ul style="list-style-type: none"> <li>Medical insurance to support the development of Chinese medicine heritage and innovation</li> <li>Policy to include eligible TCM institutions into the medical insurance designated points and to include "Internet+" TCM services into the scope of medical insurance payment</li> </ul>
Jun. 2022	MoF	<i>Support rare disease drugs for children, medical insurance negotiations are imminent, and competition rules will be improved</i> 《支持儿童用药罕见病用药 医保谈判在即 竞争规则再完善》	<ul style="list-style-type: none"> <li>According to the policy, the 2022 medical insurance catalog adjustment will mainly include COVID-19 drugs, children's drugs and drugs for rare diseases.</li> <li>Negotiated drugs that expire at the end of this year, or drugs with significant changes in indications or functionalities will have the opportunity to be re-included in the negotiation list.</li> <li>It is expected that this year's medical insurance catalog will have a certain focus on pediatric drugs and rare disease drugs, and the medical insurance catalog will further expand the scope of disease coverage.</li> </ul>

Source: Government Website, Frost & Sullivan Analysis

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# Overview of Healthcare Insurance System in China

Public Medical Insurance	UEBMIS	<b>Urban Employee Basic Medical Insurance Scheme (UEBMIS)</b> <ul style="list-style-type: none"> <li>The scheme for urban employees, which is jointly funded by employers and employees, was established in 1998 to provide reimbursement for medical services and drugs.</li> <li>Under UEBMIS, employees including retirees are entitled to the healthcare insurance benefits. Generally, it is funded by (i) monthly payments from the beneficiary, such as the employee, and (ii) co-payments made by the employer of the beneficiary, both of which are subject to a ratio set forth by the local Labor and Social Security Authority. The ratio is calculated based on the monthly salary of the employee.</li> </ul>
	URBMIS & NRCMIS	<b>Urban Resident Basic Medical Insurance Scheme (URBMIS)</b> <ul style="list-style-type: none"> <li>The scheme for urban residents, financed by governments and individuals, was set up in 2007, and is now administered by the MOHRSS to provide coverage for major illnesses for urban residents not covered under UEBMIS.</li> <li>Most of its participants are urban residents who are currently unemployed or retired. Participants of the URBMIS are required to contribute to the payment of insurance premiums on a monthly basis.</li> </ul> <b>New Rural Cooperative Medical Insurance Scheme (NRCMIS)</b> <ul style="list-style-type: none"> <li>The NRCMIS piloted in 2003 given the government's dedication to establish the rural cooperative medical care system so as to improve access to medical services and drug supply in rural areas. The NRCMIS is funded by allocations from the central government, subsidies from local governments and fees paid by rural Chinese who participate the system voluntarily.</li> </ul> <b>Consolidation of URBMIS and NRCMIS</b> <ul style="list-style-type: none"> <li>In 2016, a few provinces in China have piloted consolidation of NRCMIS and URBMIS because of their similarities in funding Source and levels, which paves the way towards a nationwide, consolidated, medical insurance system. Opinions of Consolidation of URBMIS and NRCMIS (《国务院关于整合城乡居民基本医疗保险制度的意见》) required all provinces must put forward implementation plans of such consolidation by the end of 2016.</li> </ul>
	Medical Aid Scheme	Medical aid schemes are subsidized by local and central government funds and private donations and vary according to the local financial situation, to benefit low income patients with non-reimbursement expenses for inpatient and outpatient services.
Commercial Medical Insurance		Private medical institutions are pressing for patient reimbursement through the social insurance schemes for services provided at private hospitals. Any difference in the reimbursed amount and the fee for service would be paid out-of-pocket or through Appendix commercial insurance. Such a move would encourage greater use of private facilities and also boost demand for private insurance.

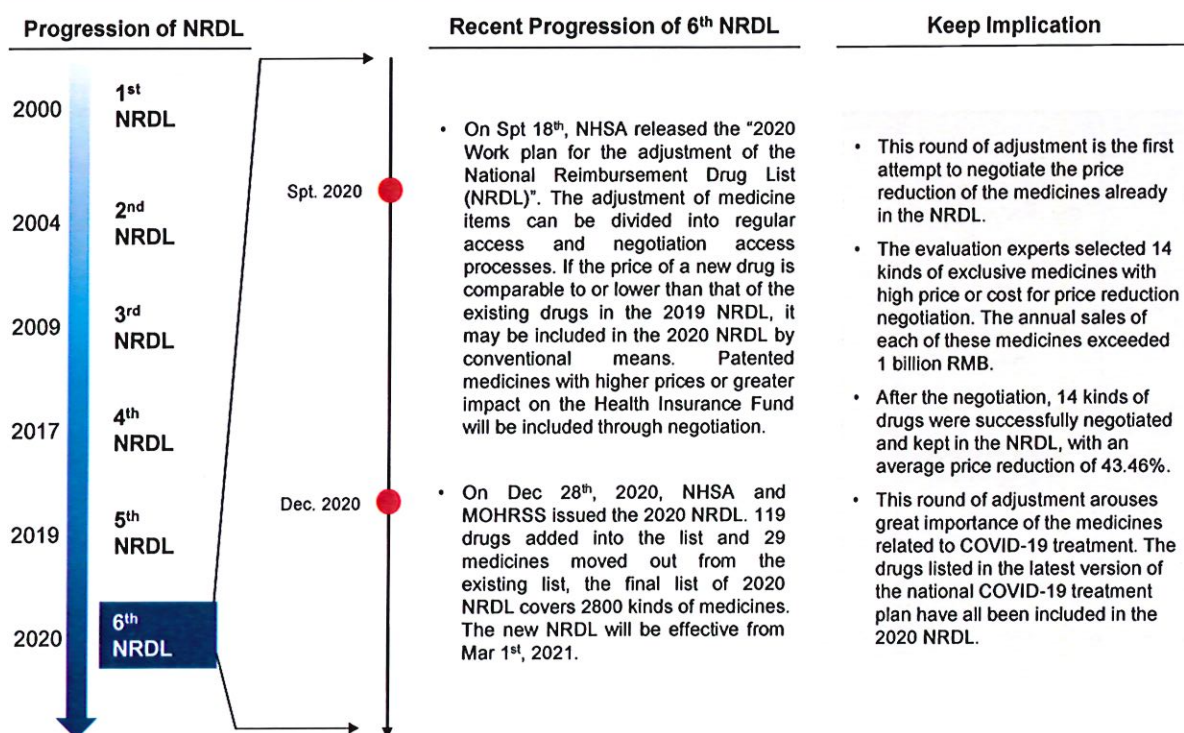
Source: NHFPC, Frost & Sullivan Analysis

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## Analysis of Healthcare Reimbursement System in China

Recent Progress and Impact of the NRDL



Source: Official Website, Frost & Sullivan Analysis

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## Threats and Challenges of Chinese Pharmaceutical Market

Pressure from Volume-Based Procurement	<ul style="list-style-type: none"> <li>China's volume-based procurement policy exerts significant price pressure on pharmaceutical companies. The government lowers drug prices through large-scale procurement, forcing many pharmaceutical companies to reduce prices to compete, which impacts their profit margins. This is especially challenging for innovative drugs, as the price pressure may make it difficult for companies to recoup R&amp;D costs, thus affecting the development and market supply of new drugs.</li> </ul>
Challenges in Innovative Drug R&D	<ul style="list-style-type: none"> <li>Chinese pharmaceutical companies face significant challenges in the R&amp;D of innovative drugs. While China has made progress in biopharmaceuticals and vaccine development, the overall level of innovation remains relatively low. The long drug development cycle and substantial financial investment, coupled with complex clinical trials and approval processes, often make it difficult for companies to bear the high risks, especially when there is insufficient capital and technological accumulation. Moreover, the imperfect protection of intellectual property for domestic innovative drugs may dampen companies' enthusiasm for R&amp;D.</li> </ul>
Challenges in Drug Internationalization	<ul style="list-style-type: none"> <li>China's pharmaceutical industry faces numerous challenges in its internationalization process. Although the domestic market is growing rapidly, Chinese pharmaceutical companies seeking to enter international markets often encounter challenges related to culture, law, and regulation. The differences in drug approval standards across various countries and regions result in longer timelines for products to reach international markets. Additionally, international competition is becoming increasingly intense, and local companies have weaker brand recognition and influence, requiring more effort to meet international market demands.</li> </ul>
Intense Market Competition	<ul style="list-style-type: none"> <li>The Chinese pharmaceutical market is highly competitive, with intense rivalry both among domestic companies and from multinational pharmaceutical firms. The widespread use of generic drugs and price-based competition has further compressed the profit margins of drugs. Many companies engage in price wars and promotional tactics to capture market share, which not only disrupts market order but also negatively impacts drug quality and innovative R&amp;D.</li> </ul>
Limited Patient Capacity	<ul style="list-style-type: none"> <li>Despite China's large population, certain disease areas have relatively limited patient populations, especially in rare diseases and specific therapeutic areas. The smaller patient pools in these fields make it difficult for pharmaceutical companies to generate substantial market returns. Additionally, the limited ability of patients to pay and narrow medical insurance coverage pose significant barriers for the promotion of high-priced drugs in the market.</li> </ul>

Source: Frost & Sullivan Analysis

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## Growth Drivers of Chinese Pharmaceutical Market (1/2)

Enlarging Patient Pool	<ul style="list-style-type: none"> <li>China's aging population is growing, leading to enlarging patient pool of a series of age-related health issues, such as chronic diseases and cancer. For example, the number of diabetic patients in China reached 143.4 million in 2023 and is expected to reach 157.6 million in 2030. In China, incidence of cancers has achieved 4.9 million in 2023 and is projected to reach 5.6 million in 2030. The increasing number of patients is expected to spur the demands for medications and treatments, driving growth in the China pharmaceutical market.</li> </ul>
Increasing Medical Insurance Expenditure	<ul style="list-style-type: none"> <li>In recent years, the government of China has continuously increased its investment in medical security. This kind of investment not only improves the people's medical security level, but also provides a broad market space for pharmaceutical enterprises. For instance, the expenditure of the basic medical insurance fund increased from 1,782.2 billion RMB in 2018 to 2,814.0 billion RMB in 2023, with a CAGR of 9.6%.</li> <li>New drugs are quickly incorporated into medical insurance after listing, which provides opportunities for pharmaceutical companies to quickly recover their R&amp;D investment, thus further stimulating the innovation vitality of enterprises.</li> <li>At the same time, the national population participation rate is stable at around 95%, and the reimbursement rate of hospitalization expenses within the scope of employee medical insurance and urban and rural residents' medical insurance policies is also very high. This means that more people can enjoy the benefits brought by medical insurance, which further enhances the demand of the pharmaceutical market.</li> </ul>
Increasing Capital Investment	<ul style="list-style-type: none"> <li>Pharmaceutical industry has the capital-intensive nature and require heavy investment on both research &amp; development as well as manufacturing process. China has great potential in the pharmaceutical R&amp;D environment, with spending USD30.1 billion on drug research and development in 2023, with the CAGR of 11.5% from 2018 to 2023. This is expected to grow to USD76.0 billion by 2030. The investment provide the abundant capital for innovative drugs R&amp;D, investigations of emerging categories and the establishment of manufacturing facilities.</li> </ul>
Technology Advancement	<ul style="list-style-type: none"> <li>The development of technology promotes the development of China pharmaceutical industry. Biotechnology can create substances that cannot be found in nature, integrate two substances into one molecule to exploit benefits from both of them, and even utilize viruses for their unique features.</li> <li>Multidisciplinary such as genome technology and information technology has promoted the development of precision medicine, which will increase the need for innovative chemical medicine.</li> </ul>

Source: Frost & Sullivan Analysis

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## Future Trends of Chinese Pharmaceutical Market (2/2)

### Focusing on Chronic Diseases

- In China, according to *China's Mid - and Long-term Plan for Chronic Diseases (2017-2025)* 《中国防治慢性病中长期规划 (2017-2025年)》 issued by the State Council, chronic diseases account for 86.6% of total deaths, and the disease burden has accounted for more than 70% of the total disease burden. Therefore, from the perspective of clinical demand, China's innovative drug research and development in the future will mainly focus on cardiovascular diseases, diabetes and other chronic diseases.

### Cooperative Innovation

- Pharmaceutical enterprises can obtain resources from other entities to shorten the research and development time, reduce the research and production costs, and accelerate the entry of innovative drugs into the market. Pharmaceutical enterprises can entrust manufacturing enterprises with the production of innovative drugs, thus saving the capital and time of self-built factories and production lines. And pharmaceutical enterprises can cooperate with universities, research institutes CROs to do innovative drug research, which can reduce the cost and share the risk.

### Improving Affordability

- The average disposable income of the Chinese population is expected to continue growing rapidly, increasing the willingness and ability of patients to pay for medications. As more Chinese households increase their spending power, they can afford more expensive medical treatments, particularly for life-threatening diseases.

Source: Frost & Sullivan Analysis

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## Entry Barriers of Chinese Pharmaceutical Market

### Regulatory hurdles

- Regulatory challenges are a hallmark of the Chinese pharmaceutical market for new entrants, with stringent regulations overseen by the NMPA to uphold the safety, efficacy, and quality of drugs within the country. Entities seeking to participate in the market must comply with these regulations, encompassing demands for clinical trials, product testing, manufacturing standards, and marketing approvals. Navigating this regulatory terrain demands substantial investments in regulatory affairs expertise and resources. As a result, companies operating in China's pharmaceutical sector face significant hurdles in meeting the demanding regulatory requirements, which can impede market entry and product commercialization efforts.

### Established competition

- The Chinese pharmaceutical market is highly competitive, with numerous domestic and global players vying for market share. Established companies often have strong brand recognition, existing distribution networks, and established relationships with healthcare providers and regulatory authorities. Companies, whether domestic or foreign, face the challenge of competing with these entrenched players, who may have significant resources and experience in navigating the complexities of the local market.

### Quality and compliance requirements

- Ensuring compliance with stringent quality standards and regulatory requirements can pose a barrier to entry for smaller pharmaceutical companies with limited resources. Meeting Good Manufacturing Practice (GMP) standards, quality control measures, and regulatory obligations demands substantial investments in infrastructure, technology, and expertise. Companies that fail to meet these standards may struggle to gain market acceptance and face challenges in securing necessary approvals for their products.

Source: Frost & Sullivan Analysis

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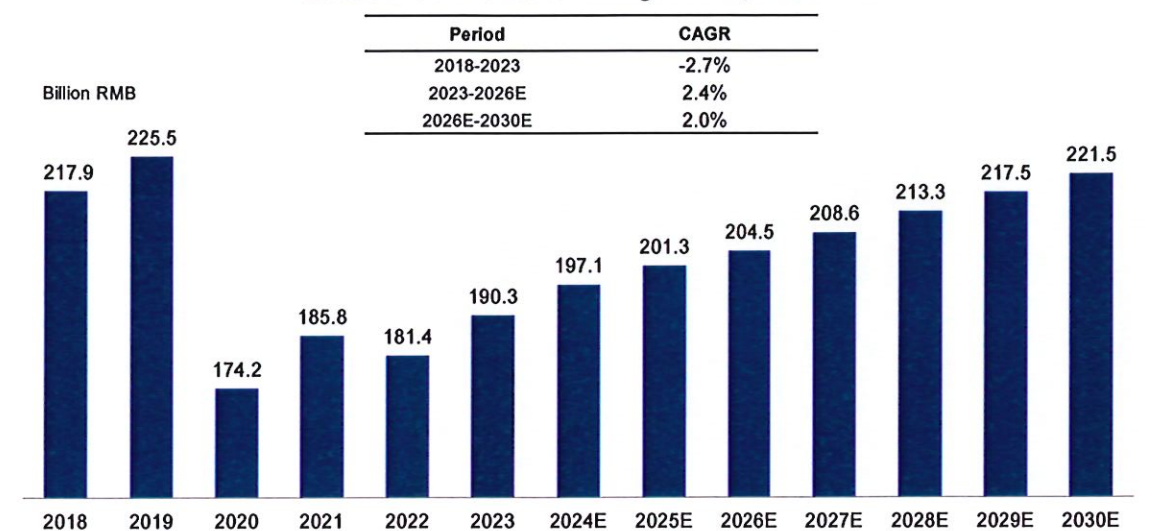
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## Market Size of Anti-infective Drug in China, 2018-2030E

- Due to the impact of the COVID-19 in 2020, the number of infective cases has decreased, and the market size has declined. In 2023, the market size of anti-infective drug in China reached 190.3 billion RMB. It is predicted that the market size of anti-infective drug in China will continue to grow in the future, reaching 204.5 billion RMB in 2026 and further increasing to 221.5 billion RMB in 2030.

Market Size of Anti-infective Drug in China, 2018-2030E



Source: NHC, Frost & Sullivan Analysis

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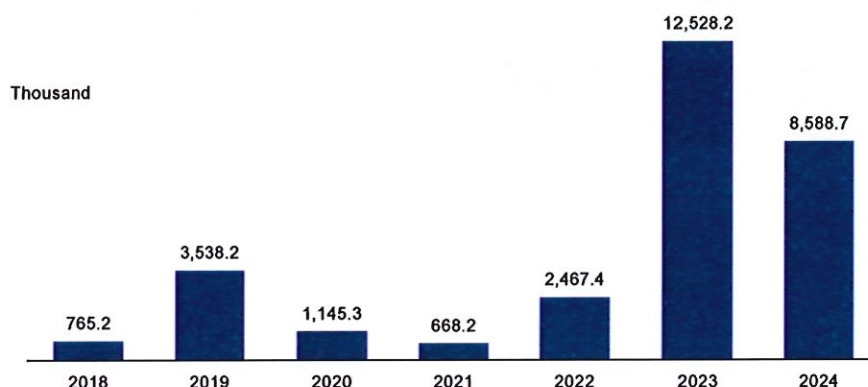
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## Number of New Influenza Cases Reported in China

- Influenza is an infectious disease, with a high incidence in children under 5 and the elderly. In virus classification, influenza virus is the four genera RNA viruses of Orthomyxoviridae A/B/C/D. Cells infected by influenza will produce a large number of pro-inflammatory cytokines and chemokines, which can cause fever, headache, fatigue and other common symptoms.
- According to the Statistical Report on China's Health Care Development, there were 8.6 million new influenza cases reported in 2024.

New Influenza Cases Reported in China, 2018-2024



Source: Statistical Report on China's Health Care Development, Frost & Sullivan Analysis

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## Comparison of Main Influenza Antiviral Drugs in China

Drug Class	Neuraminidase inhibitor		Hemagglutinin inhibitors	M2 ion channel blocker	Cap-dependent endonuclease inhibitors
Mechanism	Bind to influenza virus neuraminidase and interfere with viral release from host cells		Inhibit the fusion of influenza virus lipid membrane with host cells	Block H <sup>+</sup> transport into the virus through M2 protein channel to prevent viral particles from uncoating	Inhibit viral replication by inhibiting viral RNA polymerase
Drug Name	Oseltamivir	Peramivir	Arbidol	Rimantadine	Baloxavir marboxil
Indication	Influenza A/B	Influenza A/B	Influenza A/B	Influenza A	Influenza A/B
Suitable Patient	All ages	All ages	Adult	Adult	Adults/Children over 5
Treatment/Prevention	Treatment/Prevention	Treatment	Treatment	Treatment/Prevention	Treatment
Dosage Form	Oral	Injection	Oral	Oral	Oral
Notice	Drug resistance is prone to develop after prolonged drug exposure or treatment with large therapeutic doses, especially in children, immunodeficient patients, and prophylactic users.		The efficacy and side effects should be closely observed as the clinical application data are limited in China.	Drug resistance and poor clinical safety	Avoid taking with dairy products, calcium-fortified drinks, laxatives with high cationic values, antacids, or oral supplements
Approval Time	2001.01	2013.01	2005.01	2001.01	2021.04

Note: 1. Traditional dosage forms (granules, capsules, etc.) can be used for the treatment of influenza A and B in adults and children over one year old;  
2. Dry suspension can be used for the treatment of influenza A and B in adults and children over 2 weeks.

Source: Frost & Sullivan analysis

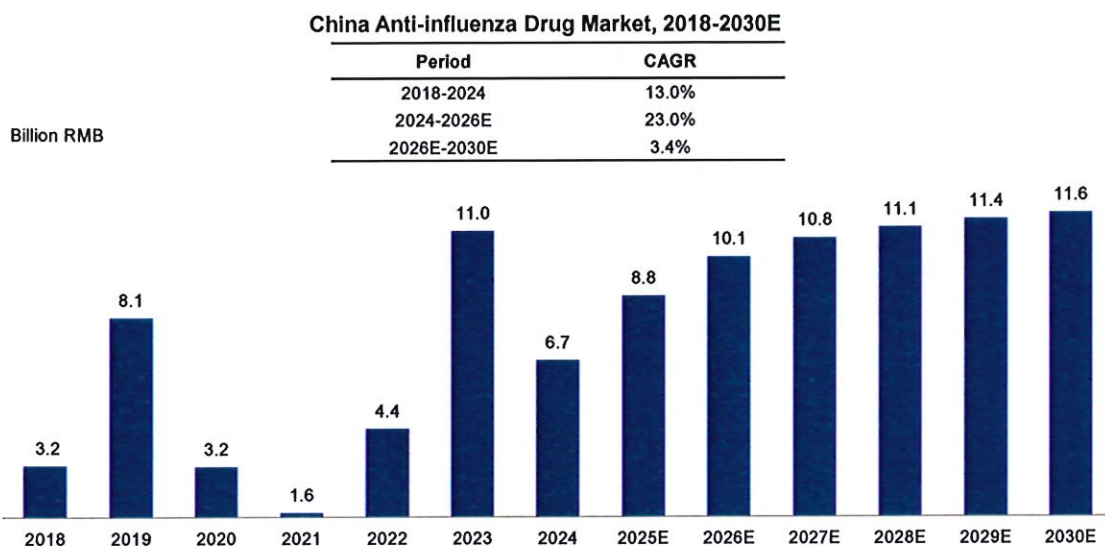
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## China Anti-influenza Drugs Market, 2018-2030E

- China anti-influenza drug market has achieved RMB 8.1 billion RMB in 2019. Due to the impact of the COVID-19 in 2020, the number of influenza cases has decreased, and the market size has declined. In 2023, the market dramatically grow to RMB 11.0 billion driven by the outbreak of influenza in China. Due to the reduction of influenza incidence in 2024, the market is reduced to 6.7 billion RMB. The market is expected to achieve RMB 11.6 billion in 2030.



Note: Excluding traditional Chinese medicines.

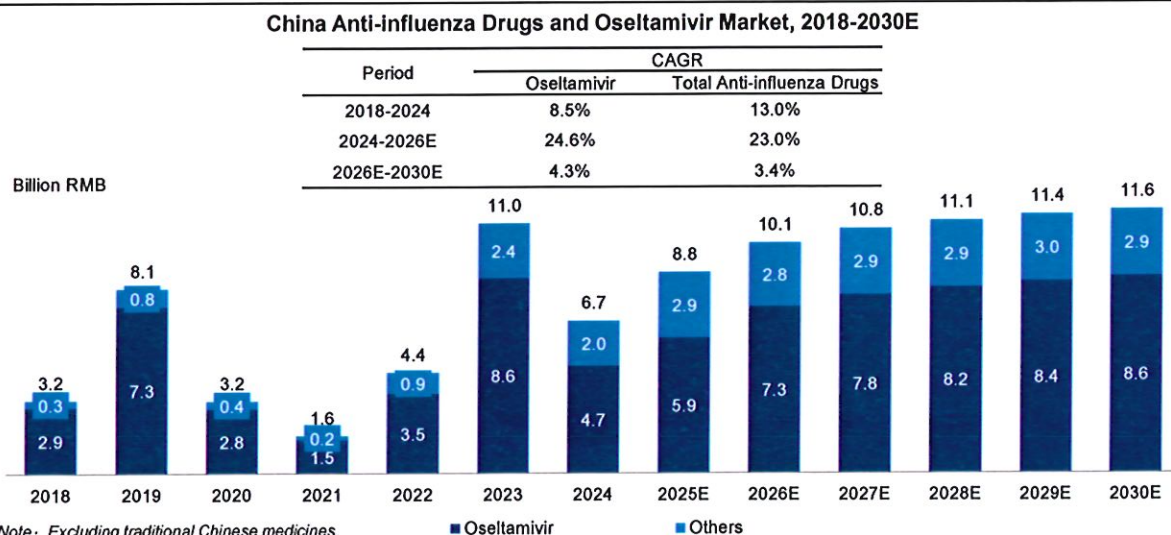
Source: Frost & Sullivan analysis

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## China Anti-influenza Drugs and Oseltamivir Market, 2018-2030E

- China anti-influenza drug market has achieved RMB 8.1 billion RMB in 2019. Due to the impact of the COVID-19 in 2020, the number of influenza cases has decreased, and the market size has declined. In 2023, the market dramatically grow to RMB 11.0 billion driven by the outbreak of influenza in China. Due to the reduction of influenza incidence in 2024, the market is reduced to 6.7 billion RMB. The market is expected to achieve RMB 11.6 billion in 2030.
- From 2018-2024, China oseltamivir drug market has increased from RMB 2.9 billion to RMB 4.7 billion, representing a CAGR of 8.5%. Due to the less severe influenza outbreak in 2024 compared to 2023, overall sales of oseltamivir have declined. As public awareness of influenza treatment increases and the penetration of antiviral drugs (including oseltamivir) continues to rise among patient populations, the market is expected to expand gradually. It is forecasted to reach to RMB 7.3 billion by 2026 and to RMB 8.6 billion by 2030, which represents a CAGR of 24.6% from 2024 to 2026, a CAGR of 4.3% from 2026 to 2030.



Note: Excluding traditional Chinese medicines.

Source: Frost & Sullivan analysis

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## Threats and Challenges of Anti-Influenza Drugs Market in China

<b>Emerging and Mutating Influenza Strains</b>	The continuous mutation of influenza viruses poses a significant challenge to the efficacy of existing antiviral drugs. While oseltamivir remains a widely used treatment, resistance to neuraminidase inhibitors has been reported in certain influenza strains, potentially reducing the drug's effectiveness. This could not only impact patient outcomes but also lead to decreased demand for existing drug. This necessitates ongoing R&D investments in next-generation antiviral therapies, which can be costly and time-consuming with uncertain commercial returns.
<b>Policy Changes May Introduce Market Uncertainty</b>	The Chinese government's drug procurement and price control policies may impact the influenza drug market. For example, the Volume-Based Procurement (VBP) policy could lead to further price reductions, squeezing profit margins for manufacturers. Additionally, adjustments to the reimbursement drug list and changes in insurance policies may affect market performance. While these policies aim to improve drug accessibility, they may also increase market uncertainty and operational risks for companies.
<b>Intensifying Competition from Domestic Players</b>	The Chinese anti-influenza drug market is highly competitive. Currently, leading companies such as Roche, Sunshine Lake Pharma, and Guangzhou Yipinhong dominate approximately 85% of the market. However, the increasing participation of generic drug manufacturers has intensified price competition. For example, the expiration of Sunshine Lake Pharma's key patent for oseltamivir has further lowered the entry barrier, allowing more companies to introduce oseltamivir and other antiviral treatments, thereby increasing competitive pressure on well-established brands.
<b>Rising Influenza Vaccination Rates</b>	As China's influenza vaccination rate gradually increases, the demand for antiviral drugs may be impacted to some extent in the future. According to data from the Chinese Center for Disease Control and Prevention (CDC), the influenza vaccination rate was approximately 2.47% during the 2021–2022 flu season and increased to around 3.84% in the 2022–2023 flu season, showing an upward trend. Since this figure remains significantly lower than that of developed Western countries, the government is promoting vaccination programs to improve coverage. If the vaccination rate rises substantially, the number of influenza infections may decline, reducing the reliance on antiviral drugs. Although vaccination cannot completely eliminate the need for antiviral treatments, this trend could pose a potential challenge to market growth.

Source: Frost & Sullivan Analysis

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## Entry Barriers of Anti-Influenza Drugs Market in China

<b>R&amp;D Capability</b>	Influenza viruses mutate and camouflage to evade recognition and elimination by the immune system. Resistance to existing drugs has become a serious problem which requires companies to have strong R&D Capability. Meanwhile, it takes a lot of time and money.
<b>Competitive Market</b>	At present, the anti-influenza market is dominated by a few leading companies. For example, sales of oseltamivir still accounts for the majority of anti-influenza market, and the revenue of leading company, The Group, account for 88.5% of Oseltamivir market in China in 2022. A number of enterprises participated in the centralized procurement. The head enterprises improve the barriers to competition through continuous layout and expansion of product lines in order to achieve long-term victory.
<b>Sales Channels Capabilities</b>	At present, hospital channels and retail channels are the main sales channels for anti-influenza drugs. Doctors diagnose and prescribe drugs based on symptoms, so new entrants need to compete with drugs that have already been included in the centralized procurement, which is preferred by physicians. In addition, building and maintaining strong relationships with retail channel partners is a key to increase the drug's market penetration.
<b>Branding Capabilities</b>	The consumption of flu medicine has a brand tendency. When patients have mild flu symptoms, some patients wait for their body to self recover. Due to limited knowledge of medication, consumers often choose to purchase drugs based on brand awareness, or follow doctor's advice and recommendations. In order to appeal more consumers, the company need a certain amount of funding for marketing purposes
<b>Scalable Production Capabilities</b>	To meet market demand, companies need to have the capability for scaled production. Every flu outbreak, anti-influenza drugs will experience stockouts. After oseltamivir was included in the centralized procurement in 2022, this phenomenon has not been alleviated. New entrants need to be able to quickly expand production scale to address the peak demand during flu seasons and may face challenges in establishing a reliable supply chain.

Source: Frost & Sullivan Analysis

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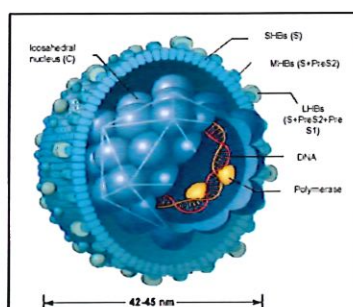
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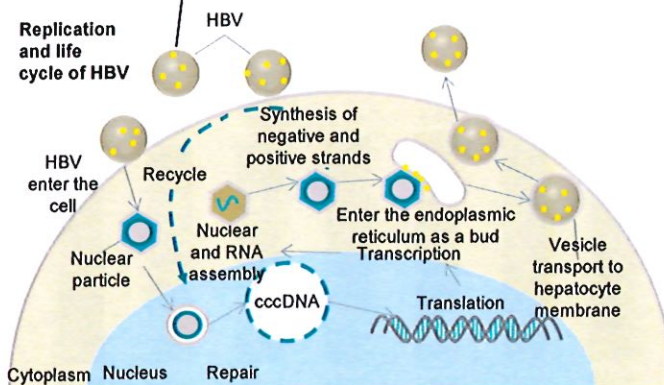
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2.1	Overview of the Anti-Infective Drugs Market
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## Overview of HBV Infection



### Description

- Hepatitis B is caused by hepatitis B virus (HBV). It is an infectious disease characterized by inflammation of the liver. The clinical symptoms include loss of appetite, liver pain, and weakness. HBV infection could develop into chronic hepatitis, cirrhosis, liver failure and liver cell carcinoma.
- Hepatitis B virus is mainly transmitted through parenteral routes such as blood, mother infant and sexual contact. It cannot transmit through respiratory tract or digestive tract. Hepatitis B serological markers are the necessary indicators for the diagnosis of hepatitis B virus infection. HBV DNA detection reflects the situation or level of virus replication.



### Mechanism of Action

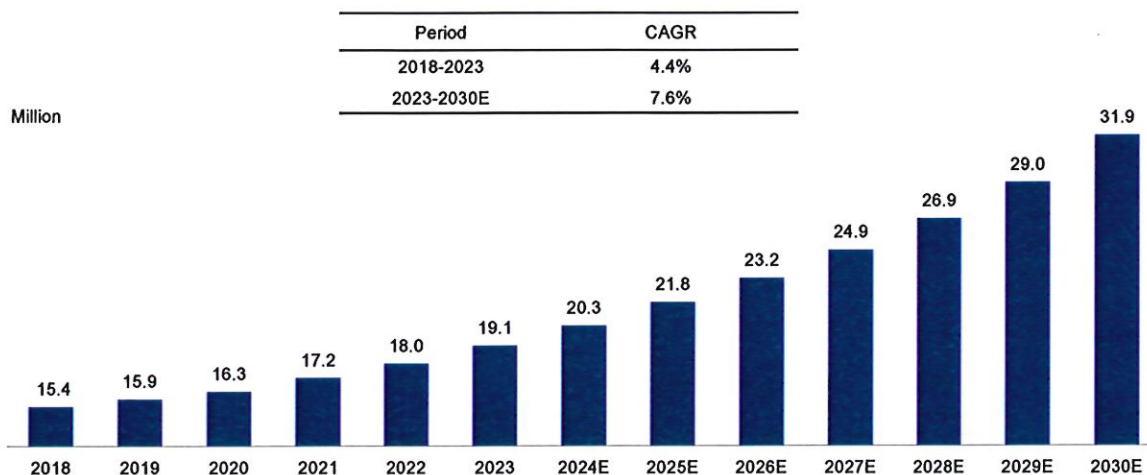
- The pathogenesis of chronic HBV infection is complicated and has not been fully discovered yet. HBV does not kill hepatocytes directly. The immune response caused by virus is the main mechanism of hepatocyte injury and inflammatory necrosis. The persistence or recurrence of inflammatory necrosis is an important factor in the progression of chronic HBV infection to liver cirrhosis and liver cancer.



## Number of Diagnosed Patients of Chronic Hepatitis B in China, 2018-2030E

- With the enhancement of health management awareness of patients with hepatitis B, the progress of detection of hepatitis B in primary medical institutions, and the listing of many innovative HBV drugs in the future, the number of patients diagnosed with hepatitis B in China will increase rapidly in the future.
- In 2018, the number of patients diagnosed with chronic hepatitis B in China was about 15.4 million, and in 2023 it was about 19.1 million, with a compound annual growth rate of 4.4%. It is estimated that it will reach about 31.9 million people in 2030 with a CAGR of 7.6%.

Number of Diagnosed Patients of Chronic Hepatitis B in China, 2018-2030E



Source: NCCR, Medicine, 2020, 99(39); Journal of ethnopharmacology, 2020, 249: 112412; Journal of Practical Oncology 2021, 36(01): 89-94; Frost & Sullivan Analysis

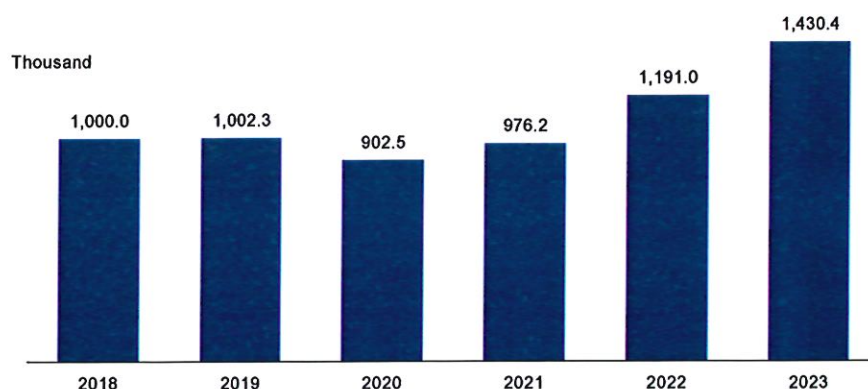
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## Number of New Hepatitis B Cases Reported in China

- According to the Statistical Report on China's Health Care Development, there were 1.4 million new hepatitis B cases reported in 2023.

New Hepatitis B Cases Reported in China, 2018-2023



Source: Statistical Report on China's Health Care Development, Frost & Sullivan Analysis

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## Treatments of Chronic HBV Infection

- Treatment goals of HBV infected patients are to maximize long-term inhibition of HBV replication, alleviate the degree of hepatocyte inflammation, necrosis, and hyperplasia of liver fibrous tissue, delay and reduce the occurrence of liver failure, decompensation of liver cirrhosis, HCC and other complications, and to improve the quality of patients' life as well as prolong their survival duration. For eligible patients, the therapy aim to achieve functional cure (or clinical cure), which refers to HBsAg seroclearance, with or without the presence of anti-HBs, based on continuous undetectable HBV DNA and HBeAg, and normal liver biochemical indicators a finite course of treatment.
- Patients should be assessed for the risk of disease progression to determine whether to start antiviral therapy based on a comprehensive analysis of serum HBV DNA levels, ALT levels, the severity of liver disease, as well as their age, family history, and concomitant diseases. Antiviral therapy is crucial for preventing the progression of cirrhosis, slowing down the progression of compensatory cirrhosis to decompensated cirrhosis, and reducing the incidence of HCC. Anti HBV drugs in China mainly include two categories: nucleoside analogues (NAs) and interferon (IFN).

### NAs and IFN treatment

Treatments	Drugs	Mechanism	Efficacy	Safety
Nucleoside analogues (NAs)	<ul style="list-style-type: none"> <li>Entecavir (ETV)</li> <li>Tenofovir Disoproxil Fumarate (TDF)</li> <li>Tenofovir Alafenamide Fumarate (TAF)</li> <li>Tenofovir Amibufenamide (TMF)</li> <li>Adefovir dipivoxil (ADV)</li> <li>L-Deoxythymidine (LdT)</li> </ul>	Inhibiting the reverse transcription of pregenomic RNA to HBV DNA. Ineffective in eliminating cccDNA and passivating immune responses	<ul style="list-style-type: none"> <li>HBeAg-positive patients: HBV DNA levels were &lt; 400 cps/mL in 64-76.7% of the patients at week 48 after drug discontinuation</li> <li>HBeAg-negative patients: HBV DNA levels were &lt; 400 cps/mL in more than 90% of patients at week 48 after drug discontinuation</li> </ul>	Generally safe and well-tolerated, serious adverse events such as renal insufficiency (TDF, ADV), hypophosphatemic bone disease (TDF, ADV), myositis/rhabdomyolysis (LdT), and lactic acidosis (ETV, LdT) can occur in rare cases, and require attention.
Interferon (IFN)	<ul style="list-style-type: none"> <li>IFN-<math>\alpha</math></li> <li>Peg-IFN-<math>\alpha</math></li> </ul>	Multiple processes that affect virus replication with average potency and high risk of resistance	<ul style="list-style-type: none"> <li>HBeAg-positive patients: HBV DNA levels were &lt; 2,000 IU/mL in 30% of the patients after drug discontinuation</li> <li>HBeAg-negative patients: HBV DNA levels were &lt; 2,000 IU/mL in 43% and 42% of patients at 24 and 48 weeks after drug withdrawal</li> </ul>	Generally adverse reactions are influenza-like syndrome, myelosuppression, mental disorders, and autoimmune diseases.

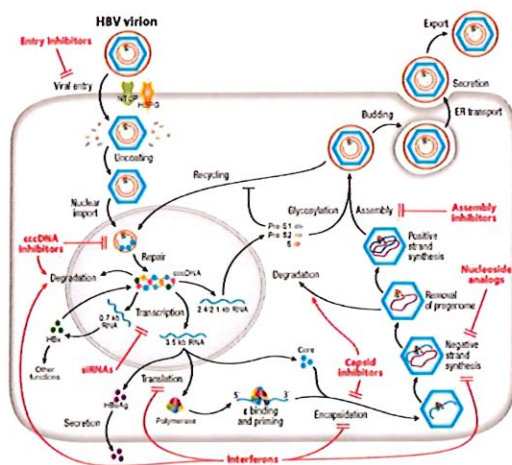
Source: Chronic Hepatitis B Guideline, Literature Search, Frost & Sullivan Analysis

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## Comparison of Capsid Inhibitor and Other Drugs in HBV Treatment

- HBV is a type of DNA virus that exists in the nucleus with a more stable structure and more complex functions, making it more difficult to fully eliminate. cccDNA is the template for the replication of pre-genome RNA of hepatitis B virus. Thus, for patients, both hepatitis B virus and cccDNA should be entirely removed.
- Current HBV therapeutics aimed at suppressing viral replication. However, it is ineffective as a cure for the disease as they do not eradicate cccDNA, which is in favor of viral persistence.



### The Advantages of Capsid Inhibitor

- **Capsid Inhibitors:** disrupt the encapsidation of pre-genomic RNA and can cause nucleocapsid disassembly, thereby affecting multiple steps of HBV replication and reduction of cccDNA pools.
- **Higher efficiency and promises in combo-therapy:** the combination of capsid assembly inhibitors and NAs may further reduce viral load and be more conducive to HBV specific immune reconstruction.

### The Limitation of Other HBV Drugs

- **Current HBV treatments using nucleos(t)ide analogs (NAs) and PEG Interferons:** cannot fully alleviate this burden as they do not affect the transcriptional activity of the tenacious cccDNA responsible for viral persistence.
- **$\alpha$ -Interferon and polyethylene glycol long-acting interferon** are only effective for 30% of hepatitis B patients, and their cure rate is about 7% to 8%, and require injections. The side effects are obvious, making them greatly restricted in clinical application;

Source: ClinicalTrials, Frost & Sullivan Analysis

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## Entry Barriers of China Anti-HBV Drugs Market

### R&D Capability

Hepatitis B is an acute or chronic inflammation of the liver caused by hepatitis B virus (HBV) infection. HBV is a specific hepatophilic DNA virus, which forms cccDNA in the nucleus after invading hepatocytes, and then uses cccDNA as a template to maintain life and reproduction, cccDNA has a long half-life and is difficult to completely remove from the body, which is the fundamental factor that hepatitis B is difficult to cure, and it is not yet completely curable. In addition, clinical trials of hepatitis B drugs require a large number of cases and long-term follow-up, which increases the difficulty and cost of research and development.

### Regulatory Environment

In 2016, the WHO proposed the goal for elimination of hepatitis B as public health threat, by 2030. China has the heaviest burden caused by hepatitis B virus (HBV) infection in the world, and serves as the major contributor to the goal of eliminating hepatitis B by 2030. There is still a long way to achieve the targets. The R&D, production, and distribution of pharmaceuticals are all subject to strict regulation and the need to meet various regulations and standards, which poses a high barrier to entry for new entrants.

Source: Frost & Sullivan Analysis

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## Growth Drivers of China Anti-HBV Drugs Market

### Large Patient Pool and Growing Awareness

- In 2022, the number of patients diagnosed with chronic hepatitis B in China was about 18.0 million, with a compound annual growth rate of 4.0%. It is estimated that it will reach about 22.5 million people in 2026 with a CAGR of 5.7% and reach about 31.6 million people in 2030 with a CAGR of 8.9%. According to the Statistical Report on China's Health Care Development, the number of reported cases of new hepatitis B patients in China has been increasing in recent years and there were 1.4 million new hepatitis B cases reported in 2023. Increasing awareness among HBV infected patients about the importance of early detection and treatment of HBV drives market growth.

### Increasing Healthcare Spending and Government Initiatives

- The rising healthcare expenditure in China allows for increased access to anti-HBV treatments, boosting market growth. In addition, China has instituted a variety of strategies and programs over time to control hepatitis B. For example, in 2017 China announced its national comprehensive action plan for viral hepatitis, which includes a plan to lower medicine costs and make more medical services and consultation on viral hepatitis available.

### Technological Advancements

- Advances in drug development and treatment options enhance the efficacy and accessibility of anti-HBV therapies, supporting market expansion. For example, capsid inhibitors disrupting the formation and function of the viral capsid, which plays a crucial role in the replication of HBV within infected hepatocytes, are expected to drive market growth. In addition, RNAi-based therapies have emerged as a novel approach to silence HBV gene expression and replication.

Source: Frost & Sullivan Analysis

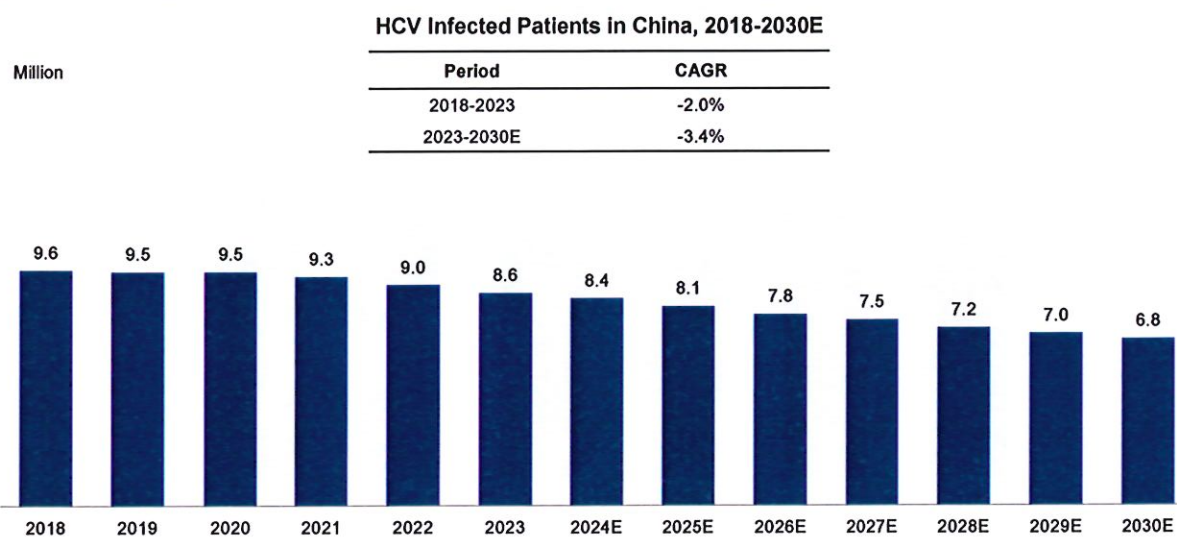
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## HCV Infected Patients in China, 2018-2030E

- The number of HCV-infected patients in China is decreasing year by year due to increased awareness of hepatitis C and the availability of curable drugs. However, because of the large population pool in China, the insidious nature of HCV infection, and the lower treatment rate than that of western developed countries, the number of HCV-infected patients is still large.
- The HCV-infected population in China was 8.6 million in 2023. The total number is estimated to reach 7.8 million by 2026, and reach 6.8 million in 2030.



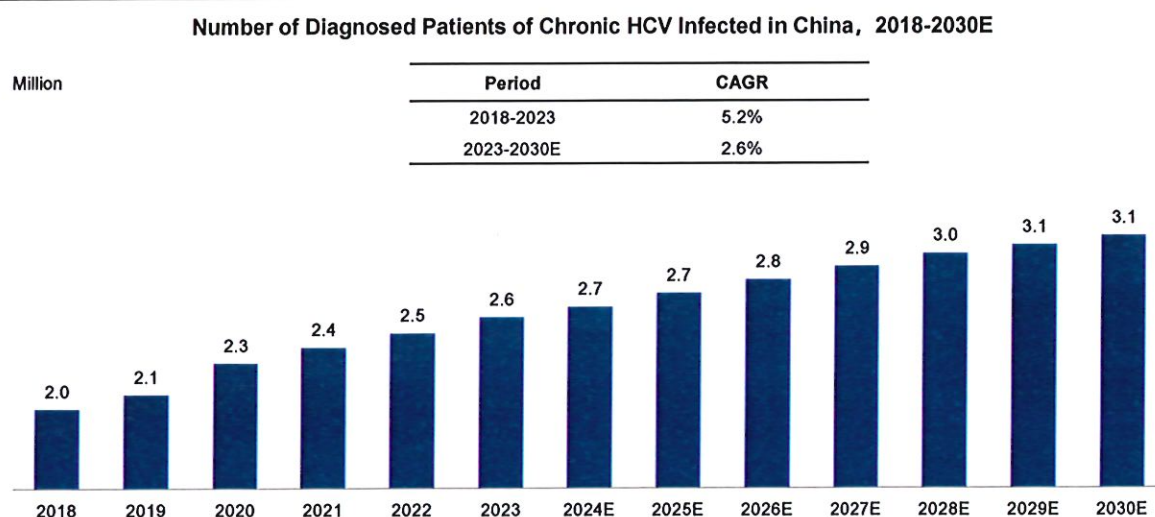
Source: Frost & Sullivan Analysis

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## Number of Diagnosed Patients of Chronic HCV Infected in China, 2018-2030E

- The current diagnosed rate of chronic hepatitis C in China is extremely low because of many factors including the lack of representative symptoms.
- Currently, the treatments are capable of fully curing HCV already. With the increasing awareness of health management of HCV, the HCV diagnosed rate would increase rapidly. The number of diagnosed patients of chronic hepatitis C in China was 2.6 million in 2023. The total number is estimated to increase, reaching 2.8 million in 2026, and reaching 3.1 million in 2030.



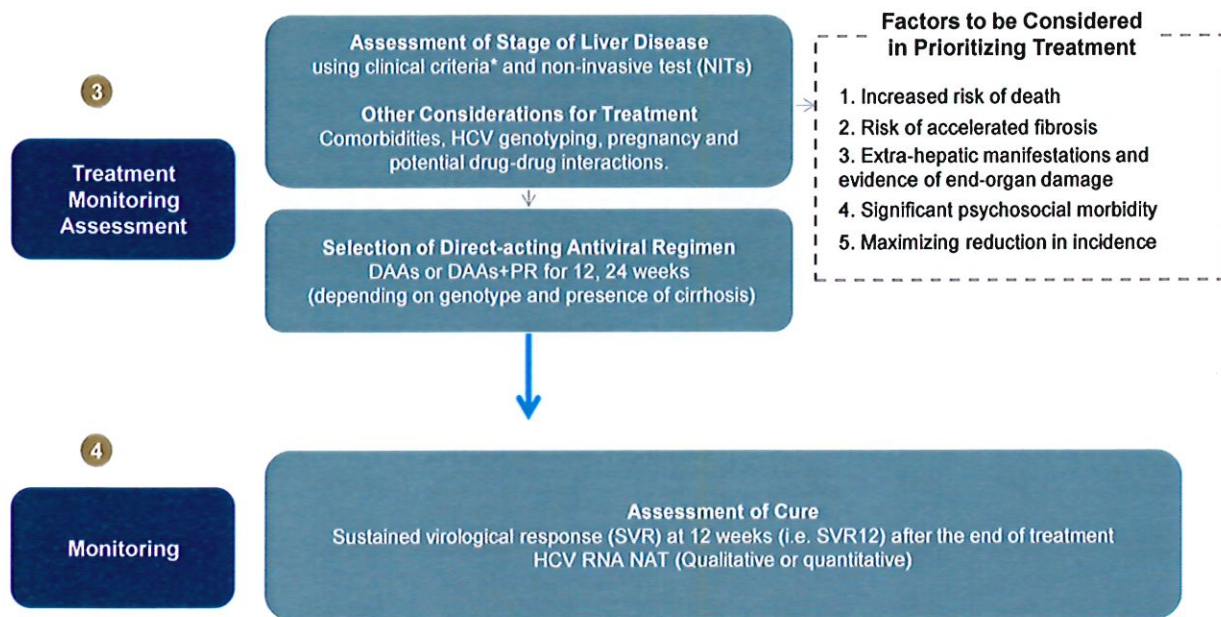
Source: Frost & Sullivan Analysis

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## Summary Algorithm for Diagnosis, Treatment, and Monitoring of Chronic HCV Infection (Continued)



\* Decompensated cirrhosis is defined by the development of portal hypertension (ascites, variceal haemorrhage and hepatic encephalopathy), coagulopathy, or liver insufficiency (jaundice). Other clinical features of advanced liver disease/cirrhosis may include: hepatomegaly, splenomegaly, pruritus, fatigue, arthralgia, palmar erythema, and oedema.

Source: WHO, Frost & Sullivan Analysis

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## The Medication Regimen of HCV Infection

- Before the approval of direct antiviral agents (DAAs) for hepatitis C, the treatment of hepatitis C in China was based on the combination of interferon and ribavirin, which had a cure rate of only 44% to 70%.
- As DAAs with excellent sustained virologic response rate (SVR) have entered the Chinese market, the cure rate of hepatitis C has been greatly improved, bringing tangible benefits to Chinese hepatitis C patients.

### Treatments of Chronic HCV Infections

Treatments	Efficacy	Safety
Interferon combined with ribavirin	SVR rates: 80% in HCV-2/3/5/6 and 40%-50% in HCV-1/4	Generally well-tolerated. Fatigue, influenza-like symptoms, hematologic abnormalities, and neuropsychiatric symptoms are most common adverse events.
DAAs	SVR rates above 90%	Generally well-tolerated. Fatigue, anemia, and dizziness are the most common adverse events.
DAA Types		Representative Drugs
Pan-genotypic DAAs	NS5B polymerase nucleoside analog inhibitors/NS5A inhibitors	Sofosbuvir/Velpatasvir Alfobuvir/Daclatasvir Sofosbuvir/Cobopasvir
	NS5B polymerase nucleoside analog inhibitors/NS5A inhibitors/NS3/4A protease inhibitors	Sofosbuvir/Velpatasvir /Voxilaprevir
	NS3/4A protease inhibitors/NS5A polymerase nucleoside analog inhibitors	Glecaprevir/Pibrentasvir
Genotype-specific DAAs	NS3/4A protease inhibitors/NS5A inhibitors	Elbasvir/Grazoprevir
	NS3/4A protease inhibitors	Ravidasvir/Danoprevir
	NS5A inhibitors/NS5B polymerase nucleoside analog inhibitors	Eimidasvir/Sofosbuvir Ledipasvir/Sofosbuvir

### The Treatment Era of Pangenotypic DAAs

- According to the guideline for the prevention and treatment of hepatitis C (2022 version), interferon-free pangenotypic regimens are preferentially recommended, which achieve sustained virologic response (SVR) in more than 90% of HCV-infected patients with both known major genotypes and major genotypic subtypes, and are regimen-uniform in multiple populations with different clinical characteristics, with fewer drug-drug interactions. With the exception of a few specific populations who are decompensated cirrhosis, failure of treatment with DAAs, the Ribavirin therapy is not required in the regimens.
- In addition, the application of pan-genotypic regimens can reduce pre-treatment testing and in-treatment monitoring, and is also more suitable for implementing treatment and management of chronic HCV-infected patients at the grassroots level.

Source: Literature review, Frost & Sullivan Analysis

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