

# Bacterial Infection and Metabolism Drug Market Study

Confidential For

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For and on behalf of  
Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.



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丹诺医药

TENNOR THERAPEUTICS

*Frost & Sullivan*  
May 2026



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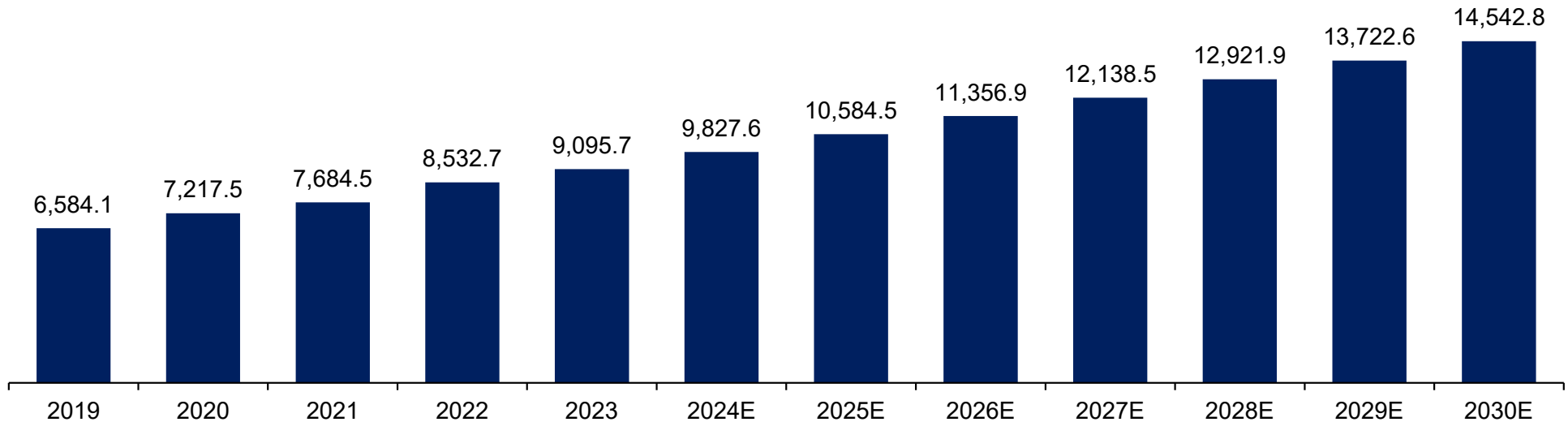
# Total Healthcare Expenditure in China, 2019-2030E

- In China, the total healthcare expenditure reached RMB 9,095.7 billion in 2023 at a CAGR of 8.4% from 2019. It is projected to further increase to RMB 11,356.9 billion in 2026, representing a CAGR of 7.7% from 2023. It is estimated that the number would achieve RMB 14,542.8 billion in 2030, representing a CAGR of 6.4% from 2026 to 2030.

## Total Healthcare Expenditure in China, 2019-2030E

Unit: Billion RMB

Period	CAGR
2019-2023	8.4%
2023-2026E	7.7%
2026E-2030E	6.4%



Source: National Health Commission, Frost & Sullivan Analysis

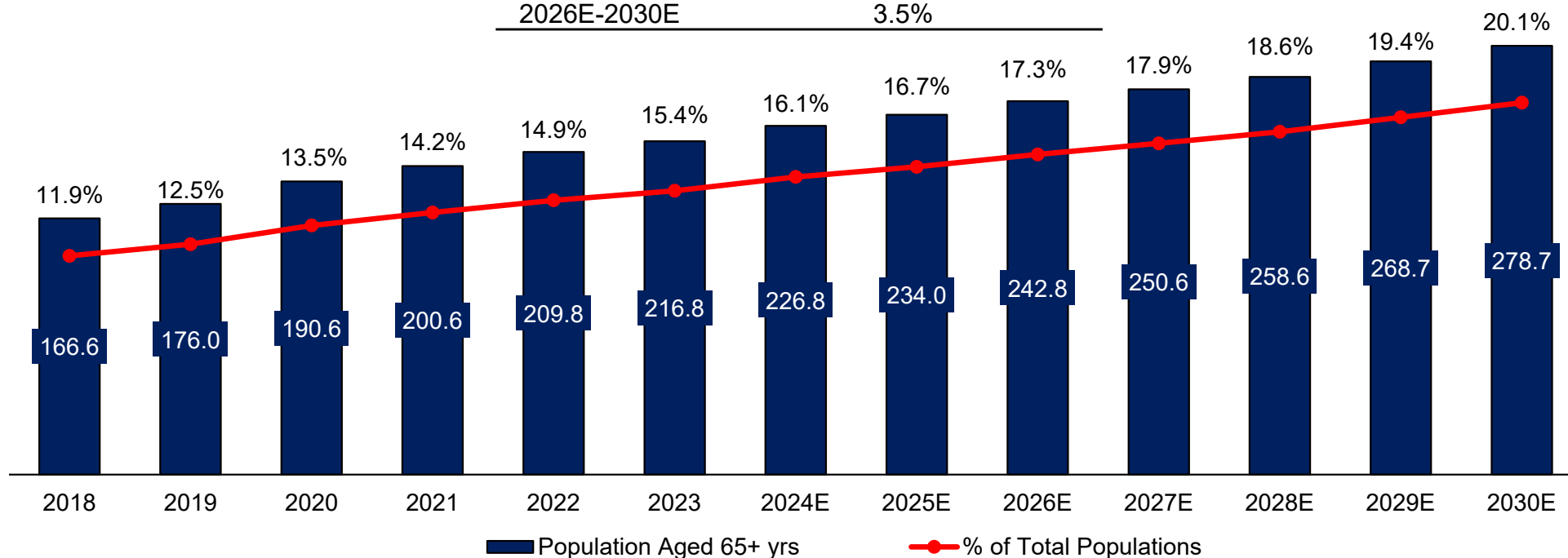
# China Aging Population Trend, 2018-2030E

- With the implementation of the 'One Child Policy' and increasing life expectancy, China has entered an aging society. From 2018 to 2023, the population is aging rapidly in China with people aged above 65 growing at a CAGR of 5.4%. According to the National Bureau of Statistics of China (NBSC), the number of individuals aged above 65 years old is estimated to be 216.8 million in 2023. The number of individuals aged above 65 years old is growing at a fairly fast pace and is expected to continue its growth momentum into the future. This number is expected to reach 278.7 million by 2030, representing a CAGR of 3.5% from 2026 to 2030.

## China Aging Population Trend, 2018-2030E

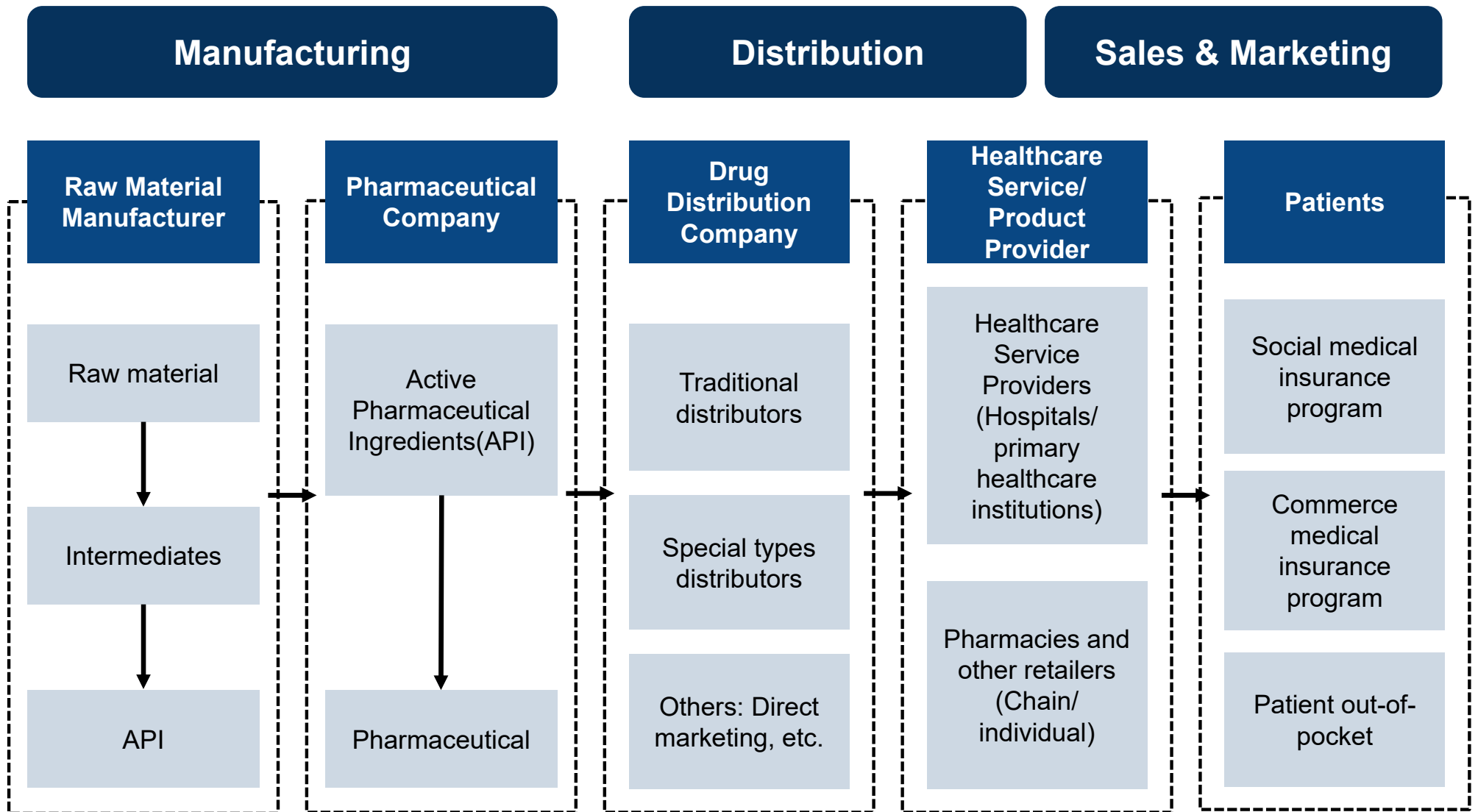
Unit: Million

Period	CAGR
2018-2023	5.4%
2023-2026E	3.9%
2026E-2030E	3.5%



Source: NBSC, Frost & Sullivan Analysis

# Industry Chain of Pharmaceutical Industry



Source: Frost & Sullivan Analysis

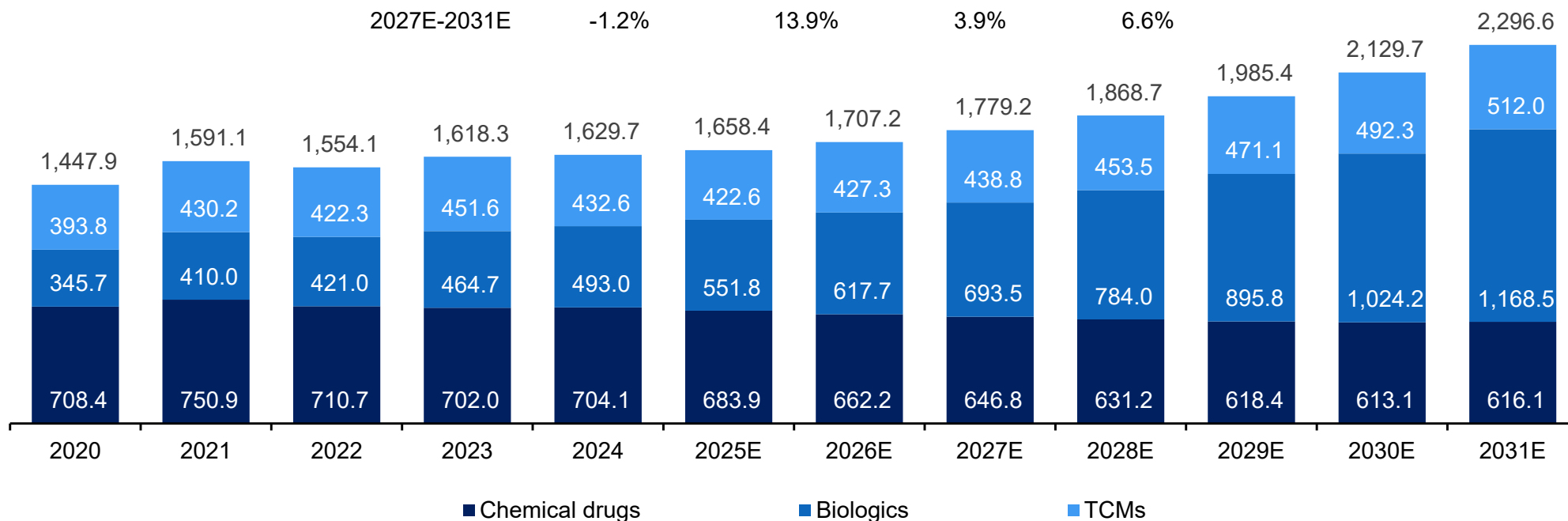
# Breakdown of China Pharmaceutical Market by Chemical Drugs, Biologics and TCMs, 2019-2030E

- China pharmaceutical market is composed by three segments, namely chemical drugs, biologics and Chinese medicines (TCMs), among which chemical drugs account for the largest market share. The size of China pharmaceutical market was RMB1,629.7 billion in 2024, and is expected to reach RMB1,779.2 billion and RMB2296.6 billion in 2027 and 2031 respectively, representing a CAGR of 7.9% from 2024 to 2027 and 6.4% from 2026 to 2030.

## Breakdown of China Pharmaceutical Market by Chemical Drugs, Biologics and TCMs, 2020-2031E

Unit: Billion RMB

CAGR	Chemical Drugs	Biologics	TCMs	Total
2020-2024	-0.2%	9.3%	2.4%	3.0%
2024-2027E	-2.8%	12.0%	0.5%	3.0%
2027E-2031E	-1.2%	13.9%	3.9%	6.6%



Source: Frost & Sullivan Analysis

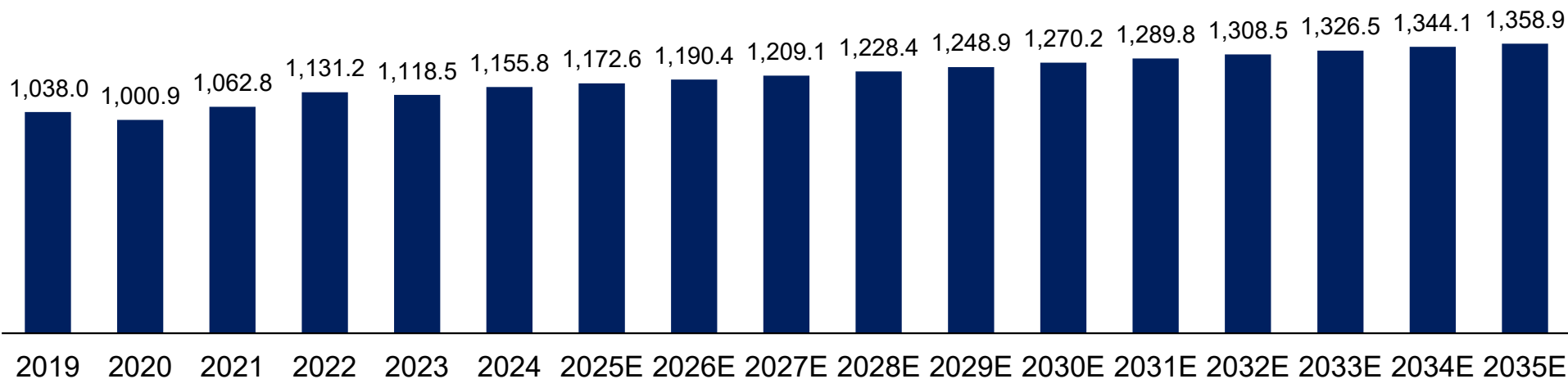
# Global Chemical Drugs Market, 2019-2035E

- In 2019, the market size was USD1,038.0 billion. From 2019 to 2024, it grew at a CAGR of 2.2%. In 2024, the market size reached 1,155.8 billion USD. The market size is expected to reach USD8.0 billion in 2027, with a CAGR of 1.6% from 2024 to 2029. The market will further grow to USD1,358.9 billion in 2035, with a CAGR of 1.4% from 2029 to 2035.
- In 2020, hospital resources focused on anti-epidemic efforts amid reduced non-urgent needs, cutting chronic treatments and elective surgeries, with lower demand for anti-cancer and cardiovascular drugs. In 2023, patent expiries for blockbusters like Humira and Stelara let generics hit original sales, while European and U.S. insurers strengthened negotiations (e.g., U.S. IRA Act), slashing prices of Januvia, Fiasp and Stelara.

## Global Chemical Drugs Market, 2019-2035E

Unit: Billion USD

Period	CAGR
2019-2024	2.2%
2024-2029E	1.6%
2029E-2035E	1.4%



Source: Frost & Sullivan Analysis

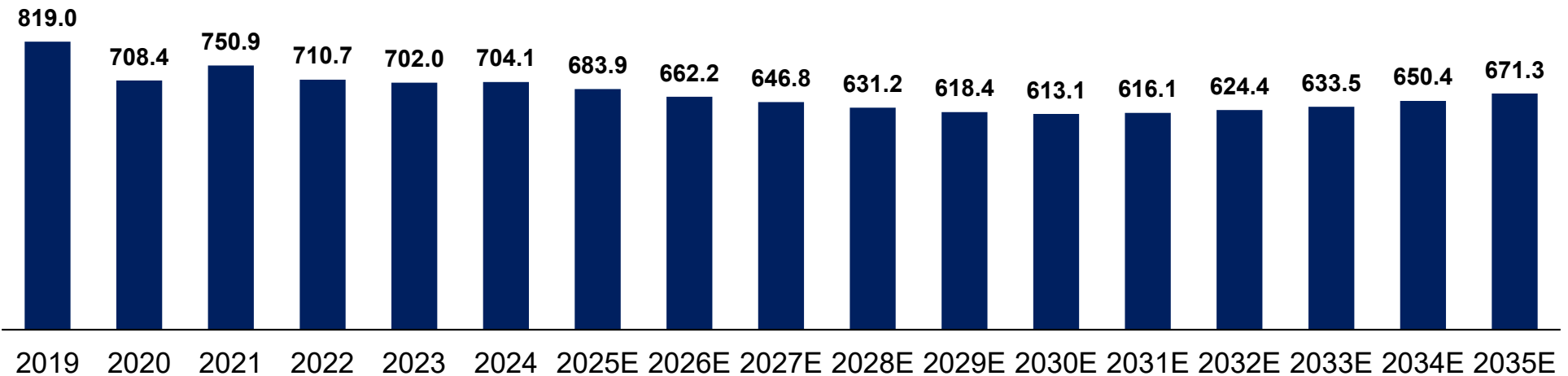
# China Chemical Drugs Market, 2019-2035E

- In 2019, the market size was RMB819.0 billion. From 2019 to 2024, it grew at a CAGR of -3.0%. In 2024, the market size reached RMB704.1 billion. The market size is expected to reach RMB646.8 billion in 2027, with a CAGR of -2.6% from 2024 to 2029. The market will further grow to RMB671.3 billion in 2035, with a CAGR of -1.0% from 2029 to 2035.
- The national volume-based procurement and medical insurance negotiation policies have led to significant price reductions for pharmaceuticals, while the consistency evaluation of generic drugs has eliminated outdated production capacity.

## China Chemical Drugs Market, 2019-2035E

Unit: Billion RMB

Period	CAGR
2019-2024	-3.0%
2024-2029E	-2.6%
2029E-2035E	-1.0%



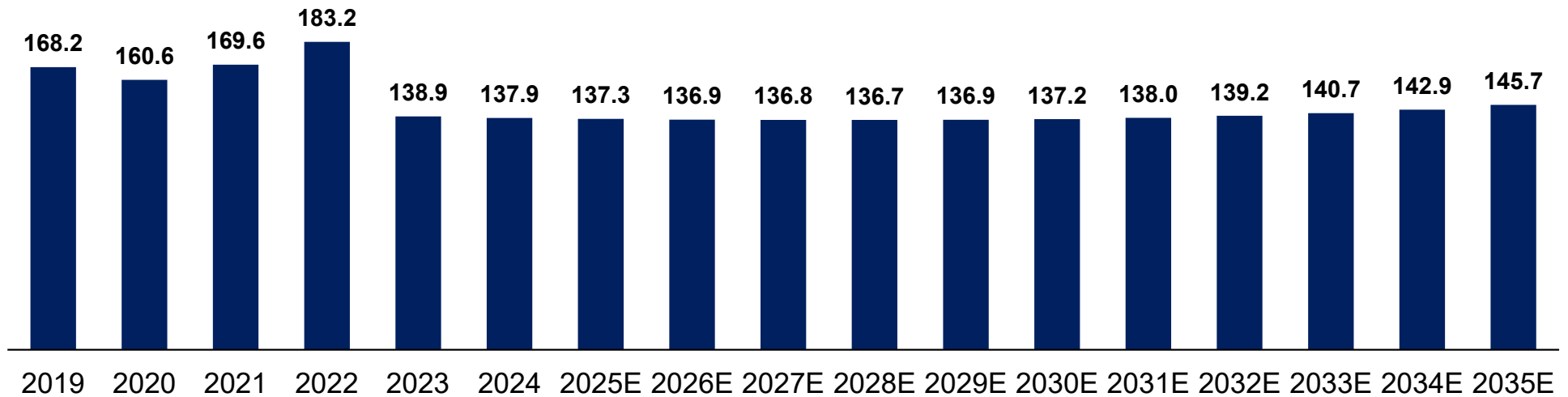
# Global Anti-infectives Drugs Market, 2019-2035E

- In 2019, the market size was USD 168.2 billion. From 2019 to 2024, it grew at a CAGR of -3.9%. In 2024, the market size reached USD137.9 billion. The market size is expected to reach USD136.8 billion in 2027, with a CAGR of -0.2% from 2024 to 2029. The market will further grow to USD145.7 billion in 2035, with a CAGR of 1.1% from 2029 to 2035.
- In 2023, sales of anti-COVID-19 drugs and vaccines such as Paxlovid and Molnupiravir dropped significantly due to the end of the global pandemic and a sharp decline in demand. Additionally, the expiration of patents for multiple HIV drugs in 2023 and the subsequent surge in generic drug availability was another factor contributing to the market decline.

## Global Anti-infectives Drugs Market, 2019-2035E

Unit: Billion USD

Period	CAGR
2019-2024	-3.9%
2024-2029E	-0.2%
2029E-2035E	1.1%



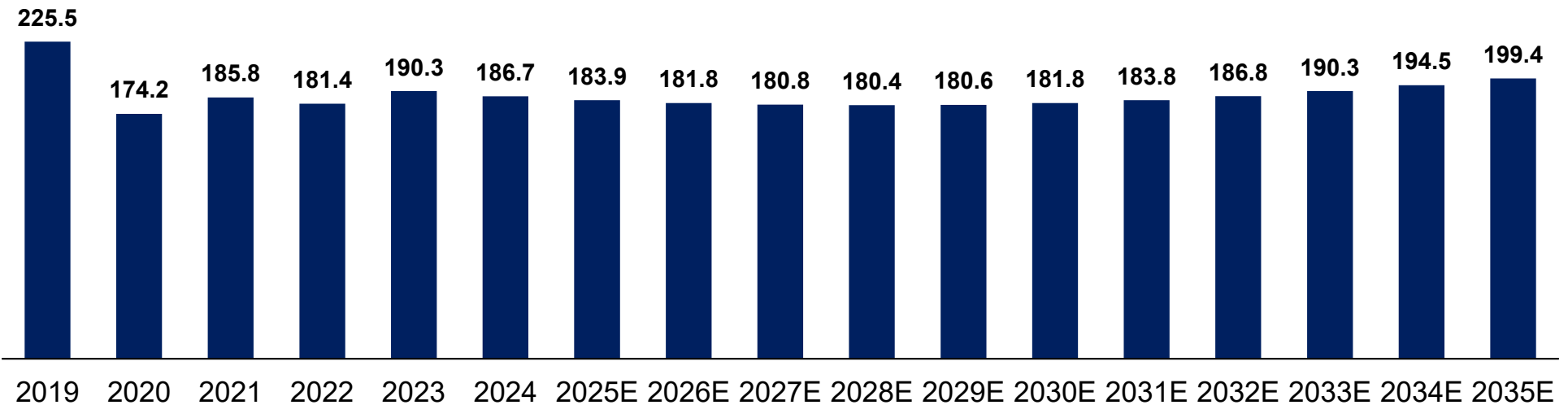
# China Anti-infectives Drugs Market, 2019-2035E

- In 2019, the market size was 225.5 billion USD. From 2019 to 2024, it grew at a compound - annual - growth rate (CAGR) of -3.7%. In 2024, the market size reached 186.7 billion USD. The market size is expected to reach USD 180.8 billion in 2027, with a CAGR of -0.7% from 2024 to 2029. The market will further grow to USD 199.4 billion in 2035, with a CAGR of 1.7% from 2029 to 2035.
- In 2020, the number of medical consultations plummeted due to the COVID-19 pandemic, coupled with price reductions under the first round of volume-based procurement, leading to a decline. In 2022 and 2024, the downward trend continued due to the ninth round of volume-based procurement and the deepening of antibiotics restriction policies.

China Anti-infectives rugs Market, 2019-2035E

Unit: Billion RMB

Period	CAGR
2019-2024	-3.7%
2024-2029E	-0.7%
2029E-2035E	1.7%



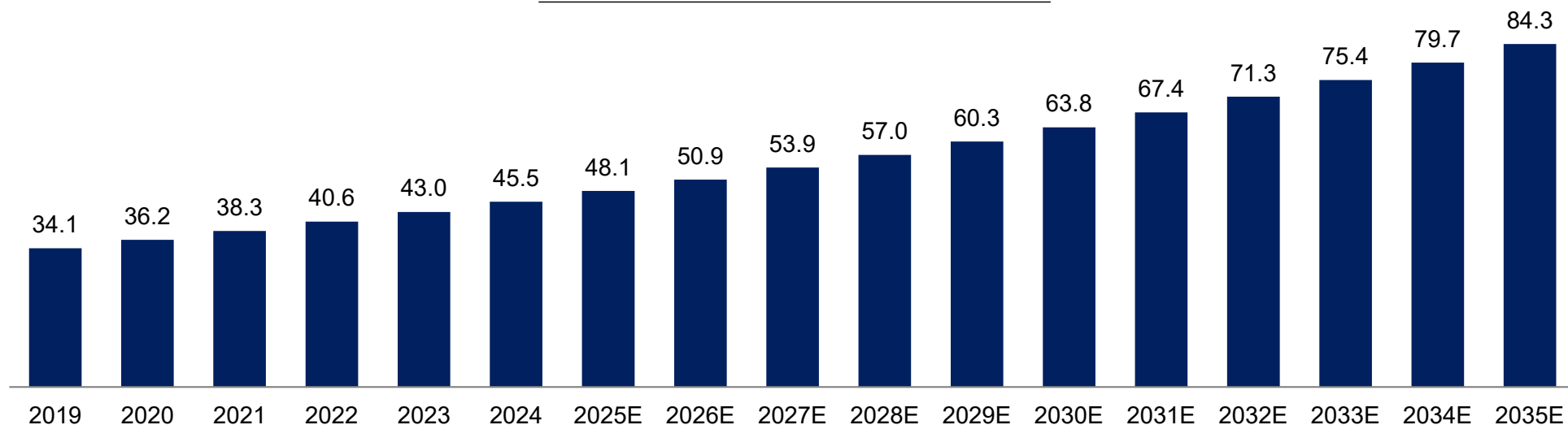
# Global Antibacterial Agents Market Size

- In 2019, the market size was USD34.1 billion. From 2019 to 2024, it grew at a CAGR of 5.9%. In 2024, the market size reached USD45.5 billion. The market size is expected to reach USD60.3 billion in 2029, with a CAGR of 5.8% from 2024 to 2029. The market will further grow to USD84.3 billion in 2035, with a CAGR of 5.7% from 2029 to 2035..

## Global Antibacterial Agents Market Size, 2019-2035E

Unit: Billion USD  
At wholesales price level

Period	CAGR
2019-2024	5.9%
2024-2029E	5.8%
2029E-2035E	5.7%



Source: Frost & Sullivan analysis

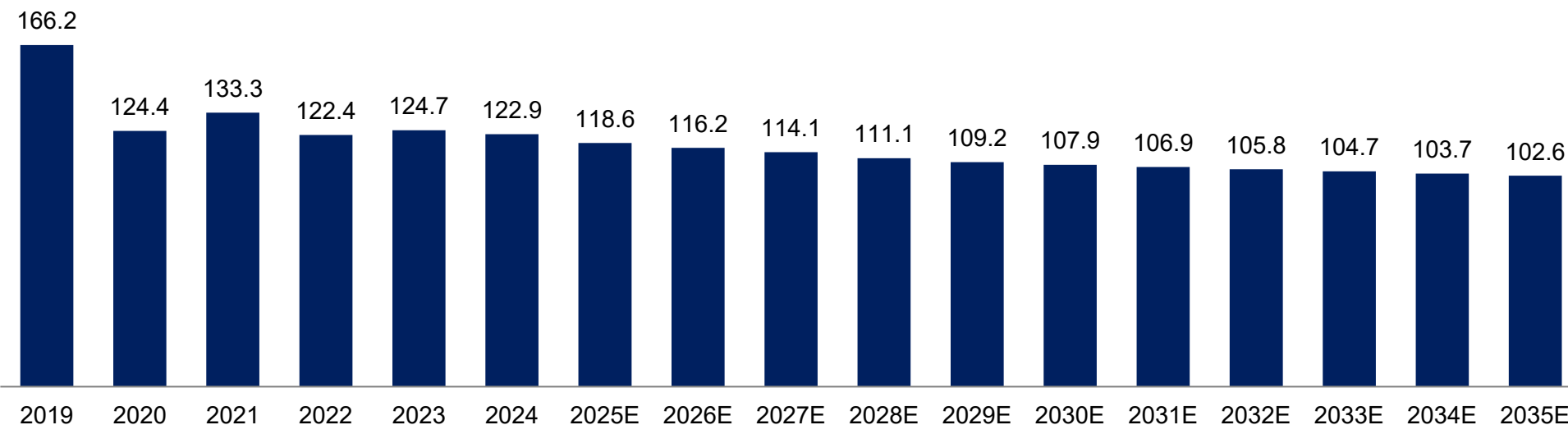
# China Antibacterial Agents Market Size

- China's systemic antibiotic market declined from RMB 166.2 billion in 2019 to RMB 124.4 billion in 2020, rebounded to RMB 133.3 billion in 2021, then dropped to RMB 122.4 billion in 2022 and slightly recovered to RMB 124.7 billion in 2023. While the long-term decline reflects strengthened antimicrobial stewardship and hospital prescribing restrictions, short-term fluctuations were driven by VBP. In 2021, despite early signs of recovery, key products like piperacillin/tazobactam and cefoperazone/sulbactam had already entered VBP with significant price cuts, partially offsetting market growth. The later inclusion of ceftazidime in late 2021, followed by broader procurement in 2022–2023, drove further market contraction—ceftazidime alone saw a nearly 60% YoY drop after its price cut.

## China Prosthetic Joint Infection Drugs Market Size, 2019-2035E

Unit: Billion RMB  
At ex-factory price level

Period	CAGR
2019-2024	-5.9%
2024-2029E	-2.3%
2029E-2035E	-1.0%



Source: Frost & Sullivan analysis

# Market Trends and Key Growth Drivers of China Pharmaceutical Market

## Growing Disease Incidence

- Driven by unhealthy lifestyles, pollution, and the aging population, the number of patients with chronic diseases in China continues to expand. For example, in the therapeutic areas of Company's products, total annual cancer incidence in China increased from 4,521.4 thousand in 2019 to **5,026.4 thousand in 2024**, and this number is expected to reach **5,533.3** thousand in 2030. In the area of metabolic diseases, prevalence is also expected to increase. Chemical drugs have excellent clinical effects on many chronic diseases, including cancer and diabetes, and the huge patient population pool will further drive market growth.

## Increasing Healthcare Expenditure

- The total healthcare expenditure of China has experienced steady growth. From 2019 to 2024, the total healthcare expenditure of China has increased from RMB 6,584.1 billion to RMB 9,764.1 billion, representing a CAGR of 8.3%. Furthermore, the rapid increasing trend in China's healthcare expenditures is expected to continue in the near future. The total healthcare expenditure of China is forecasted to reach to RMB **14,549.9** billion by 2030, which represents a CAGR of 6.8% from 2023 to 2030.

## Regulatory Reform and Favorable Government Policies

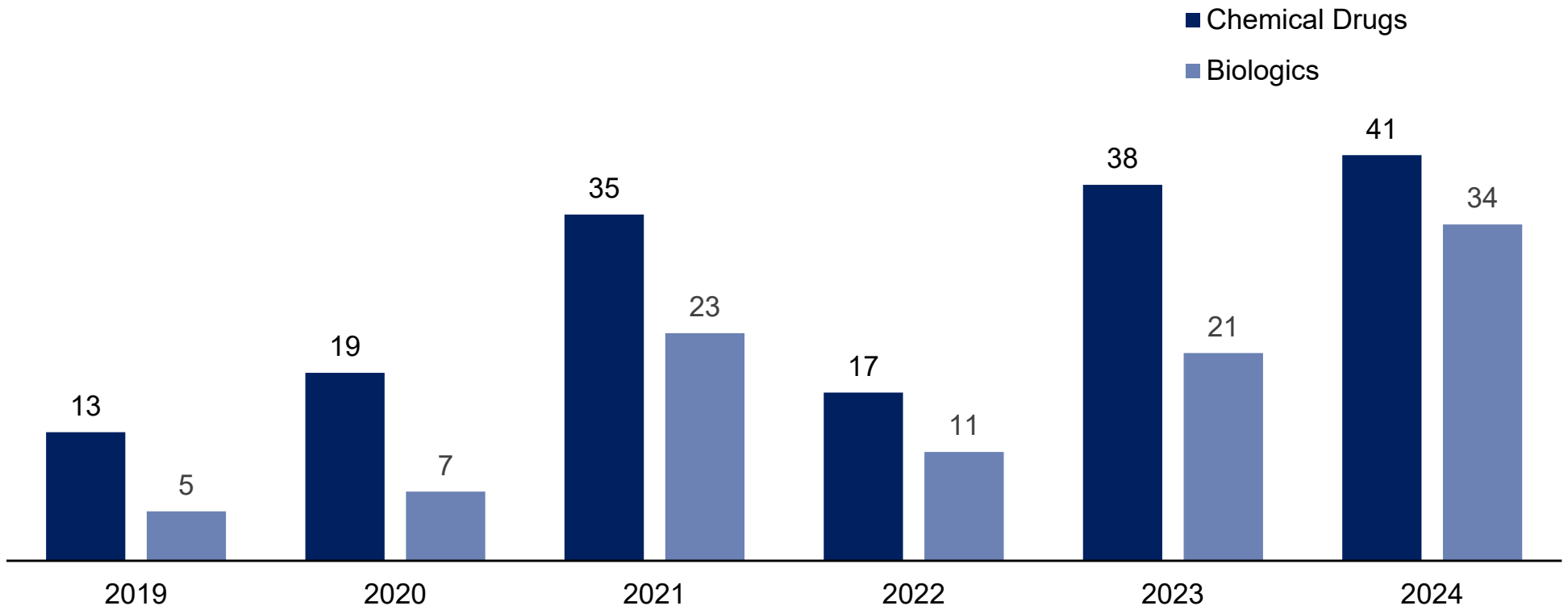
- The China government has established a set of regulations and policies to support the development of China's antibacterial drug market to promote open innovation and the high-quality development of the antibacterial drug market. These include Notice for Further Strengthening the Management of Antibacterial Drugs to Curb Bacterial Resistance, from the NHFPC General Office 《国家卫计委办公厅关于进一步加强抗菌药物临床应用管理遏制细菌耐药的通知》, Notice for Continually Improving the Management of Antibacterial Drugs Clinical Us 《关于持续做好抗菌药物临床应用管理有关工作的通知》, Notice for the National Action Plan for Curbing Bacterial Resistance (2022-2025) 《关于印发遏制细菌耐药国家行动计划 (2022-2025年) 的通知》.

## Increasing Affordability and Healthcare Awareness

- In China, the per capita disposable income has grown rapidly from RMB30,733 in 2018 to **RMB41,314 in 2024**. This increase in disposable income is reflected in the increase in healthcare expenditure, and this trend is expected to continue. In recent years, the inclusion of anti-infective drug into NRDL further increases accessibility and affordability of anti-infective drug. Anti-virus drugs have been newly included. in the (review and approval scope), such as cefmenoxime for injection and ampicillin sodium and sulbactam sodium for injection, along with increased health awareness would further drive market growth as sales volume is expected to increase.

# Innovative Drugs Approved by NMPA, 2019-2024

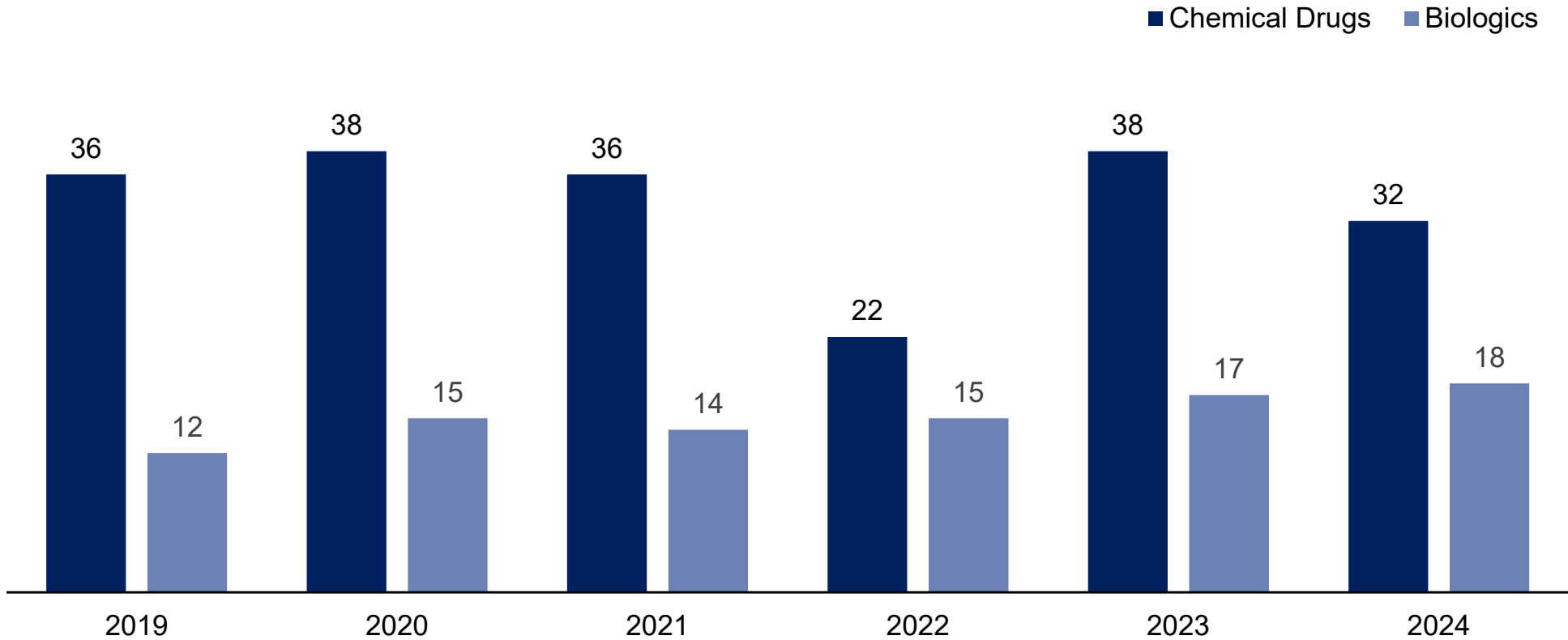
- The following bar chart set forth the number of chemical drugs approved by NMPA from 2019 to 2024. More chemical drugs approved than biologics.



Source: NMPA, Frost & Sullivan Analysis

# Innovative Drugs Approved by FDA, 2019-2024

• The following bar presents the number of chemical drugs and biologics approved by FDA from 2019 to 2024.



Source: FDA, Frost & Sullivan Analysis

# Favorable Government Policy of Pharmaceutical Industry

## Review of Clinical Trial and New Drug Application

Release Date	Issuing Authority	Policies	Contents
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>
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 putted forward from the perspectives of exploratory and confirmatory trials.</li> </ul>
Feb, 2022	CDE	<i>Notice for soliciting opinions on the “CDE to Accelerate the Review Procedures for Innovative Drug Applications (Trial)</i> 关于《药审中心加快创新药上市申请审评工作程序（试行）》征求意见的通知	<ul style="list-style-type: none"> <li>Encouraging the research and development of new drugs to meet clinical drug needs.</li> <li>Speeding up the review of innovative drugs.</li> </ul>

Source: Government Website, Frost & Sullivan Analysis

# Favorable Government Policy of Pharmaceutical Industry

## Review of Clinical Trial and New Drug Application

Release Date	Issuing Authority	Policies	Contents
March, 2023	CDE	Guidelines for the applicability of single-arm clinical trials to support new drug applications for anti-tumor drugs 《单臂临床试验用于支持抗肿瘤药上市申请的适用性技术指导原则》	<ul style="list-style-type: none"> <li>Clarify the current scientific understanding of the applicability of single-arm clinical trials to support new drug applications for anti-tumor drugs, and guide companies to better assess whether it is appropriate to conduct single-arm clinical trials as key clinical studies after completing early studies.</li> </ul>
April, 2022	CDE	<i>CDE to Accelerate the Review Procedures for Innovative Drug Applications</i> 《药审中心加快创新药上市申请审评工作程序（试行）》	<ul style="list-style-type: none"> <li>Encouraging the research and development of new drugs to meet clinical drug needs.</li> <li>Speeding up the review of innovative drugs.</li> </ul>
Nov, 2023	NMPA	<i>the Measures for the Supervision and Inspection of Drug Clinical Trial Institutions (Trial)</i> 《药物临床试验机构监督检查办法（试行）》	<ul style="list-style-type: none"> <li>According to the nature and purpose of the inspection, inspections carried out on testing institutions are divided into daily supervision inspections, reasoned inspections and other inspections. Different types of inspections can be combined.</li> </ul>
Dec, 2023	CDE	<i>Guiding Principles for Clinical Safety Evaluation of New Drugs</i> 《新药临床安全性评价技术指导原则》	<ul style="list-style-type: none"> <li>Clinical safety evaluation of new drugs is an important basis for benefit-risk assessment of new drugs. This document aims to provide scientific methods and technical guidance for the clinical safety evaluation of new drugs.</li> </ul>

Source: Government Website, Frost & Sullivan Analysis

# Favorable Government Policy of Pharmaceutical Industry

## Review of Clinical Trial and New Drug Application

Release Date	Issuing Authority	Policies	Contents
July, 2024	NMPA	Optimized Work Plan for Pilot Projects of Clinical Trial Review and Approval of Innovative Drug 《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>Clarify the current scientific understanding of the applicability of single-arm clinical trials to support new drug applications for anti-tumor drugs, and guide companies to better assess whether it is appropriate to conduct single-arm clinical trials as key clinical studies after completing early studies.</li> </ul>
January, 2025	General Office of the State Council	Opinions on Comprehensively Deepening the Supervision Reform of Pharmaceuticals and Medical Devices to Promote the High-Quality Development of the Medical Industry 《关于全面深化药品医疗器械监管改革促进医药产业高质量发展的意见》	<ul style="list-style-type: none"> <li>Exempt eligible innovative drugs for rare - diseases from clinical trials; reduce the number of registration inspection batches of rare - disease drugs from 3 to 1.</li> </ul>

Source: Government Website, Frost & Sullivan Analysis

# Favorable Government Policy of Pharmaceutical Industry

## Review of Innovation Encouragement

Release Date	Issuing Authority	Policies	Contents
Feb, 2019	MoF	<i>Notice on VAT policy for rare disease drugs</i> 《关于罕见病药品增值税政策的通知》	<ul style="list-style-type: none"> <li>To encourage the development of the rare disease pharmaceutical industry and reduce the cost of medication for patients. VAT general taxpayers who produce, wholesale and retail rare disease drugs can pay VAT at a 3% levy rate according to the simple method, starting from March 1, 2019.</li> </ul>
Jul, 2019	NMPA	<i>Announcement on Further Improving the Correlated Matters of Drug Related Evaluation, Approval and Supervision</i> 《关于进一步完善药品关联审评审批和监管工作有关事宜的公告》	<ul style="list-style-type: none"> <li>Encourage innovative drugs by optimizing the approval process.</li> <li>Further clarifies the review, approval and supervision of the association between active pharmaceutical ingredients, excipients, and immediate packaging materials and containers as well as pharmaceutical products.</li> </ul>
Aug, 2019	NMPA	<i>Pharmaceutical Administration Law of the People's Republic of China</i> 《中华人民共和国药品管理法》	<ul style="list-style-type: none"> <li>It is the second major systematic and structural amendment to the Pharmaceutical Administration Law since its first promulgation in 1984.</li> <li>Focus on supporting clinical value-oriented drug innovations which have significant effects on human disease. Encourage the development of new medicines with new treatment mechanism on severely life-threatening diseases, rare diseases and children's diseases.</li> <li>Establish related laws of clinical trial acquiescence system, clinical trial institution filing management system, priority review and approval system, conditional approval system, etc.</li> <li>Established a listing authorization system to encourage innovation.</li> </ul>

Source: Government Website, Frost & Sullivan Analysis

# Favorable Government Policy of Pharmaceutical Industry

## Review of Innovation Encouragement

Release Date	Issuing Authority	Policies	Contents
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:               <ol style="list-style-type: none"> <li>Review and Evaluation Procedures for Breakthrough Therapy Drugs (Trial)</li> <li>Review and Approval Procedures for conditionally approved marketing application of drugs (Trial)</li> <li>Procedure for Priority Evaluation and Approval of Drug Marketing Authorization (Trial)</li> </ol> </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

# Favorable Government Policy of Pharmaceutical Industry

## Review of Innovation Encouragement

Release Date	Issuing Authority	Policies	Contents
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>
May, 2022	The State Council	<i>14th Five-Year National Health Plan</i> 《十四五国民健康规划》	<ul style="list-style-type: none"> <li>• Encourage the research and development of new drugs for the treatment of major diseases that are urgently needed in clinical settings, and support the research and development of high-quality generic drugs.</li> <li>• Deepen the reform of the review and approval system for drugs and medical devices, and speed up the review and approval of innovative drugs, urgently clinically needed drugs and medical devices, and rare disease treatment drugs.</li> </ul>
July, 2023	National Healthcare Security Administration	<i>Rules for Negotiating Drug Contract Renewals</i> 《谈判药品续约规则》	<ul style="list-style-type: none"> <li>• For Category 1 chemical drugs, Category 1 therapeutic biological agents, Category 1 and Category 3 proprietary Chinese medicines approved in accordance with the current registration management methods, when the renewal triggers the price reduction mechanism, manufacturers can apply for renewal through renegotiation. The government will organize experts to calculate through the program, and the reduction in negotiated renewal does not need to be higher than the reduction stipulated in the simple renewal.</li> </ul>

Source: Government Website, Frost & Sullivan Analysis

# Favorable Government Policy of Pharmaceutical Industry

## Review of Innovation Encouragement

Release Date	Issuing Authority	Policies	Contents
Jan, 2024	General Office of the CPC Central Committee, The State Council	Pudong New Area Comprehensive Reform Pilot Implementation Plan (2023-2027)	<ul style="list-style-type: none"> <li>Establish a collaborative relationship among medical institutions, universities, and research institutes to strengthen clinical research cooperation, allow new launched products to be priced according to similar international drugs in accordance with relevant regulations, and support the development of innovative drugs and medical device.</li> </ul>
Feb, 2024	National Medical Insurance Administration	<p><i>Notice on establishing a first-time price formation mechanism for newly launched chemical drugs to encourage high-quality innovation (Draft for Comments)</i></p> <p>关于建立新上市化学药品首发价格形成机制 鼓励高质量创新的通知（征求意见稿）</p>	<ul style="list-style-type: none"> <li>For newly launched chemical drugs, manufacturers can self-evaluate from the perspective of pharmacy, clinical value and evidence-based evidence based on the evaluation scale published by the medical insurance department. The self-evaluation score can reflect its innovativeness. The stronger the innovation, the higher initial price that the drug can set.</li> </ul>
July, 2024	General Office of the CPC Central Committee, The State Council	Implementation Plan for Supporting the Development of Innovative Drugs Throughout the Entire Chain<全链条支持创新药发展实施方案>	<ul style="list-style-type: none"> <li>Significant innovativeness (new targets, new mechanisms, new structures, new technologies); Addressing unmet clinical needs; Clear clinical value (either no existing treatment available, or significantly superior efficacy compared to current therapies, or efficacy comparable to the current best - in - class therapies but with significantly beneficial safety profiles).</li> </ul>

Source: Government Website, Frost & Sullivan Analysis

# Favorable Government Policy of Pharmaceutical Industry

## Review of Innovation Encouragement

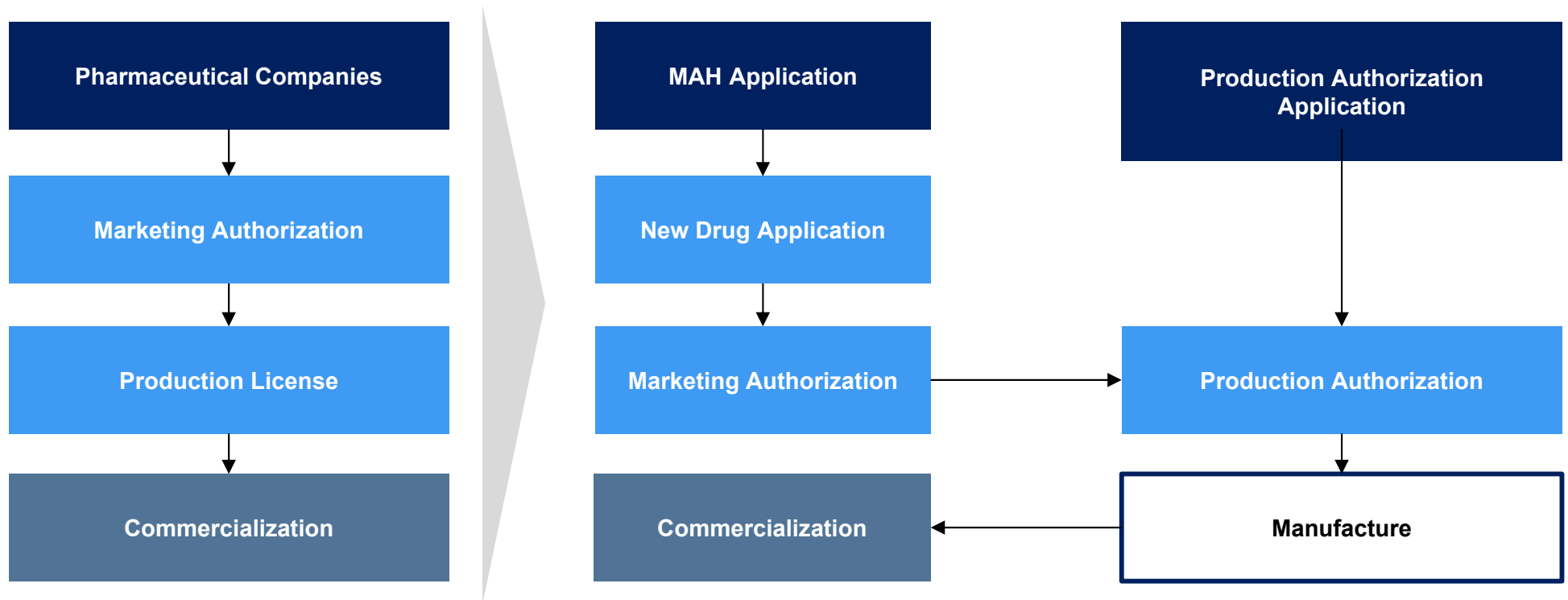
Release Date	Issuing Authority	Policies	Contents
July, 2025	National Medical Insurance Administration, National Health Commission	Measures for Supporting the High - Quality Development of Innovative Drugs 《支持创新药高质量发展的若干措施》	<ul style="list-style-type: none"> <li>Support the use of medical insurance data in innovative drug research and development, encourage commercial health insurance to expand investment in innovative drugs, strengthen policy guidance on drug catalog access, coordinate and promote innovative drug research and development, improve the dynamic adjustment mechanism of the basic medical insurance drug catalog, reasonably determine the medical insurance payment standards for innovative drugs, add a commercial health insurance innovative drug catalog, and strengthen real-world research on innovative drugs.</li> </ul>

Source: Government Website, Frost & Sullivan Analysis

# Policy Analysis of Marketing Authorization Holder (MAH)

- 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.

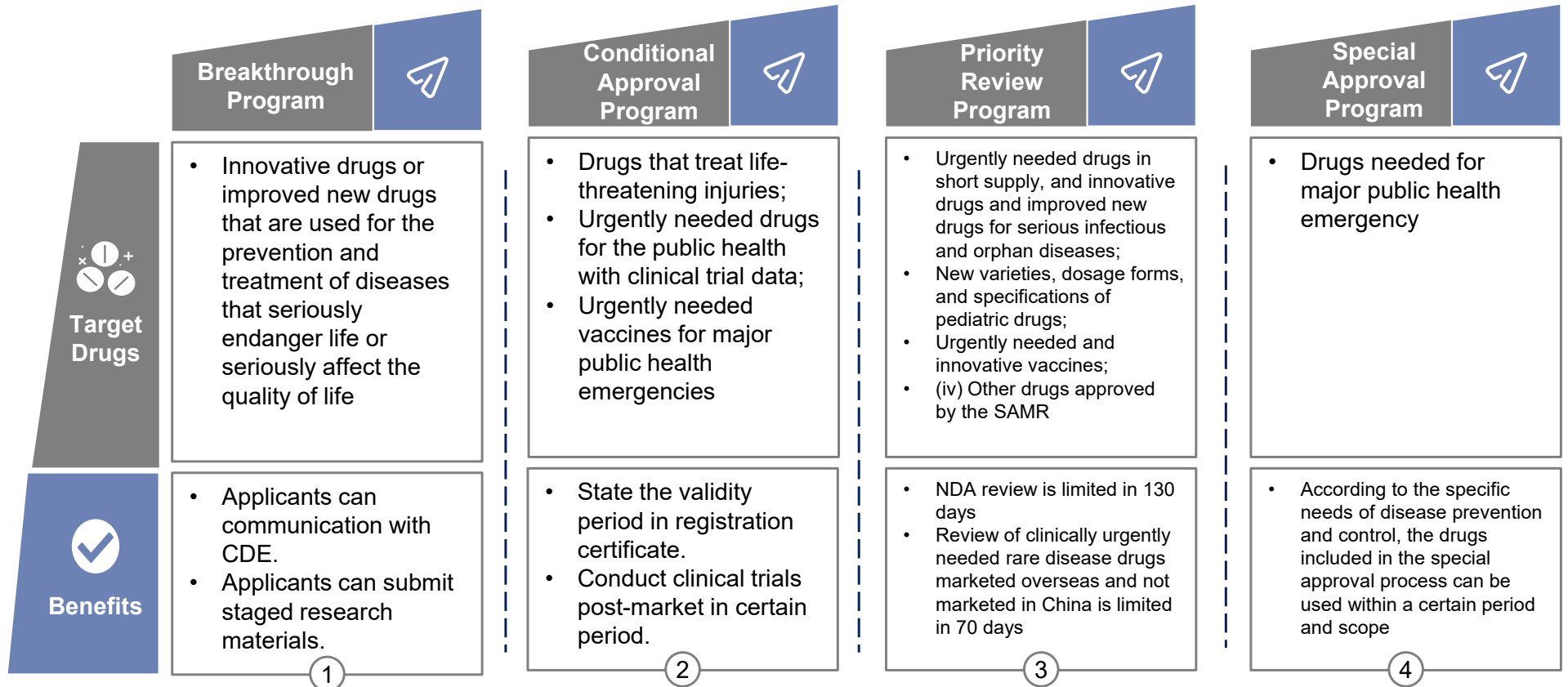
## Evolution of MAH System in China



Source: Government Website, Frost & Sullivan Analysis

# Grants Programs to Innovative Drugs in China

On March 30, 2020, the State Administration for Market Regulation (SAMR), released a revised Drug Registration Regulation (Revised DRR) as part of its efforts to strengthen and streamline its regulation of the pharmaceutical industry, which went into effect on July 1, 2020. There are four programs included in the regulation, target drugs and benefit of each program are illustrated as follows:



Source: Frost & Sullivan Analysis

# Overview of Healthcare Insurance System in China

Public Medical Insurance	UEBMIS	<p><b>Urban Employee Basic Medical Insurance Scheme (UEBMIS)</b></p> <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	<p><b>Urban Resident Basic Medical Insurance Scheme (URBMIS)</b></p> <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> <p><b>New Rural Cooperative Medical Insurance Scheme (NRCMIS)</b></p> <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> <p><b>Consolidation of URBMIS and NRCMIS</b></p> <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	<p>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.</p>
Commercial Medical Insurance	<p>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.</p>	

Source: NHFPC, Frost & Sullivan Analysis

# Analysis of Healthcare Reimbursement System in China

## Recent Progress and Impact of the 2024 NRDL

- In the 2024 NRDL, 91 drugs were newly included in the list, with a price reduction of 63%. The inclusion of numerous domestic innovative drugs has significantly promoted the sales of innovative drugs and the transformation of Chinese pharmaceutical industry to innovation.

### Progression of NRDL



### Recent Progression of 2024 NRDL

- In Dec 2024, NHSA and MOHRSS finished the work for the adjustment of the 2024 NRDL, and the 2024 NRDL will implement from Jan 1st 2024. The negotiation aims to eliminate medications with unreasonably high prices, optimize clinical use of medications, and further lower prices of current drugs by inducing virtuous competition.
- 117 kinds of drugs were involved in price negotiation, and 89 of them were smoothly negotiated. 91 kinds of drugs have been newly included in NRDL for the first time, leading to a 63% decline in prices.
- 1 previously included drugs were removed from the list, all of which are the varieties that have been cancelled by the NMPA.
- indicating the government Anti-tumor drugs, rare disease drugs and anti-infective drugs have been newly included. in the (review and approval scope). Such as cefmenoxime for injection and ampicillin sodium and sulbactam sodium for injection. is speeding up the review and approval of innovative drugs, urgently clinically needed drugs and rare disease treatment drugs.

### Implication for Innovation

The inclusion of NRDL promoted the sales of innovative drugs significantly. At the same time, pharmaceutical companies need to embrace continuous innovation and accelerate the pace. Only those pharmaceutical companies that develop drugs with independent IP rights can win the industrial competition and keep a higher margin.

2024 NRDL restricts the price of drugs strictly by adding rules for non-exclusive drug bidding. If a drug is included in the list through bidding, the lowest price quoted by each enterprise shall be taken as the payment standard for the generic name drug.

Numerous domestic innovative drugs were included by 2024 NRDL, marking the initiation of a rapid increase of sales and the rapid transformation of the Chinese pharmaceutical industry towards innovation.

Since the implementation of the self-declaration system of pharma, only drugs that meet the conditions of 2024 NRDL plans can be included in the adjustment scope.

Source: MORHSS, Frost & Sullivan Analysis

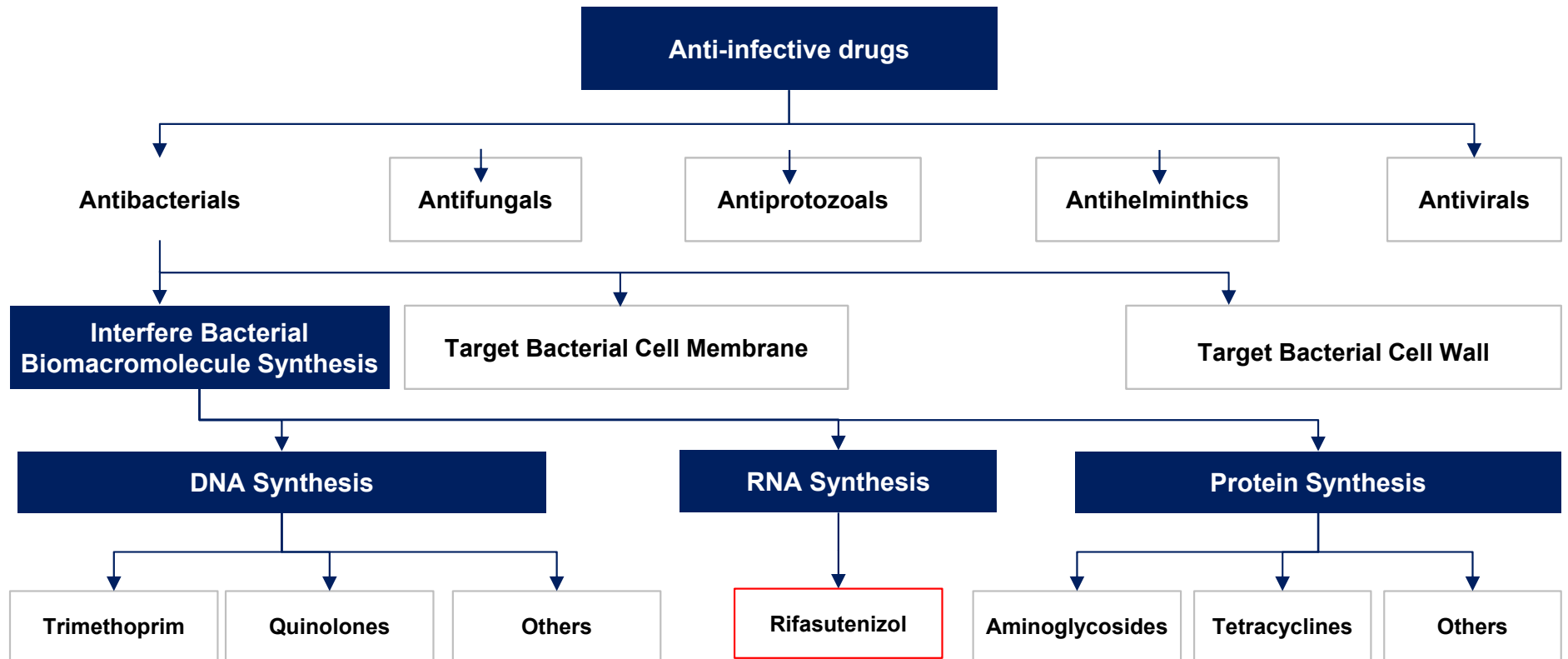
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# Introduction of Infectious Disease

• Anti-infectives is a group of drug to kill or inhibit different kinds of pathogenic microbes though oral, intramuscular injection, intravenous injection or topical use. Anti-infectives are widely used in all kinds of infectious disease and complication triggered by other disease. As one of the most popular categories of clinical drug, there are a variety of anti-infectives. It can be classified into following general categories:



Company's pipeline

Source: Frost & Sullivan Analysis

# Introduction of Anti-infective Drugs

---

## Antifungal

- Antifungal can be classified into three categories: targeting synthesis of sterols like Imidazole; targeting cell wall synthesis like echinocandin and targeting nucleic acid synthesis like 5-fluorocytosine.

## Antibacterial

- Antibacterial agents may either kill or inhibit the growth of bacteria. A limited number of Antibacterials also possess antiprotozoal activity. Antibacterials are commonly classified based on their mechanism of action. Those that target the bacterial cell wall like penicillins or the cell membrane like polymyxins or interfere with essential bacterial enzymes like rifamycins have bactericidal activities.
- Antibacterials revolutionized medicine in the 20th century. However, their effectiveness and easy access have also led to their overuse, prompting bacteria to develop resistance. This has led to widespread problems.

## Antiviral

- Antiviral drugs are a class of medication used specifically for treating viral infections. Most antivirals are used for specific viral infections, while a broad-spectrum antiviral is effective against a wide range of viruses. Unlike most Antibacterials, antiviral drugs do not destroy their target pathogen; instead, they inhibit its development.

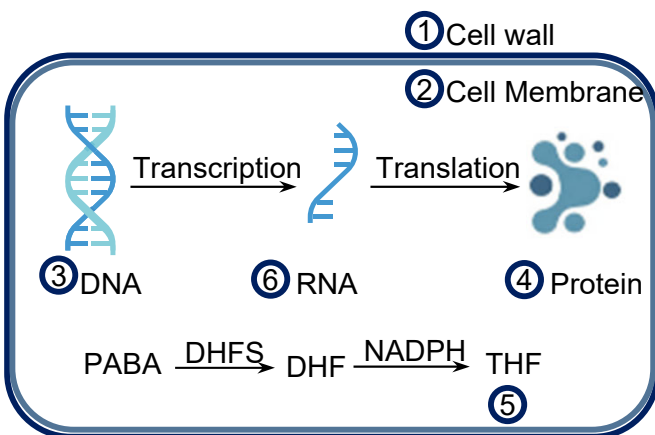
## Other types

- Other types of anti-infectives like targeting chlamydia, mycoplasma, worm or rickettsia. Those factors can trigger infection as well.

Source: Frost & Sullivan Analysis

# Overview of Antibacterial Drugs

- Bacteria are a type of biological cell. Typically, a few micrometres in length, bacteria have a number of shapes, ranging from spheres to rods and spirals. Bacteria have basic structures such as cell wall, cell membrane, cytoplasm and nucleoplasm, and some bacteria also have special structures such as capsule, flagella, fimbria and spores. Bacteria are the causative agent of many diseases, and can spread diseases among normal human body through various methods, such as contact, digestive tract, respiratory tract, insect bites, etc., with strong infectivity and significant harm to society.
- Antibacterials are a type of antimicrobial substance active against bacteria. It is the most important type of antimicrobial agent for fighting bacterial infections, and antibacterial medications are widely used in the treatment and prevention of such infections.



The basic structure of Bacterial

	Target and Action	Representative Drugs
1. Cell Wall Construction	Inhibit synthesis of cell wall by inhibiting formation of the peptidoglycan layer, dephosphorylation of C55 - Ip or inactivating the MurA	$\beta$ - lactams, Glycopeptides, Bacitracin, Fosfomycin
2. Structure and Function of Cell Membrane	Disrupt both the outer and inner membranes	Colistin, Polymyxin B
3. Structure and Function of DNA	Prevent DNA from unwinding and duplicating	Quinolones, Nitrofurantoin
4. Protein Synthesis	Truncate the biosynthesis of proteins by disturbs peptide elongation at the ribosomal subunit, giving rise to inaccurate mRNA translation	Aminoglycosides, Lincosamide, Macrolides, Oxazolidone, Tetracyclines
5. Folic Acid Synthesis	Inhibit synthesis of folic acid by inhibiting interfering with the enzyme DHPS	Sulfonamides, Trimethoprim
6. RNA Synthesis	Inhibit the synthesis of RNA by targeting bacterial RNA polymerase, blocking the transcription process to prevent bacterial gene expression and protein production	Rifampin, Rifaximin

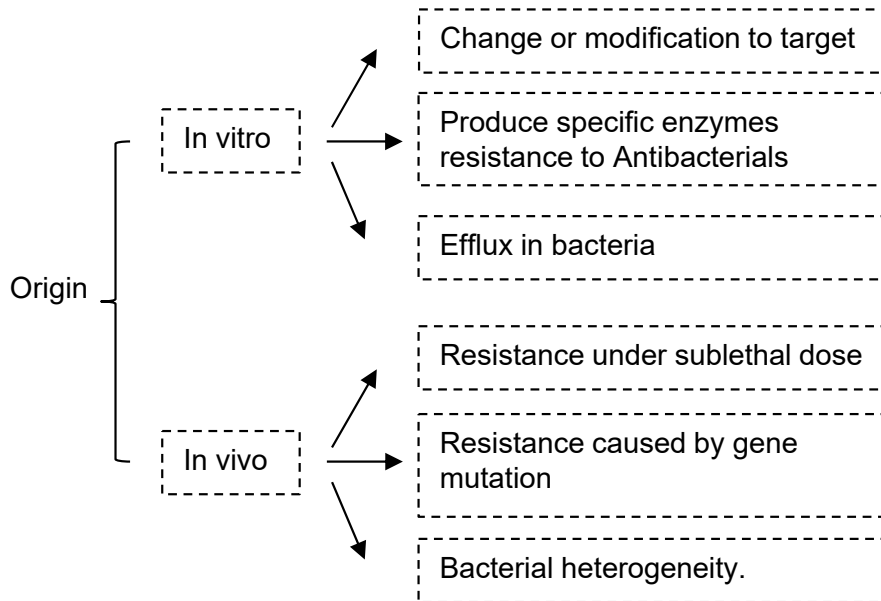
Source: Frost & Sullivan Analysis

# Overview of Multi-drug Resistance (MDR)

## Definition of MDR

- Bacteria constantly evolve and develop cross-resistance, resulting in the emergence of multidrug-resistant bacteria. Multidrug-resistant bacteria refer to the resistance of three or more types of antibacterial drugs, which is caused by repeated use of broad-spectrum antibacterial drugs to treat bacteria in the body and therefore, develop strong resistance.

## Mechanisms of Resistance



Source: Frost & Sullivan Analysis

## Main Types of MDR

Vancomycin-resistant enterococci (VRE)

Methicillin-resistant staphylococcus aureus (MRSA)

Methicillin-resistant coagulase negative staphylococci (MRCNS)



What's MRSA?

- Staphylococcus aureus is an important pathogenic gram-positive bacterium in clinical practice. It can cause severe infections such as endocarditis, meningitis, sepsis, as well as common infections such as wounds, respiratory tract, and urinary tract infections. Methicillin-resistant Staphylococcus aureus (MRSA) is a strain of Staphylococcus aureus that has developed resistance to some Antibacterials used to treat infections caused by Staphylococcus aureus. The spread of MRSA infection is a serious public health issue.



### Mechanisms of MRSA Resistance

- The decreased affinity with Antibacterials reduces the ability of Antibacterials to inhibit the synthesis of cell wall peptidoglycan. MRSA can produce a large amount of beta-lactamase, which can hydrolyze beta-lactam Antibacterials.
- Blocking the binding of vancomycin to the target sites on the peptidoglycan precursor, thus leading to vancomycin resistance.
- Multi-drug resistant possibility.

# Spectrum of Representative Antibacterial Drugs

- The 1st generation and 2nd generation cephalosporins, classified as unrestricted-use antibacterial drugs, not only are applicable to most tissue infections, endocarditis caused by MSSA, group A hemolytic streptococcus and pneumococcus, but also are widely used in perioperative prevention.
- Ceftazidime is the only drug in 3rd-generation Cephalosporins which is effective in *Pseudomonas* infection.
- Vancomycin is considered as the last defense against severe infections that are ineffective against all Antibacterials, such as “superbugs”- methicillin-resistant *Staphylococcus aureus* infections(MRSA).

## Spectrum of Representative Antibacterial Drugs

	G(+) Bacteria		G(-) Bacteria			
	MRSA	Other G(+) Bacteria	Other G(-) Bacteria			Pseudomonas
Penicillins						
1st-gen cephalosporins						
<b>2nd-gen cephalosporins</b>						
<b>3rd-gen cephalosporins</b>						<b>Ceftazidime</b>
4th-gen cephalosporins						
Aminoglycosides						
Quinolones						
Makrolides						
Polymyxins						
Fosfomycin						
<b>Vancomycin</b>						
Lincosamide						
linezolid						

Source: Frost & Sullivan Analysis

# Emerging Trends in Antibacterial Drug Development

- Antibacterial resistance has become an urgent global public health crisis requiring immediate action, with significant unmet clinical needs driving the development of innovative antibacterial drugs. Numerous novel therapeutic approaches are being actively explored worldwide.
- Several next-generation antibacterial agents have already received market approval, including New-generation  $\beta$ -lactamase inhibitors, Advanced cephalosporins, Topoisomerase inhibitors.
- Additionally, as emerging research directions, multiple innovative adjunctive therapies and microbiome-based therapeutics are currently under development.

Category	Therapeutic Mechanism	Treatment
<b>Novel Target Mechanisms</b>	<ul style="list-style-type: none"> <li>- Novel <math>\beta</math>-Lactamase Inhibitors</li> <li>- Next-Generation Cephalosporins</li> <li>- Topoisomerase Inhibitors</li> </ul>	<ul style="list-style-type: none"> <li>- Cefiderocol, a novel siderophore cephalosporin, utilizes a "Trojan horse" mechanism—transport into bacterial cells via iron-uptake pathways—before binding to penicillin-binding proteins (PBPs) to exert bactericidal effects.</li> <li>- Gepotidacin, the first triazaacenaphthylene topoisomerase inhibitor, selectively targets bacterial DNA gyrase and topoisomerase IV through a unique dual-binding mechanism.</li> </ul>
<b>Adjunctive Therapies (topical administration)</b>	<ul style="list-style-type: none"> <li>- Antibacterial agents as adjunctive therapy to improve prognosis in the treatment of other diseases</li> </ul>	<ul style="list-style-type: none"> <li>- When systemic administration fails to achieve therapeutic concentrations at the infection site, adjunctive postoperative infections, local drug delivery may be employed.</li> <li>- Such as monoclonal antibodies, small molecules that inhibit bacterial biofilms</li> </ul>
<b>Microecological Interventions</b>	<ul style="list-style-type: none"> <li>- Modulating Human Microecology for Disease Prevention and Treatment</li> <li>- Gut Microbiota Reprogramming</li> <li>- Microbial Metabolite Modulation</li> <li>- Immune-Microbiome Crosstalk</li> </ul>	<ul style="list-style-type: none"> <li>- Fecal microbiota transplantation, dietary regulation, and supplementation of probiotics and prebiotics.</li> </ul>

Source: Literature Review, Frost & Sullivan Analysis

# Comparison of Clinical Antibacterial Use Guidelines between China and U.S.

	<u>CHINA</u>	<u>U.S.</u>
Regulatory Basis	<ul style="list-style-type: none"> <li>• <b>Administrative Measures for Clinical Application of Antibacterial Drugs</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>ASHP</b>: American Society of Health - System Pharmacists</li> <li>• <b>IDSA</b>: Infectious Diseases Society of America</li> <li>• <b>SHEA</b>: Society for Healthcare Epidemiology of America</li> <li>• <b>AMS</b>: Antimicrobial Stewardship</li> </ul>
Grading Management	<ul style="list-style-type: none"> <li>• Antibacterial drugs are classified into three tiers based on safety, efficacy, bacterial resistance, and price:               <ul style="list-style-type: none"> <li>- Non-restricted Use</li> <li>- Restricted Use</li> <li>- Special Use</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• No national grading system; hospitals implement tiered management systems (e.g., first-line, second-line, third-line) with dynamic restrictions (e.g., prior authorization for high-tier drugs).</li> </ul>
Regulatory Body	<ul style="list-style-type: none"> <li>• Governed by the National Health Commission (NHC)</li> <li>• provincial health departments formulate grading formularies;</li> <li>• strict compliance with national standards is required.</li> </ul>	<ul style="list-style-type: none"> <li>• Hospital-autonomous management; guided by CDC Core Elements of ASP (leadership, pharmacy expertise, prospective audit, etc.) without federal mandates.</li> </ul>
Usage Restrictions	<ul style="list-style-type: none"> <li>• Strict adherence to grading formularies; Special Use drugs prohibited in outpatient settings; inpatient use requires consultation or senior physician approval.</li> </ul>	<ul style="list-style-type: none"> <li>• Dynamic interventions:               <ul style="list-style-type: none"> <li>- <b>Prior Authorization (PA)</b>: Required for third-line drugs (justification to pharmacy/ID teams).</li> <li>- Automatic stop orders: Time-limited prescriptions (e.g., 48–72 hours) for high-tier drugs.</li> <li>- De-escalation: Switch to narrow-spectrum agents based on microbiology results.</li> </ul> </li> </ul>
AMR Surveillance	<ul style="list-style-type: none"> <li>• National Center for Antimicrobial Resistance Surveillance (CARSS) monitors clinical isolates, but excludes agricultural/environmental sectors.</li> </ul>	<ul style="list-style-type: none"> <li>• National Antimicrobial Resistance Monitoring System (NARMS) integrates data from healthcare, agriculture, and the environment, including whole-genome sequencing for resistance genes.</li> </ul>

Source: Literature review, Frost & Sullivan Analysis

# National Regulations of China Antibacterial Drug Market - I

- Due to increasing anti-infectives abuse and severer bacterial resistance, China government has been consistently introducing laws, regulations and policies to guide rational anti-infectives clinical use and restrict clinical abuse since 2004. The following table sets forth primary related regulations and policies which were issued since 2004:



Source: Government Documents, Frost & Sullivan Analysis

# National Regulations of China Antibacterial Drug Market - II

- 
- 2012 ●
- Administrative measures for the clinical use of antibacterial drugs**  
**《抗菌药物临床应用管理办法》**
- The regulation is issued by the NHFPC to standardize administration of the clinical use of antibacterial drugs, which expressly illustrate the three-level antibacterial drug classification management system. Provincial antibacterial drug lists should be formulated and drugs can be prescribed by qualified doctors. Medical institutions shall strictly control the types and amount of antibacterial drugs in supply.
- 2013 ●
- Notice on strengthening the surveillance of clinical use of antibacterial drugs and bacterial resistance**  
**关于加强抗菌药物临床应用和细菌耐药监测工作的通知**
- Expand the surveillance network of clinical use of antibacterial drugs and bacterial resistance to 1,349 class II and Class III hospitals.
- 2014 ●
- Notice on further conducting the special campaign of the clinical use of antibacterial drugs**  
**关于进一步开展全国抗菌药物临床应用专项整治活动的通知**
- Consolidate and expand the management of clinical use of antibacterial drugs.
- 2014 ●
- Notice on further efforts on implementing the administration of the clinical use of antibacterial drugs in 2014, from the NHFPC General Office**  
**国家卫生计生委办公厅关于做好2014年抗菌药物临床应用管理工作的通知**
- Improve management of clinical use of antibacterial drugs in class II hospitals and primary medical institutions.
- 2015 ●
- Notice on releasing a special plan to further improve the medical services**  
**关于印发进一步改善医疗服务行动计划的通知**
- The antibacterial drug utilization rate of inpatients shall not be more than 60% and total antibacterial drug dosage in 100 patients per day shall be under 40 DDDs (Defined Daily Doses) in general hospitals by 2017. The indicators in other hospitals shall meet the standard of clinical application of antibacterial drugs.
- 2015 ●
- Guiding principles for the clinical use of antibacterial drugs, 2015 version**  
**《抗菌药物应用指导原则（2015年版）》**
- The Principles give the detailed instructions on the clinical use of antibacterial drugs for the therapeutic and preventive purpose. The indications and precautions of various antibacterial drugs are summarized accordingly as well. The Principle requires all medical institutions to establish the management system of the clinical use of antibacterial drugs.

Source: Government Documents, Frost & Sullivan Analysis

# National Regulations of China Antibacterial Drug Market - III



Source: Government Documents, Frost & Sullivan Analysis

# National Regulations of China Antibacterial Drug Market – IV

2024



## Notice of the General Office of the National Health Commission on Issuing the National Medical Quality and Safety Improvement Goals for 2024

《国家卫生健康委办公厅关于印发2024年国家医疗质量安全改进目标的通知》

Improving the Rate of Etiological Testing Before Antibacterial Drug Treatment for Inpatients (PIT-2024-39)

- Medical institutions shall strengthen the coordinated management of departments such as hospital infection control, medical affairs, pharmacy, and laboratory testing.
- Medical institutions shall standardize the procedures and operations for specimen collection and submission, reduce contamination of etiological testing specimens, and increase the timely submission rate of qualified specimens.
- Medical institutions shall focus on standardizing the awareness of antibacterial drug use. Strengthen publicity and training, conduct regular training for all departments and key populations, and achieve full coverage of relevant medical personnel.

Source: Government Documents, Frost & Sullivan Analysis

# Antibacterial Drug Approved by NMPA

## Global Marketed Bacterial Vaginitis Drug Competitive Landscape<sup>1-4</sup>



Generic Name	Brand Name	Target/ MoA	Company	Indication	Drug Type	Approval Date
Lefamulin Acetate	Xenleta	50S rProteins	Sumitomo pharma/ Nabriva Therapeutics	Community-Acquired Pneumonia	Small Molecule Drugs	2025-6-30
Telavancin	-	Peptidoglycan	SciClone Pharmaceuticals/ Cumberland Pharmaceuticals	HABP, VABP, cSSSI	Small Molecule Drugs	2025-02-11
Pretomanid	Dovprela	DprE2	Mylan	Pulmonary Tuberculosis	Small Molecule Drugs	2024-12-01
Sulbactam/ Durlobactam	Xacduro	Beta-lactamase	Entasis Therapeutics	Infection with Acinetobacter calcoaceticus - Acinetobacter baumannii Complex	Small Molecule Drugs	2024-05-15
Ertapenem Hydrochloride	Xerava	30S rProteins	Everest Medicines	Complicated intra- abdominal infections	Small Molecule Drugs	2023-03-15

1. Only includes originator, excluding generic drugs and compound drugs

Source : CDE (as of 04/05/2026), Frost & Sullivan analysis

# Antibacterial Drug Approved by NMPA

## Global Marketed Bacterial Vaginitis Drug Competitive Landscape<sup>1-4</sup>



Generic Name	Brand Name	Target/ MoA	Company	Indication	Drug Type	Approval Date
Omadacycline Tosilate	Nuzyra	30S Ribosomal Subunit	Zai Lab	Acute Bacterial Skin and Skin Structure Infections, Community - Acquired Pneumonia ( "Community - Acquired Pneumonia" ( CAP )	Small Molecule Drugs	2021-12-14
Cefcapene Pivoxil Hydrochloride Granules		PBP	Shionogi	Bacterial pneumoni	Small Molecule Drugs	2021-09-09
Nemonoxacin Malate	-	TOP2	Zhejiang Medicine	Community-Acquired Pneumonia	Small Molecule Drugs	2021-06-18
Contezolid	-	50S Ribosomal Subunit	Micurx	Skin and Soft Tissue Infections	Small Molecule Drugs	2021-06-01

1. Only includes originator, excluding generic drugs and compound drugs

Source : CDE (as of 04/05/2026), Frost & Sullivan analysis

# Antibacterial Drug Approved by FDA (1/2)

## Global Marketed Bacterial Vaginitis Drug Competitive Landscape<sup>1-4</sup>



Generic Name	Brand Name	Target/ MoA	Company	Indication	Drug Type	Approval Date
Gepotidacin mesylate	Bujepai	TOP IV, DNA gyrase	GSK	Uncomplicated urinary tract infection	Small Molecule Drugs	2025-03-25
Ceftobiprole medocartil sodium	Zevtera	PBP	ISTX	Staphylococcus aureus bacteremia, acute bacterial skin and skin structure infections, community-acquired pneumonia	Small Molecule Drugs	2024-04-03
Durlobactam	Xacduro	Beta-lactamase	Entasis Therapeutics	Acinetobacter calcoaceticus - Acinetobacter baumannii complex infection	Small Molecule Drugs	2023-05-23
SER-109	Vowst	Microbime	Seres Therapeutics	CDI	Biologics	2023-04-26

1. Only includes originator, excluding generic drugs and compound drugs

2. Excluding compound preparations

Source : ClinicalTrials (as of 04/05/2026), Frost & Sullivan analysis

# Antibacterial Drug Approved by FDA (2/2)

## Global Marketed Bacterial Vaginitis Drug Competitive Landscape<sup>1-4</sup>



Generic Name	Brand Name	Target/ MoA	Company	Indication	Drug Type	Approval Date
Rebyota	Rebyota	Fecal Microbiota Transplantation	Ferring Pharmace	Clostridioides difficile infection	Biologics	2022.11.30
Cefiderocol Sulfate Tosylate	Fetroja	PBP	Shionogi Inc	Complicated Urinary Tract Infection, Hospital-Acquired Pneumonia, Ventilator-Associated Pneumonia	Small Molecule Drugs	2019-11-14
Lefamulin	Xenleta	50S Ribosomal Subunit	Nabriva Therapeutics	Community-Acquired Pneumonia	Small Molecule Drugs	2019-08-19
Pretomanid	Pretomanid	Nitroimidazole compounds	TB Alliance	Mycobacterium Tuberculosis Infection	Small Molecule Drugs	2019-08-14

1. Only includes originator, excluding generic drugs and compound drugs

2. Excluding compound preparations

Source : ClinicalTrials (as of 04/05/2026), Frost & Sullivan analysis

# Growth Driver of the Antibacterial Drug Market

## High prevalence of infectious diseases

- Infectious diseases remain a major global health challenge, particularly in regions with limited healthcare infrastructure. The widespread occurrence of respiratory infections, urinary tract infections, and surgical site infections continues to sustain strong clinical demand for antibacterial therapies. The growing number of immunocompromised patients, especially among the elderly and those undergoing complex medical procedures, further contributes to the sustained use of antibacterial drugs across both inpatient and outpatient settings.

## Rising threat of antimicrobial resistance

- The increasing prevalence of drug-resistant pathogens is a key factor reshaping the antibacterial drug market. Traditional treatment options are becoming less effective due to decades of overuse and inappropriate prescribing of Antibacterials. As resistant infections become more difficult to treat, healthcare systems are under mounting pressure to adopt new therapeutic strategies. This unmet clinical need is driving interest in next-generation Antibacterials capable of addressing resistant bacterial strains with novel mechanisms of action.

## Advancements in antibacterial innovation

- Scientific and technological breakthroughs are accelerating the discovery of new antibacterial agents. Advances in molecular biology, computational drug design, and microbial genomics are enabling more targeted approaches to antibacterial development. These innovations are reducing early-stage failure rates and opening new avenues for addressing previously untreatable infections. As a result, pharmaceutical research pipelines are gradually shifting focus toward differentiated compounds with innovative biological targets.

## Policy incentive

- Government-led initiatives serve as a vital force reinvigorating antibacterial research. Policymakers are establishing dedicated funding channels, designing outcome-based procurement systems, and implementing reward schemes tied to successful market entry. These targeted interventions aim to address the structural disincentives that have historically hindered antibacterial innovation. By creating clearer return pathways, such measures contribute to restoring developer confidence while encouraging sustained participation in this strategically important field.

Source: Frost & Sullivan Analysis

# Growth Driver of the Antibacterial Drug Market - Policy incentive

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## China

- In 2018, the National Health Commission in China issued the Notice for Continually Improving the Management of Antibacterial Drugs Clinical Use (關於持續做好抗菌藥物臨床應用管理有關工作的通知), emphasizing stricter control over key antibiotic use, and reducing irrational prophylactic and intravenous antibiotic use.
- In 2022, the National Health Commission issued the Notice for the National Action Plan for Curbing Bacterial Resistance (2022-2025) (關於印發遏制細菌耐藥國家行動計畫(2022-2025年)的通知), aiming to reduce drug-resistant infections, improve public awareness and appropriate antibiotic use, and ensure that 100% of retail antimicrobial sales are prescription-based.

## USA

- The Generating Antibiotic Incentives Now (GAIN) Act, enacted in 2012, introduced the Qualified Infectious Disease Product (QIDP) designation, offering benefits such as Fast Track designation, Priority Review, and an additional five years of market exclusivity on top of existing exclusivities.
- Ongoing legislative efforts such as the PASTEUR Act (start in 2023) propose a subscription-style payment model—decoupling payment from volume sold—to guarantee predictable returns for developers of critically needed antibiotics.
- US CDC released the National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB) 2020–2025, and subsequently the 2023–2028 update, which outline coordinated federal strategies to support innovation, surveillance, and appropriate antimicrobial use.

## Europe

- The Council of the EU in 2023 recommended further development of a coordinated EU-wide pull incentive framework, acknowledging the need for long-term and predictable rewards for successful antibiotic development.
- EU-JAMRAI (Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections) have also emphasized the importance of sustainable financing, public-private collaboration, and access-oriented innovation.

Source: Frost & Sullivan Analysis

# Growth Drivers of Antibacterial Drug Submarkets

## Helicobacter Pylori Infection

**Innovation in treatment drives market growth**

- Updates in Helicobacter pylori treatment regimens are key to market expansion. Traditional triple therapy combines a proton pump inhibitor (PPI) with two Antibacterials like clarithromycin and amoxicillin or metronidazole but has declined in effectiveness due to rising resistance and lower eradication rates. Quadruple therapy adds bismuth or adjusts Antibacterials combinations, significantly improving success rates. Healthcare providers increasingly adopt these more effective and personalized treatments to combat resistance. This shift accelerates the development of new antibacterial drugs and combination therapies, meeting diverse clinical needs. New treatments enhance outcomes and simplify medication regimens, supporting sustained market growth.

## Bacterial Vaginitis

**Advancements in diagnostic technology**

- Traditional diagnostic approaches are often time-consuming and have limited accuracy, resulting in many patients being diagnosed late or incorrectly. With the widespread adoption of molecular diagnostics and rapid testing tools, bacterial vaginosis detection has become faster and more precise, enabling doctors to identify infections earlier and develop targeted treatment plans. Timely and accurate diagnosis not only improves treatment effectiveness but also significantly reduces recurrence and complications. The increasing demand for efficient diagnosis and treatment encourages healthcare providers and pharmaceutical companies to invest more in related products and services, thereby driving the expansion and development of the overall market.

## Clostridioides Difficile Infection

**High recurrence rate**

- Clostridioides difficile infection is characterized by a high rate of recurrence, particularly among hospitalized patients and those with prior Antibacterials use, posing ongoing health risks and significant medical burdens. This challenge has prompted healthcare providers to place greater emphasis on early intervention and recurrence prevention, driving the development of novel treatment approaches such as targeted Antibacterials, microbiome-based therapies, and fecal microbiota transplantation. As the demand for effective recurrence control continues to grow, pharmaceutical companies are accelerating the development of innovative therapies for Clostridioides difficile, contributing to sustained market expansion.

Source: Frost & Sullivan Analysis

# Growth Drivers of Antibacterial Drug Submarkets

## Bacterial Biofilm And Medical Device-Related Infections

### Low treatment success rate and requirement for surgical intervention

- The low treatment success rate of bacterial biofilm and medical device-related infections has become a core driver of market growth. Bacterial biofilms significantly enhance resistance to Antibacterials, making conventional therapies less effective and leading to prolonged treatment cycles and frequent recurrence. This therapeutic challenge highlights a substantial gap in clinical demand, prompting healthcare providers and pharmaceutical companies to accelerate the development of more effective solutions. Innovations such as anti-biofilm agents, anti-adhesion surface materials, and optimized device designs are emerging as key areas of focus, collectively fueling the expansion of related products and technologies in the market.

## Prosthetic Joint Infection

### High recurrence rate

- Prosthetic joint infection presents a significant clinical challenge due to its complex treatment and high rate of recurrence. Patients often require multiple surgeries and prolonged Antibacterials therapy, resulting in lengthy and unpredictable recovery processes that severely impact rehabilitation outcomes. This situation has led to a rapid increase in demand for more effective prevention and treatment methods, driving accelerated development of antimicrobial materials, local drug delivery systems, and innovative therapies. As these technologies and products continue to emerge, the prosthetic joint infection market is steadily expanding.

## ABSSSI

### Increasing resistance

- The continuous increase in Antibacterials-resistant strains is a core driver of growth in the ABSSSI (acute bacterial skin and skin structure infections) market. As resistance rises, traditional Antibacterials become less effective, leading to harder-to-control infections, longer treatment durations, and higher risks of recurrence. This challenge has driven healthcare providers and pharmaceutical companies to accelerate the development of new antimicrobial therapies to meet the urgent need for safer and more effective treatment options.

Source: Frost & Sullivan Analysis

# Growth Drivers of Antibacterial Drug Submarkets

## Hepatic Encephalopathy

### Increasing patient population

- The rising prevalence of cirrhosis and chronic liver diseases has directly led to a continuous increase in the number of patients with hepatic encephalopathy (HE). As the base population of liver disease patients expands, the incidence of HE, a common and serious complication, rises accordingly. The growing patient population intensifies the clinical demand for effective management and treatment options, driving healthcare providers and pharmaceutical companies to accelerate the development of new therapies. This expanding patient base not only enlarges the treatment market but also promotes the sustained growth of related products and services.

## Irritable Bowel Syndrome

### Increasing demand for symptom control

- Patients with irritable bowel syndrome (IBS) experience complex and recurring symptoms that significantly impact their quality of life. With improved awareness and advances in diagnostic techniques, more patients are being accurately diagnosed. The growing need for effective treatments to relieve symptoms such as abdominal pain, diarrhea, and constipation drives pharmaceutical companies to accelerate the development of diverse and personalized therapies, promoting sustained growth in the IBS market.

## Diabetic Foot Infection

### Increasing patient population

- The increasing number of diabetes patients has led to a significant rise in cases of diabetic foot infection (DFI). Due to poor blood sugar control and compromised immune function, diabetic patients are more prone to foot infections, which also heal slowly. The growing patient base intensifies the demand for effective prevention and treatment options, driving healthcare providers and pharmaceutical companies to accelerate the development of antimicrobial drugs and comprehensive therapies, thereby promoting sustained growth in the DFI market.

Source: Frost & Sullivan Analysis

# Future trends in the Antibacterial Drug Market

## Emergence of novel therapeutic approaches

- The market is witnessing a gradual shift away from conventional Antibacterials toward more specialized and innovative therapies. Research efforts are increasingly focused on alternatives such as bacteriophage therapy, antimicrobial peptides, and microbiome-based interventions. These approaches aim to bypass traditional resistance mechanisms and provide more sustainable treatment options. The emergence of these modalities reflects a broader rethinking of how infections should be managed in the post-Antibacterials era.

## Transition toward precision-based treatments

- There is a growing emphasis on the development of targeted antibacterial agents designed to eliminate specific pathogens while preserving the patient's natural microbiota. This shift is aligned with broader trends in precision medicine, where treatment decisions are guided by diagnostic tools that identify the causative organism. By minimizing collateral damage to beneficial bacteria, targeted therapies offer the potential for improved clinical outcomes and reduced risk of resistance development.

## Optimization of drug delivery strategies

- Formulation innovation is becoming increasingly important in enhancing the clinical utility of antibacterial agents. The development of convenient dosage forms—such as long-acting injectables, orally bioavailable formulations, and depot-based delivery systems—is improving patient compliance and treatment efficiency. These improvements are particularly valuable in outpatient care, where adherence challenges often undermine the effectiveness of traditional Antibacterials regimens.

## Evolution of commercial models in antibacterial development

- The antibacterial drug market is gradually adopting new commercial models that prioritize therapeutic value over sales volume. These models aim to decouple profitability from consumption, thereby reducing the incentive for inappropriate use. Meanwhile, industry consolidation is leading to a more concentrated competitive landscape, with large pharmaceutical companies focusing on portfolio integration and smaller biotech firms driving early-stage innovation.

Source: Frost & Sullivan Analysis

# Future trends in the Antibacterial Drug Submarkets

<b>Helicobacter Pylori Infection</b>	<b>Optimized treatment strategies</b>	<ul style="list-style-type: none"><li>• The treatment of <i>Helicobacter pylori</i> infection is shifting from standardized regimens to more personalized approaches. As Antibacterials resistance becomes increasingly prevalent and diagnostic tools like molecular testing and susceptibility profiling become more widely used, clinicians are opting for tailored drug combinations based on specific bacterial strains and resistance patterns. The adoption of bismuth-containing quadruple therapies and individualized treatment plans not only improves eradication rates but also reduces the risk of recurrence. This trend is driving the continued development of novel antimicrobials and combination formulations, expanding the market toward more effective and refined solutions.</li></ul>
<b>Bacterial Vaginitis</b>	<b>Precision therapy</b>	<ul style="list-style-type: none"><li>• As medical understanding of the pathogenesis of bacterial vaginitis (BV) deepens, clinical management is shifting from traditional broad-spectrum Antibacterials use to more targeted precision treatment. The adoption of advanced molecular diagnostic technologies enables clinicians to identify specific pathogenic bacterial profiles and resistance patterns, allowing for treatment plans tailored to individual patient conditions. This precision-based approach not only improves therapeutic outcomes but also reduces recurrence rates and enhances long-term prognosis. The advancement of precision therapy is becoming a key direction in the field, continuously driving product innovation and the growth of segmented markets.</li></ul>
<b>Clostridioides Difficile Infection</b>	<b>Rise of microecological therapy</b>	<ul style="list-style-type: none"><li>• <i>Clostridioides difficile</i> infection (CDI) treatment is shifting from traditional Antibacterials toward microecological therapy. As Antibacterials use can disrupt gut microbial balance and trigger recurrence, approaches such as fecal microbiota transplantation (FMT) and probiotic formulations are gaining increasing clinical attention. These therapies help restore intestinal microbiota, thereby suppressing pathogenic overgrowth and fundamentally reducing recurrence rates. With regulatory pathways becoming clearer and research advancing, microbiota-based therapies are emerging as a key direction in CDI management, driving pipeline diversification and leading to a more segmented market landscape.</li></ul>

Source: Frost & Sullivan Analysis

# Future trends in the Antibacterial Drug Submarkets

## Bacterial Biofilm And Medical Device-Related Infections

### Technological innovation

- In response to the treatment challenges posed by bacterial biofilms, innovative technologies such as anti-adhesive materials, biofilm-disrupting drugs, and localized drug delivery systems have continuously emerged. These technologies not only effectively prevent bacterial attachment on medical device surfaces but also break down existing biofilm structures, significantly improving infection control. By enhancing drug targeting and local concentration while reducing systemic side effects, treatments become more precise and efficient. These innovations are driving the development and application of related products and have become key directions for the future development of medical device-related infection treatments.

## Prosthetic Joint Infection

### Multidisciplinary collaboration

- Treatment of periprosthetic joint infection is increasingly based on close cooperation among infectious disease specialists, orthopedists, microbiologists, and other experts, forming a comprehensive diagnostic and treatment model. This collaboration allows for more accurate infection diagnosis and personalized treatment plans, including surgery timing, Antibacterials use, and rehabilitation. It improves treatment effectiveness, reduces recurrence and complications, and advances infection management toward greater precision and integration.

## ABSSSI

### Optimized treatment strategies

- Clinical management of acute bacterial skin and skin structure infections is increasingly adopting a combined oral and intravenous Antibacterials strategy, which not only ensures effective infection control but also significantly reduces patient hospitalization time. This approach facilitates early discharge and outpatient treatment, greatly improving patients' quality of life and treatment adherence. Meanwhile, shortening hospital stays helps decrease healthcare resource consumption and the risk of hospital-acquired infections, driving treatment toward greater efficiency and sustainability.

Source: Frost & Sullivan Analysis

# Future trends in the Antibacterial Drug Submarkets

## Hepatic Encephalopathy

### Enhancing early diagnostic capability

- Hepatic encephalopathy is often overlooked or difficult to detect in its early stages, leading to delayed treatment and poor prognosis. With the advancement of neuroimaging techniques, cognitive function assessment tools, and specific biomarkers (such as serum ammonia and neuroinflammatory markers), clinicians are now able to identify subtle brain dysfunction and early neurological damage with greater accuracy. Early diagnosis not only enables timely intervention and slows disease progression but also provides a foundation for developing individualized treatment plans, significantly improving patients' quality of life and survival rates.

## Irritable Bowel Syndrome

### Modulating the gut microbiota

- Extensive research has demonstrated that the gut microbiota plays a key role in the pathogenesis of irritable bowel syndrome (IBS), particularly in regulating intestinal barrier function, immune responses, and gut-brain axis signaling. Patients with IBS often exhibit dysbiosis, characterized by a reduction in beneficial bacteria and an increase in harmful microbes, suggesting that microbiota-targeted interventions hold significant therapeutic potential. As a result, treatment strategies aimed at modulating the gut microbiota are rapidly advancing, including the use of probiotics, prebiotics, synbiotics, and fecal microbiota transplantation.

## Diabetic Foot Infection

### Application of new therapeutic technologies

- As diabetic foot infections (DFIs) become increasingly complex, traditional treatments face limitations. Emerging approaches such as negative pressure wound therapy (NPWT), bioactive dressings, and localized antimicrobial delivery systems have shown clear advantages in promoting drainage, controlling infection, and accelerating wound healing. These innovations are driving DFI treatment toward minimally invasive, bioengineered, and personalized care, significantly improving healing rates and reducing the risk of amputation.

Source: Frost & Sullivan Analysis

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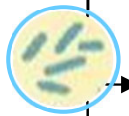
# Overview of Gut Bacterial Metabolism-Related Disease

- The main organ functions of the intestine are food digestion and nutrient absorption, and the intestine also establishes a protective epithelial barrier in this digestive environment. Additionally, due to its moist, anaerobic, and optimal pH conditions, the intestine serves as the primary site for microbial colonization. The gut microbiota, a collection of bacteria, archaea, fungi, and viruses 定植 (colonizing) the intestine, performs numerous critical physiological functions, such as regulating digestive metabolism and host immunity.

## Definition

- The gut microbiota refers to diverse microbial communities residing in the intestinal tract, primarily including bacteria, fungi, viruses, and protozoa, with bacteria being the dominant component. Common intestinal bacteria include *Bacteroides*, *Bifidobacterium*, *Lactobacillus*, and *Firmicutes*.
- Gut microbiota play a vital role in maintaining human health. They not only participate in fundamental physiological functions such as digestion, immunity, and metabolism but also indirectly regulate overall health by influencing multiple systems, including the nervous system.

## Relationship With The Host



### Symbiotic Microbial Communities

- Mainly include *Bacteroides*, *Clostridium*, *Bifidobacterium*, and *Lactobacillus*.
- They inhabit the intestinal tract for a long-term, forming a relatively stable community. Symbiotic bacteria account for over 99% of the intestinal microbial population. They co-exist in a mutually dependent and restrictive relationship with the host and are an integral part of the organism.



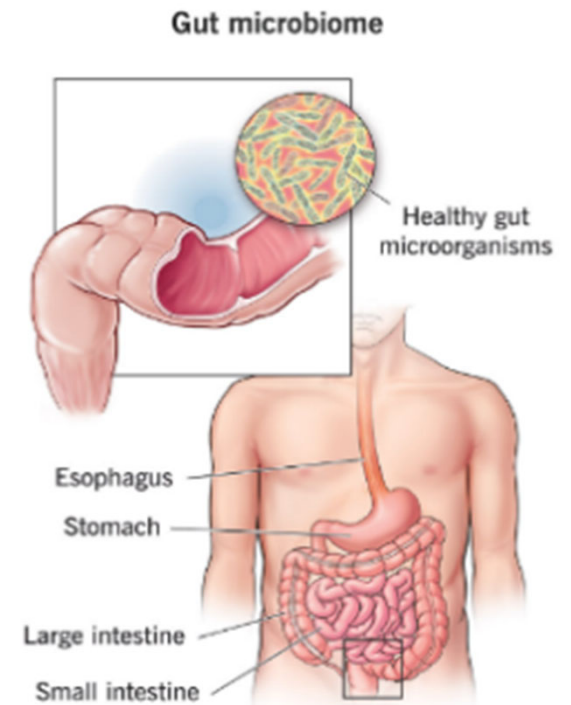
### Harmful Microbiota

- Mainly include *Enterococcus* and *Enterobacter*.
- When the intestinal tract is healthy, due to the large number of symbiotic bacteria present, conditionally pathogenic bacteria are not likely to multiply in large numbers and cause harm. When the symbiotic bacteria are disrupted, conditionally pathogenic bacteria can trigger a variety of intestinal diseases.



### Intermediate Microbiota

- Mainly include *Salmonella*, pathogenic *Escherichia coli*, *Staphylococcus aureus*, etc.
- Usually, they do not colonize the intestinal tract. Once ingested from the outside environment, they can cause diseases. For example, ingesting pathogenic *Escherichia coli* can lead to diarrhea or acute gastroenteritis.

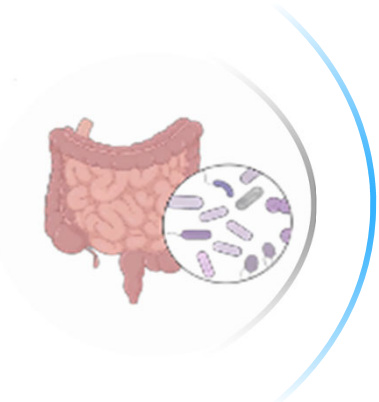


Source: Literature review, Frost & Sullivan analysis

# Overview of Gut Bacterial Metabolism-Related Disease

- Gut microbiota exist throughout the host's life cycle. Typically, from birth to around 3 - 4 years of age, individuals gradually develop their major resident microbiota. Although the gut microbiota undergoes a longer - term development process, the final - formed microbiota will have a composition as unique as a fingerprint. The human intestine (with 200 - 300 square meters of mucosa) provides an ideal habitat for the growth and proliferation of various microbial communities, including at least 50 bacterial phyla and approximately 100 - 1,000 species of bacteria. The number of genes in the gut microbiota is about 150 times that of the human genome.

## Physiological Status and Microbiota Distribution in Different Intestinal Segments



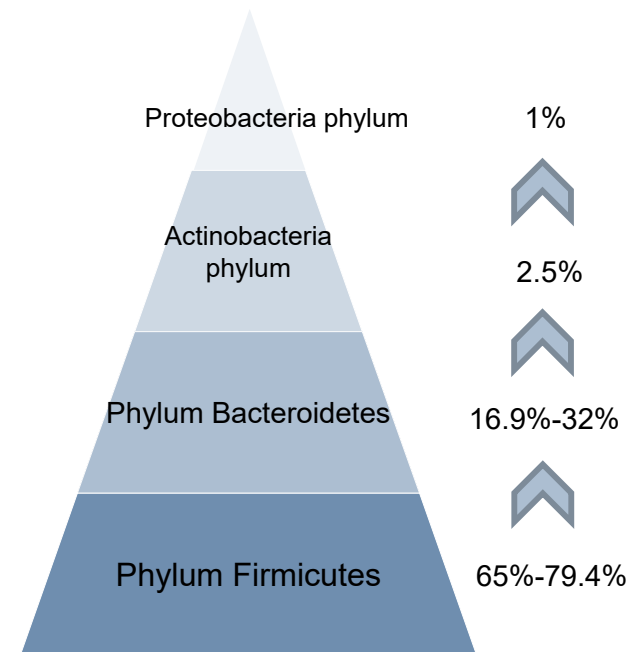
- Small intestine: Duodenum, Jejunum  
Pancreatic enzymes, bicarbonate ions, bile salts; (pH 5.7 - 6.4)  
<math>10^3 - 10^4</math> colony - forming units per milliliter (CFU/ml)  
*Lactobacillus, Enterococcus, Streptococcus, Actinomyces*
- Small intestine: Ileum  
(pH 7.3 - 7.7)  
<math>10^7 - 10^9</math> colony - forming units per milliliter (CFU/ml)  
*Enterococcus, Bacteroidetes, Lactobacillus, Clostridium, Corynebacterium*
- Large intestine: Cecum, Colon  
Mucus, bicarbonate; (pH 5.5 - 6.8)  
<math>10^{10} - 10^{12}</math> colony - forming units per milliliter (CFU/ml)  
*Bacteroidetes, Clostridium, Prevotella, Porphyromonas, Eubacterium, Ruminococcus, Streptococcus, Enterococcus, Lactobacillus, Peptostreptococcus, Fusobacterium*

Aerobes



Anaerobes

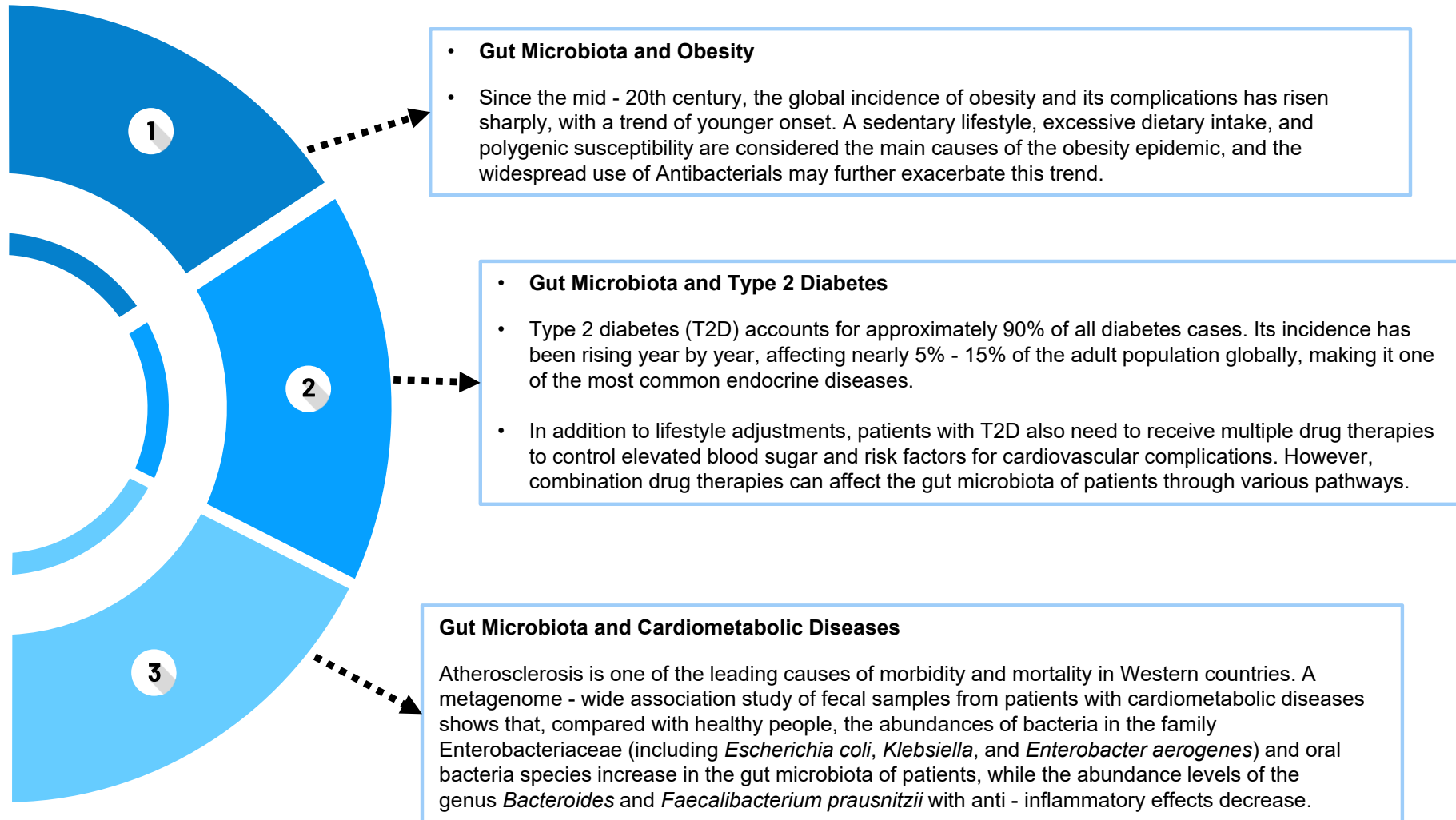
## Distribution of Major Gut Bacterial Phyla



Source: Literature review, Frost & Sullivan analysis

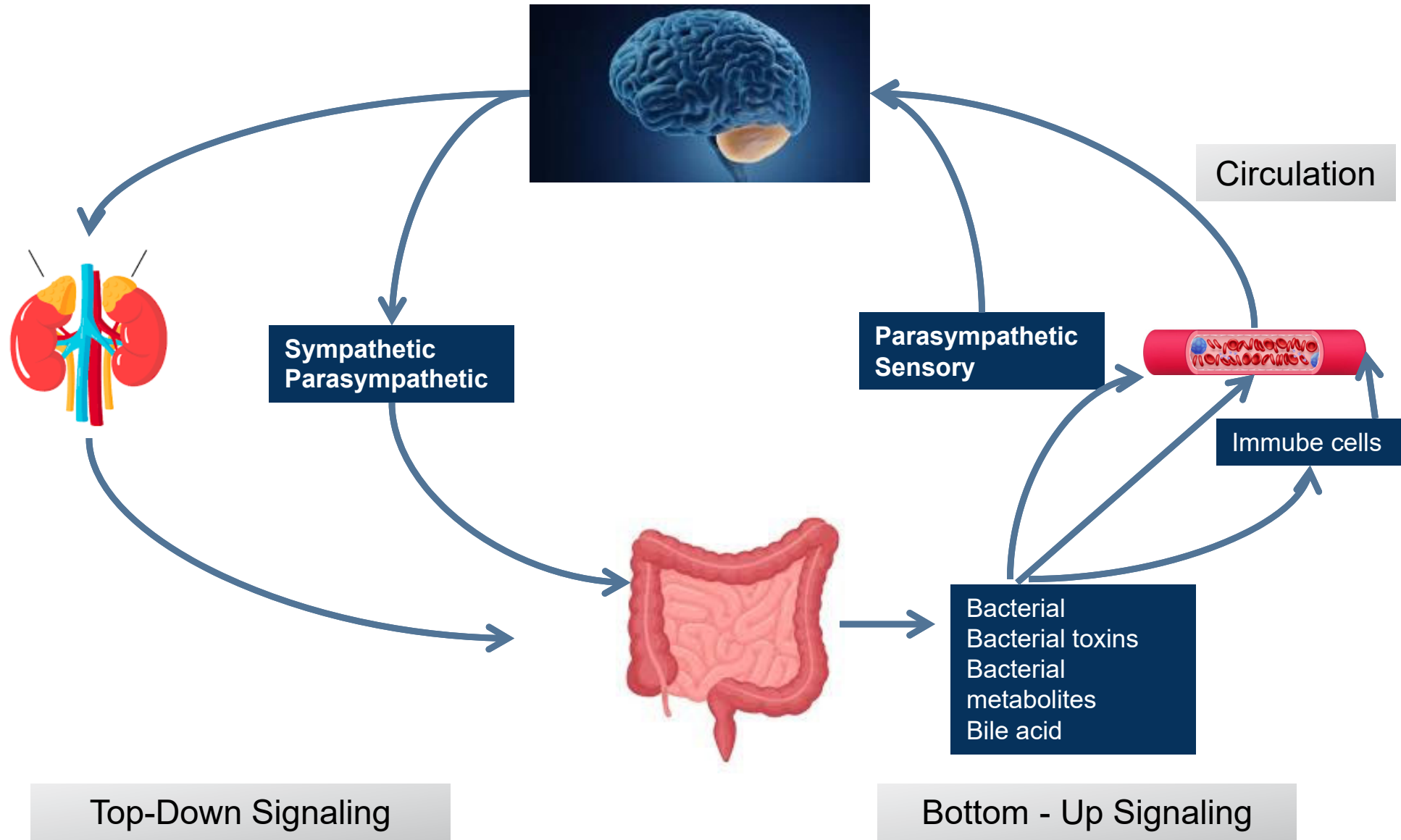
# Gut Microbiota Dysregulation and Metabolism-Related Diseases

- The gut microbiota is closely associated with the occurrence and development of metabolic diseases. Treating gut microbiota dysbiosis through means such as probiotics and fecal microbiota transplantation helps alleviate these diseases.



Source: Frost & Sullivan analysis

# Gut Microbiota Dysregulation and Metabolism-Related Diseases



Source: Frost & Sullivan analysis

# NMPA Landscape of Gut Bacterial Metabolism-Related Drug

## China Marketed Gut Bacterial Metabolism-Related Drug Competitive Landscape<sup>1-4</sup>



None

## China Gut Bacterial Metabolism-Related Drug Pipeline<sup>1-5</sup>



Generic Name	Target/MOA	Company	Indication	Clinical Stage	First Posted Date
SK08	Clostridium butyricum	Guangzhou Zhiyi Biotechnology Co., Ltd	Diarrhea-predominant Irritable Bowel Syndrome	Phase 3	2023-11-24
Lc262-1	Lactobacillus crispatus	SUZHOU OSWK BIO-PHARM CO.,LTD	Bacterial vaginitis	Phase 3	2021-04-07
WST03	Combined live bacterial preparation	SPH Sine Pharmaceutical Laboratories	Bacterial vaginitis	Phase 2	2025-01-22
BPR-101	Engineered lysozyme + prebiotic	Chengdu Beite Biopharmaceutical Co.,	Bacterial vaginitis	Phase 2	2024-09-20

1. Only includes originator, excluding generic drugs and compound drugs

2. The nature of the sponsor is enterprise

Source : NMPA (as of 04/05/2026), Frost & Sullivan analysis

# FDA Landscape of Gut Bacterial Metabolism-Related Drug

## Global Marketed Gut Bacterial Metabolism-Related Drug Competitive Landscape<sup>1-4</sup>



Generic Name	Brand Name	Target/MOA	Company	Indication	Approval Date
SER-109	VOWST	Biologically derived microbiome	Seres Therapeutics	Clostridioides difficile infection	2023.04
Rebyota	REBYOTA	FMT	Ferring Pharmace	Clostridioides difficile infection	2022.11

## Global Gut Bacterial Metabolism-Related Drug Pipeline



Generic Name	Target/MOA	Company	Indication	Clinical Stage	First Posted Date
VE303	Multi-strain commensal bacteria combination preparation	Vedanta Biosciences, Inc.	Prevention of recurrent Clostridioides difficile infection (rCDI)	Phase 3	2024-02-01
MBK-01	Multi-strain probiotic combination preparation	Mikrobiomik Healthcare Company S.L.	Clostridium Difficile Infections	Phase 2	2024-11-13
AUP-16	IL-4R $\alpha$ \ FGFR \ CSFR	Aurealis Oy	Diabetic Foot Ulcer	Phase 2	2023-11-01
MaaT033	Whole ecosystem microbiome enema	MaaT Pharma	Transplant Complication	Phase 2	2023-02-27
VE202	Multi-strain commensal bacteria combination preparation	Vedanta Biosciences, Inc.	Ulcerative Colitis, Colitis, Ulcerative	Phase 2	2022-05-12

1. Only includes originator, excluding generic drugs and compound drugs
2. The nature of the sponsor is enterprise
3. Only retain Phase II and above clinical trials.

Source : NMPA (as of 04/05/2026), Frost & Sullivan analysis

# Growth Driver of Gut Bacterial Metabolism-Related Drug Market

## Global Burden of Gut Bacterial Metabolism-Related Disease

- Inflammatory bowel disease (IBD) imposes a heavy global disease burden and is a common condition in Europe and North America. In China, along with economic and social development, accelerated urbanization, and changes in lifestyle and diet, the incidence and prevalence of IBD have significantly increased. IBD is an independent risk factor for *Clostridioides difficile* infection (CDI). CDI is typically caused by intestinal dysbiosis due to antimicrobial drug use, serving as a major cause of comorbidities and mortality in patients, especially elderly patients, and is one of the common causes of hospital-acquired infections. With the widespread use of Antibacterials and the increase in aging populations, the therapeutic needs for related indications are continuously growing.

## Rising threat of Gut Bacterial Metabolism-Related Disease

- In recent years, research on the relationship between the gut microbiota and the pathogenesis of various diseases, as well as treatment approaches, has deepened. Gut microbiota interventions such as gut microbiota drugs, fecal microbiota transplantation (FMT), and probiotic supplementation have achieved remarkable efficacy in the treatment of diseases represented by CDI. Multiple gut microbiota drugs have been successively approved for marketing, demonstrating broad clinical application prospects and huge market potential for gut microbiota intervention technologies.

## Capital Deployment in the Gut Microbiota Field

- In recent years, with breakthroughs in basic research and the demonstration of clinical value, the gut microbiota industry has attracted significant capital attention, which has further driven the prosperity of related markets. Notably, since 2019, the total financing amount and the number of financing events in the global gut microbiota sector have surged, growing from \$100–200 million to over \$600 million in 2020. This substantial leap in financing scale has garnered widespread market attention.

Source: Frost & Sullivan Analysis

# Future trends in the Gut Bacterial Metabolism-Related Drug Market

**Significant Research  
Progress Drives  
Industrial  
Transformation in  
Healthcare**

- With the comprehensive deepening of research on the bidirectional regulatory mechanisms between the gut microbiota and host immunity, metabolism, and overall health, the academic community's understanding of the relationship between the gut microbiota and health/diseases has continuously deepened, bringing a series of opportunities for the development of novel therapies and targeted intervention strategies. Compared with the genome, the microbiome has greater plasticity, making it an excellent therapeutic target

**Improved Regulatory  
Systems Promote  
Standardized Industry  
Development**

- Standardized regulation is crucial for the clinical safe application of genetically modified strains and FMT, and it is also the cornerstone for the long-term sustainable development of the gut microbiota industry. Currently, preclinical testing and safety evaluation of FMT are relatively mature, although global regulatory classifications for this therapy vary: some countries (such as the U.S., Canada, and Australia) classify it as a strictly regulated biological agent; in other countries (such as the U.K., France, Germany, and Switzerland), it is categorized as a medicinal product or treatment and subject to differentiated regulation.

**Interdisciplinary  
Integration and  
Innovation Accelerate  
Precision Medicine  
Applications**

- Gut microbiota research has achieved breakthroughs through deep cross-disciplinary exploration. Through collaborative innovation in microbiology, genomics, bioinformatics, clinical research, and personalized medicine, cost-effective gut metagenomics has become increasingly prevalent, enabling more accurate and economical methods to understand the gut microbiota. In this process, the development of high-throughput sequencing and biocomputational tools, interdisciplinary collaboration, and integration of diverse population data have provided key support for the precise definition and comprehensive analysis of the gut microbiota.

Source: Frost & Sullivan Analysis

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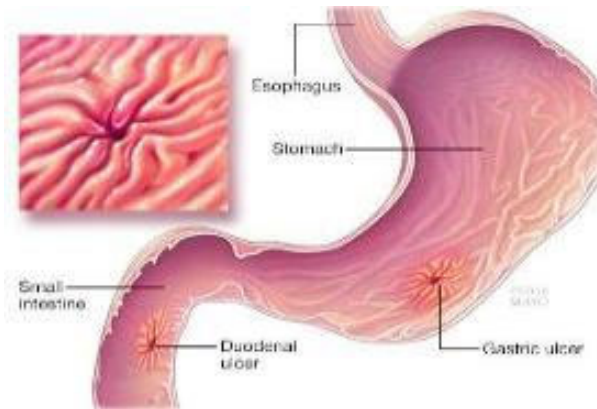
# Overview of Helicobacter Pylori Infection

- Helicobacter pylori, a gram-negative microaerophilic pathogen, causes several upper gastrointestinal diseases, such as chronic gastritis, peptic ulcer disease, and gastric cancer.

## Site of Helicobacter Pylori Infection

H. pylori attacks the lining that protects your stomach. The bacteria make an enzyme called urease. This enzyme makes stomach acids less acidic.

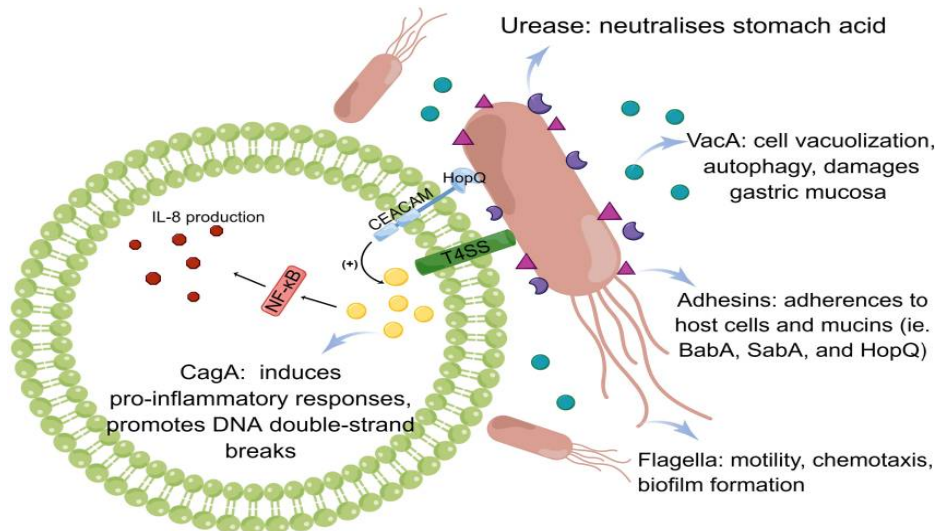
It also weakens stomach's lining which contribute to cells then have greater risk of being hurt by acid and pepsin, strong digestive fluids. That can lead to sores or ulcers in stomach or duodenum.



## Symptoms

- An ache or burning pain in your stomach (abdomen)
- Stomach pain that may be worse when your stomach is empty
- Nausea
- Loss of appetite
- Frequent burping
- Bloating
- Unintentional weight loss

## Mechanism of Helicobacter Pylori Infection



### • Acid Resistance: Urease System

Urease converts urea to ammonia, neutralizing gastric acid for survival. Nickel is essential for urease activity. Urease also triggers inflammation and links to extra-gastric diseases.

### • Movement and Colonization: Flagellar System

Flagella enable H. pylori to penetrate mucus (counterclockwise rotation) and adhere (clockwise rotation). They also promote biofilm formation, increasing resistance.

### • Adhesion: Adhesin System

Adhesins like BabA, SabA, and HopQ bind to host molecules. HopQ helps transfer CagA, an oncoprotein. Glycosylated adhesins intensify inflammation and carcinogenesis.

### • Synergistic Effects

These mechanisms collaborate: biofilms and adhesins evade immunity; urease and CagA fuel chronic inflammation via NF-κB; CagA causes DNA damage.

Source: Literature Review, Frost & Sullivan Analysis

# Analysis of the Harmfulness of Helicobacter pylori Infection

- Helicobacter pylori is closely associated with a variety of gastric diseases, including gastric ulcers, chronic progressive gastritis, and gastric cancer. Besides its pathogenic role in gastric diseases, an increasing amount of evidence suggests that H. pylori may be related to a variety of extragastric diseases. H. pylori may interfere with multiple extragastric biological processes and influence the occurrence of various extragastric diseases

## Gastric Diseases

A high CagA - positive rate in Helicobacter pylori strains links to more severe gastritis. Infections causing chronic gastritis and gastric ulcers can damage gastric mucosal cell DNA, promoting gastric cancer development.

### Progression of H. Pylori Infection

## Extragastric diseases

- H. pylori induces inflammatory factors (e.g., IL-1/2/6/8/10, TNF- $\alpha$ , IFN- $\gamma$ ), triggering chronic low-level systemic inflammation and diseases
- H. pylori antigens trigger molecular mimicry and cross-antigen reactions, causing autoimmune attacks and related diseases.

## Some of the Most Common Organ Damage Symptoms

**Ophthalmic disease:** Glaucoma

**Respiratory disease:** Asthma, Chronic Obstructive Pulmonary Disease (COPD)

**Skin diseases:** Rosacea, Chronic urticaria

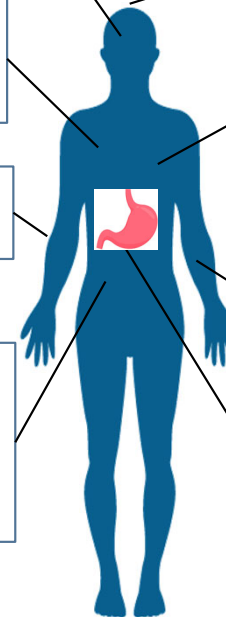
**Hepatobiliary system diseases:** Cholangiocarcinoma, Hepatic Carcinoma, Non - alcoholic fatty liver disease (NAFLD)

**Neurological diseases:** Alzheimer's disease, Parkinson's disease

**Heart and circulatory disease:** Coronary artery disease, Myocardial infarction

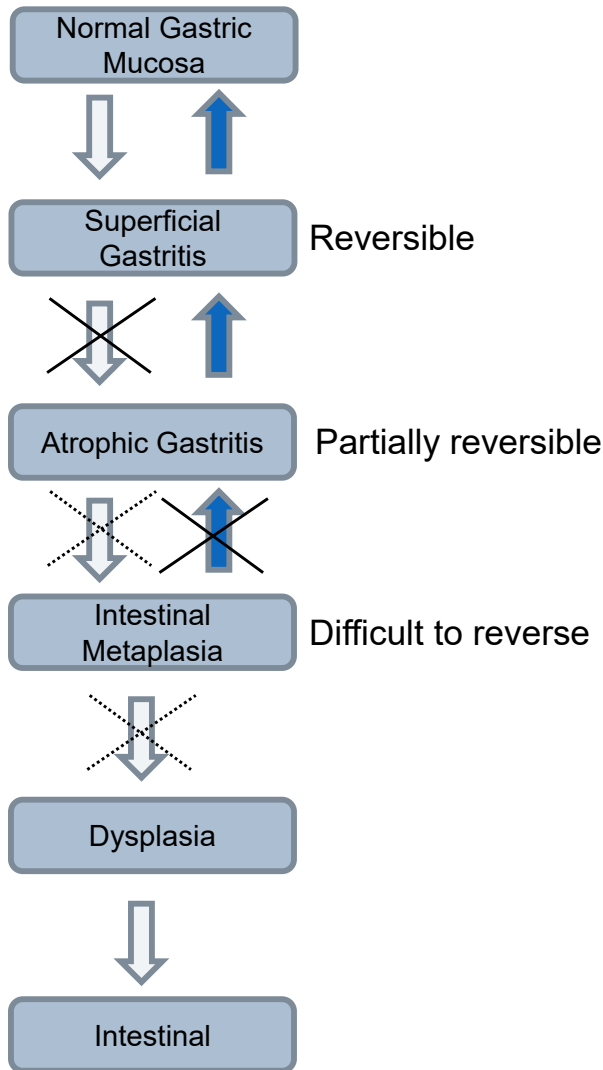
**Hematological diseases:** Iron deficiency anemia, Vitamin B12 deficiency

**Digestive system diseases:** Chronic gastritis, Peptic ulcer disease, Gastric cancer



Source: Literature Review, Frost & Sullivan Analysis

# Advantages of Early Treatment for Helicobacter pylori Infection



## ***Related to Treatment:***

### **Eradication efficacy at different treatment stages**

- Before atrophy/intestinal metaplasia occurs: 100%
- Intervention for asymptomatic population: 50%
- After endoscopic treatment for early - stage gastric cancer: 50%
- With a family history of gastric cancer: 70%



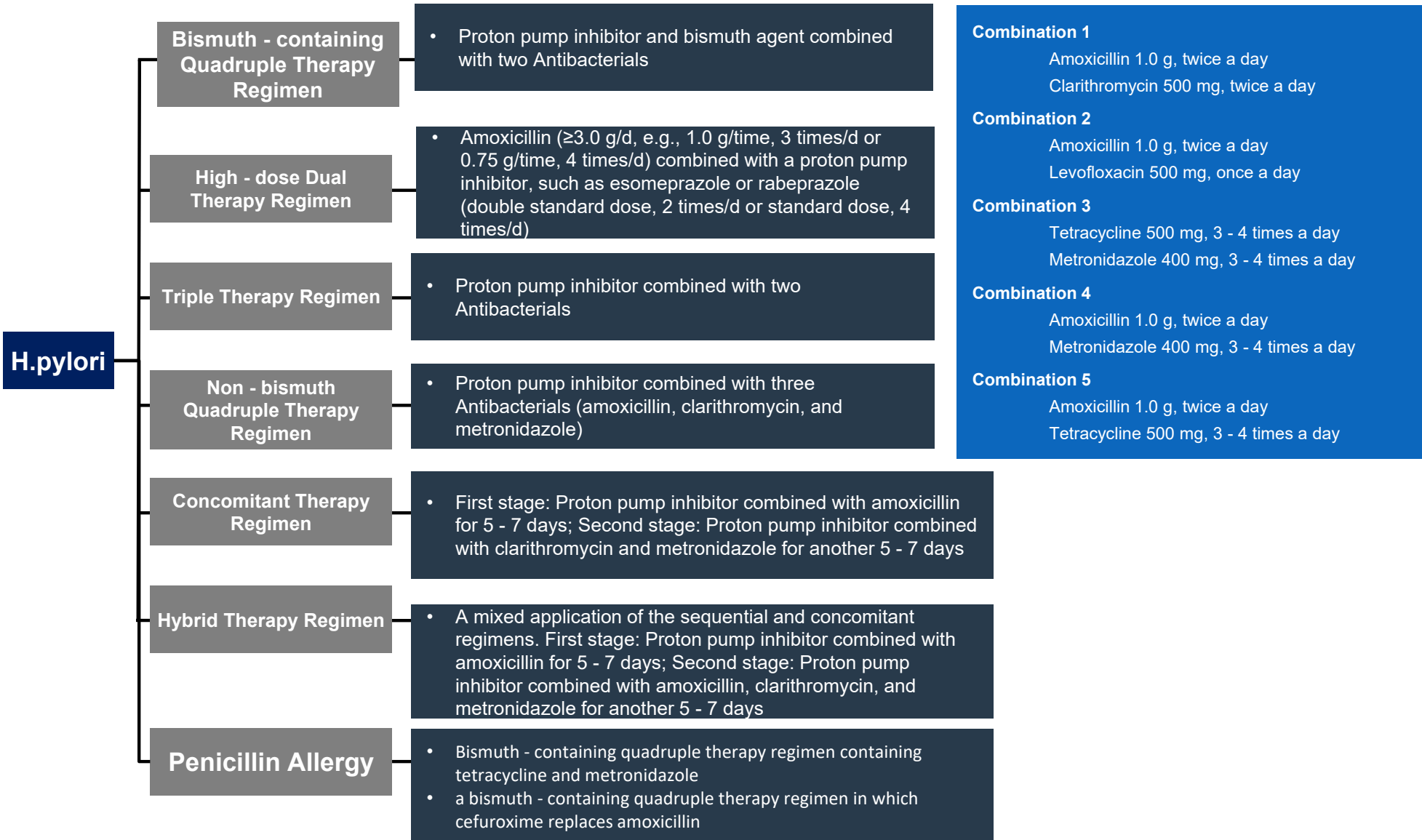
## ***Related to Disease:***

### **Reduce the risk of gastric cancer**

- Although *Helicobacter pylori* (Hp) infection is not the sole causative factor for gastric cancer, it is the most important and controllable one.
- Eradicating *Helicobacter pylori* can effectively prevent gastric cancer, reducing its incidence by 39%. It also has a preventive effect on gastric cancer in people with severe precancerous lesions and the elderly population.

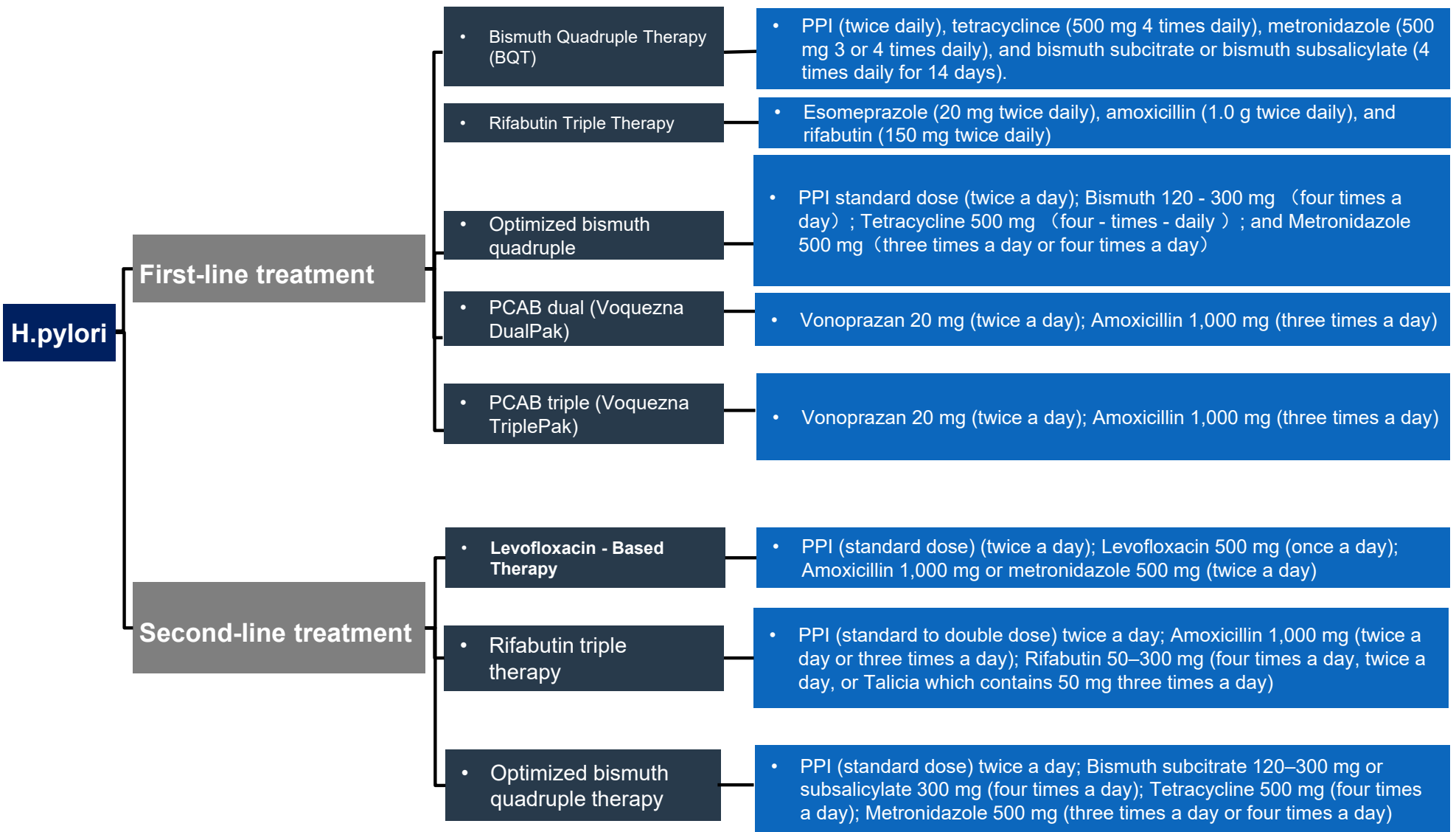
Source: Frost & Sullivan Analysis

# Treatment Paradigm of Helicobacter Pylori in China



Source: 《2022 中国幽门螺杆菌感染治疗指南》, Frost & Sullivan analysis

# Treatment Paradigm of Helicobacter Pylori in U.S.



Source: 《American College of Gastroenterology 2024》 , Frost & Sullivan analysis

# Structure of Helicobacter Pylori Treatment Regimen Utilization

Regimen Type	Drug Composition	Duration	Indicated Population	Eradication Rate
Bismuth - containing Quadruple Therapy Regimen	PPI (standard dose, e.g., Esomeprazole 20 mg bid) + bismuth agent (Bismuth Potassium Citrate 220 mg bid) + two antibiotics (postprandial). Antibiotic combinations: ① Amoxicillin 1 g bid + Clarithromycin 500 mg bid (low resistance areas) ② Amoxicillin 1 g bid + Tetracycline 500 mg tid ③ Tetracycline 500 mg tid + Furazolidone 100 mg bid (penicillin allergy) ④ Amoxicillin 1 g bid + Metronidazole 800 mg bid (high dose, low resistance areas)	10–14 days	Initial treatment, most regions (especially clarithromycin resistance <20%)	83.3%
Rifabutin Triple Therapy	PPI (standard dose, twice daily or higher dose); Amoxicillin (250 mg, three times daily); Rifabutin (12.5 mg, three times daily).	14 days	Initial treatment, amoxicillin-sensitive (resistance <10%), young patients	89%
P-CAB-containing Regimens	Vonoprazan 20 mg bid + amoxicillin 1 g tid	14 days	Fast PPI metabolizers, PPI-intolerant patients, high-resistance areas	82.1%

*Note: Examples provided are for illustrative purposes only, showcasing MRCT or real-world study data.*

# Structure of Helicobacter Pylori Treatment Regimen Utilization

Regimen Type	Drug Composition	Duration	Indicated Population	Eradication Rate
Penicillin Allergy Regimens	<ul style="list-style-type: none"> <li>① Tegoprazan 50 mg bid + bismuth 220 mg bid + cefuroxime 500 mg bid + tetracycline 500 mg tid</li> <li>② Cefuroxime 500 mg bid + levofloxacin 500 mg qd + bismuth + PPI</li> </ul>	14 days	Patients with penicillin allergy	81%-92%
Refractory Infection Regimens	<ul style="list-style-type: none"> <li>① Bismuth quadruple with antibiotic substitution (tetracycline + furazolidone + high-dose metronidazole 1600 mg/d).</li> <li>② High-dose dual therapy (amoxicillin 4 g/d, divided 4 times).</li> <li>③ P-CAB-containing quadruple (vonoprazan + bismuth + tetracycline + furazolidone).</li> </ul>	14 days	Failed initial/rescue treatment, confirmed resistance (susceptibility guidance prioritized)	85%–90%

*Note: Examples provided are for illustrative purposes only, showcasing MRCT or real-world study data.*

# Comparison of Resistance Rates of Conventional Antibiotics

## Related to *H. pylori* Eradication Therapy

Antibiotic Class / Name	Main Indications (Relevant to TNP2092)	Resistance Rate - China	Resistance Rate -US	Resistance Rate - Global
Clarithromycin	<i>H. pylori</i> Eradication (First-line)	20-50%	~10-15%	15-30%
Metronidazole	<i>H. pylori</i> Eradication (First-line)	60-90%	~30-40%	30-70%
Amoxicillin	<i>H. pylori</i> Eradication (First-line)	~10%	<5%	<5%
Levofloxacin	<i>H. pylori</i> Eradication (Second-line)	20-50%	~15-25%	15-30%
Rifabutin	<i>H. pylori</i> Eradication (Third-line)	<5%	<3%	<5%
Tetracycline	<i>H. pylori</i> Eradication (Second-line)	5-15%	<3%	<10%

## Related to MRSA & Severe Gram-Positive Infections(For PJI, ABSSSI)

Antibiotic Class / Name	Bacteria (Relevant to TNP2092)	Resistance Rate - China	Resistance Rate -US	Resistance Rate - Global
Vancomycin	MRSA, Severe G <sup>+</sup> Infections	~1.7%	MRSA: ~1-2% VISA/VRSA: Rare	<5%
Linezolid	MRSA, VRE	1-3%	MRSA: <1% VRE: ~2-3%	<2%
Daptomycin	MRSA Bacteremia, etc.	<1%	<1%	<1%
Dalbavancin	MRSA	Not available	0-2%	0-2%
Oritavancin	MRSA	Not available	0-2%	0-2%

## Related to Innovative Antibiotics

Antibiotic Class / Name	Main Indication (Relevant to TNP2092)	Resistance Rate - China	Resistance Rate -US	Resistance Rate - Global
Contezolid	Complicated Skin Infections	Currently very low (<1%)	Currently very low (Limited data)	Currently very low
NUZYRA® (Omadacycline)	Pneumonia, Skin Infections	Not available	Not available	Not available
MRX-4	Complicated Skin Infections (Targeting MRSA, etc.)	Not available	Not available	Not available

Note: Examples provided are for illustrative purposes only, showcasing MRCT or real-world study data.

# Clinical Pain Points in Helicobacter Pylori Treatment

- Quadruple therapy is the main recommended regimen for eradicating H. pylori, but the resistance rates of commonly used Antibacterials are relatively high. Quadruple therapy consists of one proton pump inhibitor (PPI), one bismuth agent, and two Antibacterials. Currently, empirical medication is still the dominant approach for H. pylori-positive patients, and selecting the two Antibacterials represents the greatest challenge in quadruple therapy. According to the "Report on Helicobacter pylori Screening of 120,000 People in China", the resistance rates in the general population of China are 53.77% for clarithromycin, 51.57% for quinolone Antibacterials (such as levofloxacin), and 7.70% for furazolidone. The relatively high levels of Antibacterials resistance will impact the precise treatment of H. pylori patients.

## Limitations Analysis

Treatment Methods	Major Treatment options
<b>Antibacterials resistance</b>	<ul style="list-style-type: none"> <li>• Currently, the resistance rates of amoxicillin, furazolidone, and tetracycline are relatively low (0% - 5%), while the resistance rates of metronidazole (40% - 70%), clarithromycin, and levofloxacin (20% - 40%) have all increased. This has led to a rising failure rate of H. pylori eradication in patients year by year.</li> </ul>
<b>Side effects and adverse reactions</b>	<ul style="list-style-type: none"> <li>• Disrupts gut microbiota, weakens the patient's constitution, and fosters drug resistance, necessitating higher - grade drugs next time and creating a vicious cycle.</li> <li>• Harms children, potentially causing organ developmental abnormalities, and in severe cases, infantile body - function failure and death.</li> <li>• Toxic; for instance, penicillin can trigger shock and, in extreme cases, death.</li> <li>• Promotes drug - resistant strains, killing non - resistant microbes and allowing resistant ones to proliferate, making patients more susceptible to diseases.</li> <li>• Related to bismuth agents: black stools, constipation Related to Antibacterials: abnormal taste (clarithromycin), peripheral neuritis (furazolidone), elevated liver enzymes</li> </ul>
<b>Adherence</b>	<ul style="list-style-type: none"> <li>• Taking 4 kinds of medications (11-14 tablets) daily leads to a higher missed dose rate than dual therapy regimens.</li> </ul>
<b>Recurrence and reinfection</b>	<ul style="list-style-type: none"> <li>• &lt;3%</li> </ul>

Source: Guidelines for Primary Diagnosis and Treatment of Atopic Dermatitis (2022), Frost & Sullivan Analysis

# NMPA Landscape of Helicobacter Pylori Infection

## China Marketed Helicobacter Pylori Infection Drug Competitive Landscape<sup>1-4</sup>



None

## China Helicobacter Pylori Infection Drug Pipeline<sup>1-5</sup>



Generic Name	Target	Company	Indication	Clinical Stage	First Posted Date
TNP-2198	RNAP/Nitroreductase	TenNor Therapeutics	Helicobacter Pylori Infection	NDA	2023.02

1. Only includes chemical originator, excluding generic drugs
2. Excluding PPI and P-CAB inhibitor (e.g. Omeprazole, Lansoprazole or Vonoprazan, Tegoprazan) for primarily act as acid suppressants, and not directly target helicobacter pylori infection
3. Excluding broad-spectrum Antibacterials (e.g., amoxicillin, azithromycin), as they are general-purpose Antibacterials rather than HPI-targeted therapies
4. The nature of the sponsor is enterprise
5. Only includes pipelines active within the past three years
6. TNP-2198 is in the NDA stage. in China

Source : NMPA (as of 04/05/2026), Frost & Sullivan analysis

# FDA Landscape of Helicobacter Pylori Infection

## Global Marketed Helicobacter Pylori Infection Drug Competitive Landscape<sup>1-4</sup>



Generic Name	Target	Company	Indication	Clinical Stage	First Posted Date
Talicia <sup>6</sup>	RNAP/PBP	RedHill Biopharma	Helicobacter Pylori Infection	NDA	2019.0

## Global Helicobacter Pylori Infection Drug Pipeline<sup>1-5</sup>



Generic Name	Target	Company	Indication	Clinical Stage	First Posted Date
TNP-2198	RNAP/Nitroreductase	TenNor Therapeutics	Helicobacter Pylori Infection	NDA	2023.02

1. Only includes chemical originator, excluding generic drugs
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3. Excluding broad-spectrum Antibacterials (e.g., amoxicillin, azithromycin), as they are general-purpose Antibacterials rather than HPI-targeted therapies
4. The nature of the sponsor is enterprise
5. Only includes pipelines active within the past three years
6. Talicia is a Type 4-combination

Source : ClinicalTrials (as of 04/05/2026), Frost & Sullivan analysis

# FDA Landscape of Helicobacter Pylori Infection

## Global Marketed Innovative Helicobacter Pylori Infection Drug Competitive Landscape<sup>1-4</sup>



Brand Name	Generic Name	Target	Company	Indication	First Posted Date
Pylera	Bismuth Subcitrate Potassium; Metronidazole; Tetracycline Hydrochlorid	NA	Juvisc Pharmaceuticals	Helicobacter Pylori Infection	2006.09

## Global Marketed Non-innovative Helicobacter Pylori Infection Drug Competitive Landscape<sup>1-4</sup>



Brand Name	Generic Name	Target	Company	Indication	First Posted Date
Voquezna Triple Pak	Amoxicillin; Clarithromycin; Vonoprazan Fumarate	H+/K+ ATPase	Phathom Pharmaceuticals	Helicobacter Pylori Infection	2022.05
Talicia	Talicia	RNAP/PBP	RedHill Biopharma	Helicobacter Pylori Infection	2019.0
Prilosec	H+/K+ ATPase	50S rProteins	Covis Pharma	Helicobacter Pylori Infection	2008.03
Prevpac	Amoxicillin; Clarithromycin; Lansoprazole	NA	Takeda Pharms Usa	Helicobacter Pylori Infection	1997.12

1. Only includes chemical originator

Source : ClinicalTrials (as of 04/05/2026), Frost & Sullivan analysis

# Global Marketed Helicobacter Pylori Infection Drug Competitive Landscape(off-label)

Drug Category	Representative Drug	First Marketed Year	Major Manufacturers	Resistance / Sensitivity	Treatment Course Cost (CN) & Insurance Coverage	Treatment Course Cost (US) & Insurance Coverage
β-lactam	Amoxicillin	1972 (US)	Many generics (Multiple)	Resistance: <1–5% globally	RMB 20–80 per course; typically reimbursed, brand-dependent	50–150 USD per course; typically reimbursed, brand-dependent
Macrolide	Clarithromycin	1991 (Japan/US)	Taisho/Abbott + generics	Resistance: 20–40% globally	RMB 5–20 per course; widely reimbursed	8–40 USD per course; widely reimbursed
Nitroimidazole	Metronidazole	Older class (1950s drugs widely used)	Many generics	Resistance: 30–70% globally	RMB 10–50 per course; insurance coverage common	100–400 USD per course; insurance coverage common
Fluoroquinolone	Levofloxacin	1990s (patent expired ~2010)	Sanofi-Aventis + generics	Resistance: 15–30% globally; China: 25–45%	RMB 200–800 per course; limited insurance coverage, usually specialist-prescribed	300–600 USD per course; limited insurance coverage, usually specialist-prescribed
Rifamycin	Rifabutin	(1950s rifamycin class; derived later)	Insmmed + generics	Resistance: <1–3% globally; rare primary resistance	RMB 10–40 per course; generally reimbursed	20–60 USD per course; generally reimbursed
Tetracycline	Tetracycline	1950s class	Many generics	Resistance: <5–10% globally	RMB 20–80 per course; typically reimbursed, brand-dependent	50–150 USD per course; typically reimbursed, brand-dependent

1. Only includes chemical originator

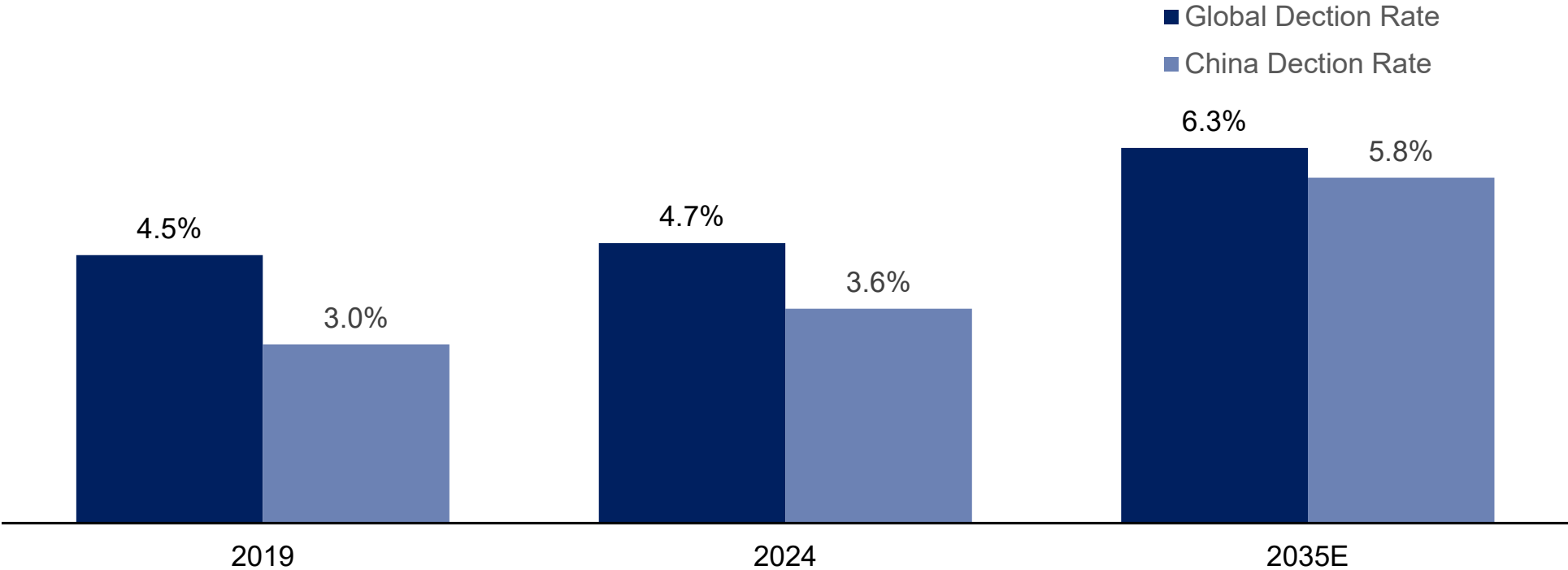
Source : ClinicalTrials (as of 04/05/2026), Frost & Sullivan analysis

# Detection Rate of Helicobacter Pylori

• In 2019, the global and china detection rate of Helicobacter Pylori was 4.5% and 3.0%. In 2024, the detection rate reached 4.7% and 3.6%. The detection rate is expected to reach 6.3% and 5.8% in 2035.

Detection Rate of Helicobacter Pylori, 2019-2035E

Unit:%



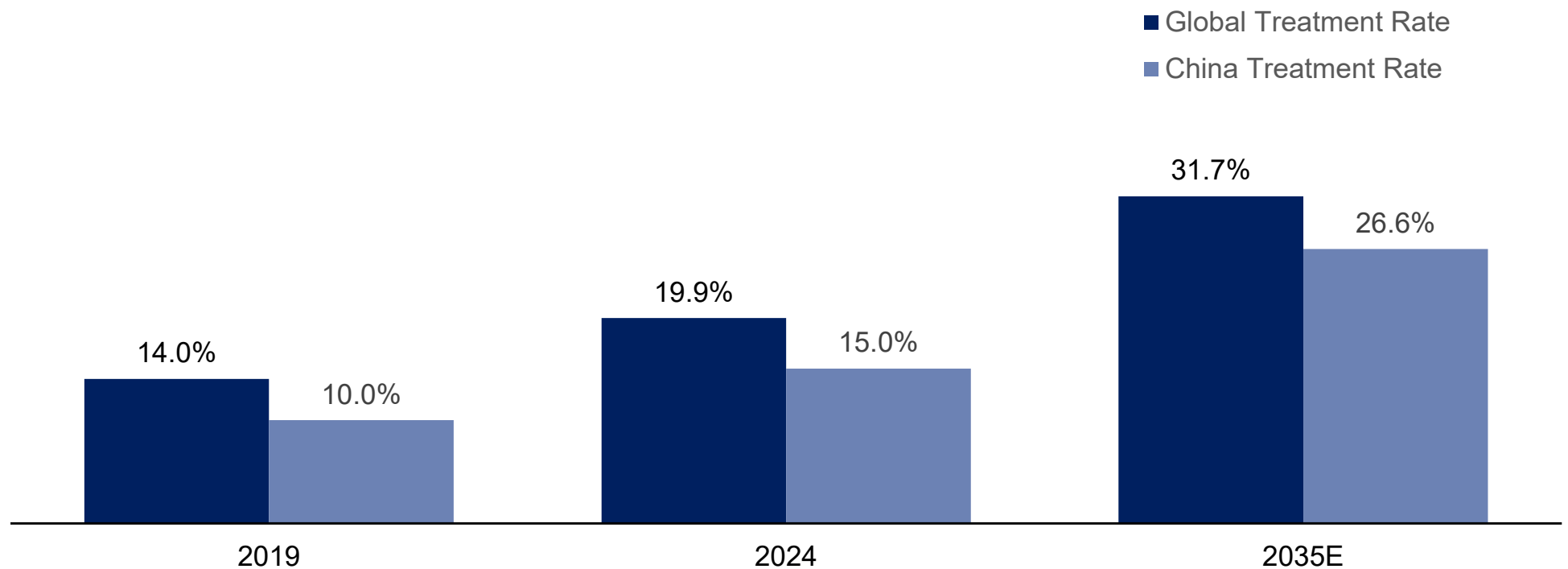
Source: Frost & Sullivan analysis

# Out-of-hospital Treatment Rate for Helicobacter Pylori Infection\*

- In 2019, the global and china treatment rate of Helicobacter Pylori was 14.0% and 10.0%. In 2024, the treatment rate reached 19.9% and 15.0%. The treatment rate is expected to reach 31.7% and 26.6% in 2035.

Treatment Rate of Helicobacter Pylori, 2019-2035E

Unit:%



NOTE: \* Out-of-hospital treatment rate for Helicobacter pylori infection among individuals diagnosed through routine health examinations  
Source: Frost & Sullivan analysis

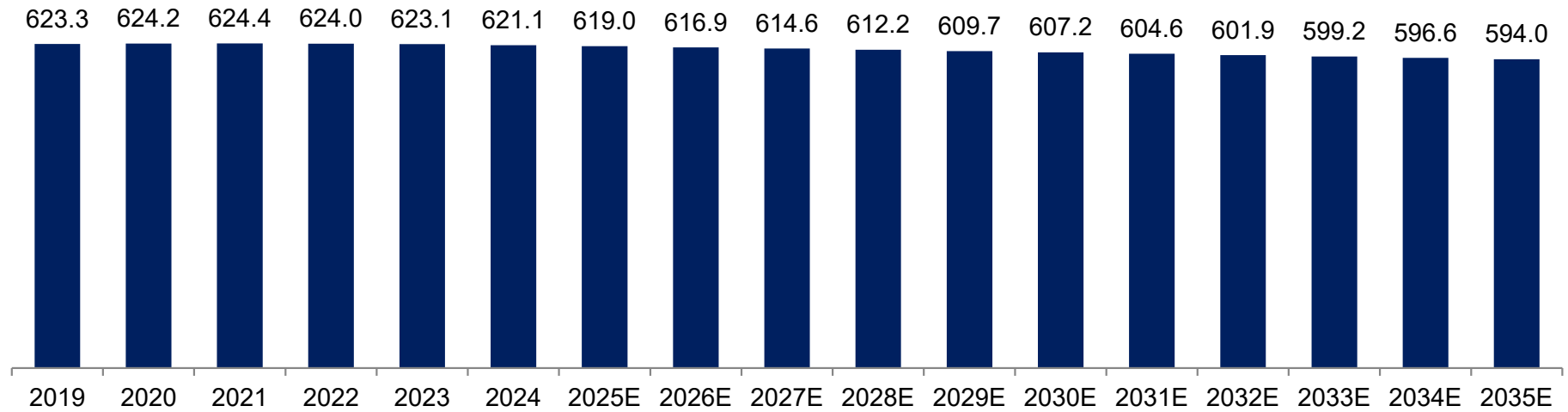
# Incidence of Helicobacter Pylori Infection in China, 2019-2035E

- Incidence number of H.pylori infection in China decreased from 623.3 million to 621.1 million in 2019 and 2024. The number is expected to reduce to 607.2 million in 2030 at a CAGR of -0.4% from 2024 to 2030. The number is expected to decrease to 594.0 million in 2035, at a CAGR of -0.4%.
- The public's health awareness has significantly increased. In 2020, China introduced the *National Action Plan to Contain Bacterial Resistance*, restricting the sale of over - the - counter antibiotics. This has reduced the risk of the spread of Helicobacter pylori drug resistance, and the incidence rate is expected to decline.

## Incidence of H.pylori Infection in China, 2019-2035E

Unit: Million

Period	CAGR
2019-2024	-0.1%
2024-2030E	-0.4%
2030E-2035E	-0.4%



Source: Literature Review, the White Paper on Helicobacter pylori Infection Prevention and Control in China , Frost & Sullivan Analysis

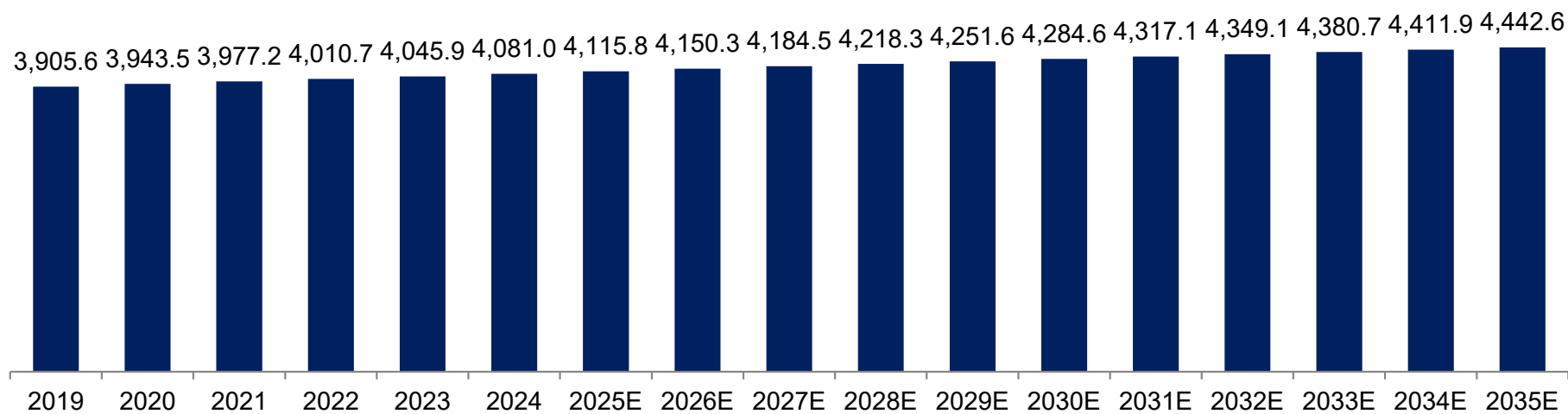
# Global Incidence of Helicobacter Pylori Infection, 2019-2035E

- Global Incidence number of H.pylori infection increased from 3,905.6 million to 4,081.0 million in 2019 and 2024. The number is expected to grow to 4,284.6 million in 2030 at a CAGR of 0.8% from 2024 to 2030. The number is expected to grow to 4,442.6 million in 2035, at a CAGR of 0.7%.

## Global Incidence of H.pylori Infection, 2019-2035E

Unit: Million

Period	CAGR
2019-2024	0.9%
2024-2030E	0.8%
2030E-2035E	0.7%



Source: Literature Review, Frost & Sullivan Analysis

# Global Helicobacter Pylori Infection Drugs Market Size

- In 2019, the market size was USD5.3 billion. From 2019 to 2024, it grew at a CAGR of 6.0%. In 2024, the market size reached USD6.9 billion. The market size is expected to reach USD10.0 billion in 2029, with a CAGR of 7.6% from 2024 to 2029. The market will further grow to USD16.1 billion in 2035, with a CAGR of 9.6% from 2029 to 2035..

## Global Helicobacter Pylori Infection Drugs Market Size, 2019-2035E

Unit: Billion USD  
At wholesales price level

Period	CAGR
2019-2024	6.0%
2024-2029E	7.6%
2029E-2035E	9.6%

Year	2019	2020	2021	2022	2023	2024	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E
Market Size (USD bn)	5.3	5.5	5.8	6.1	6.4	6.9	7.5	8.1	8.7	9.3	10.0	10.8	11.7	12.7	13.7	14.9

Source: Frost & Sullivan analysis

# China Helicobacter Pylori Infection Drugs Market Size

- In 2019, the market size was RMB5.6 billion. From 2019 to 2024, it grew at a CAGR of -0.3%. In 2024, the market size reached RMB 5.5 billion. The market size is expected to reach RMB6.8 billion in 2029, with a CAGR of 4.3% from 2024 to 2029. The market will further grow to RMB12.6 billion in 2035, with a CAGR of 10.9% from 2029 to 2035.

## China Helicobacter Pylori Infection Drugs Market Size, 2019-2035E

Unit: Billion RMB  
At ex-factory price level

Period	CAGR
2019-2024	-0.3%
2024-2029E	4.3%
2029E-2035E	10.9%

Year	2019	2020	2021	2022	2023	2024	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
Market Size (RMB bn)	5.6	5.4	5.3	5.3	5.2	5.5	5.7	5.9	6.1	6.4	6.8	7.2	7.7	8.4	9.3	10.6	12.6

Source: Frost & Sullivan analysis

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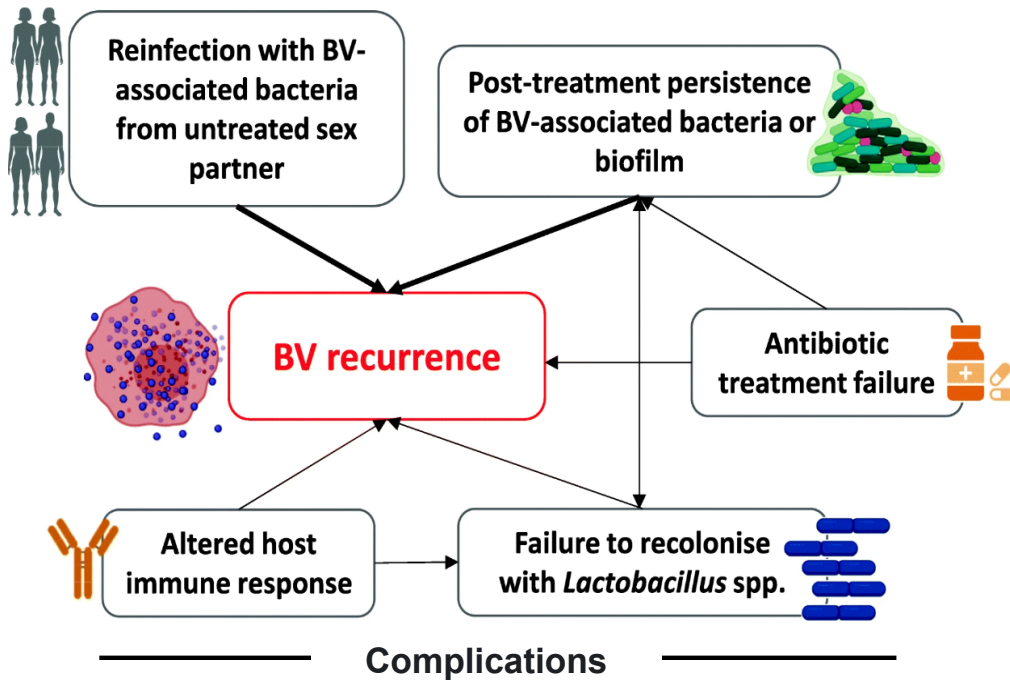
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<b>1</b>	Overview of Pharmaceutical Industry in China
<b>2</b>	Overview of Anti-infection Drug Market in China
<b>3</b>	Overview of Gut Bacterial Metabolism-Related Drug Market in China
<b>4</b>	<b>Overview of Indications for the Company's Pipeline</b>
<b>4.1</b>	Helicobacter Pylori Infection
<b>4.2</b>	<b>Bacterial Vaginitis</b>
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<b>4.8</b>	Hepatic Encephalopathy
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<b>4.10</b>	Diabetic Foot Infection

# Overview of Bacterial Vaginitis

- BV is a dysbiosis of the vaginal microbiota characterized by a shift from Lactobacilli dominance to that of a mixture of various anaerobic bacteria. It is the most common vaginal disorder worldwide in women of childbearing age. BV is associated with significant adverse healthcare outcomes, including increased susceptibility to sexually transmitted infections, urogenital infections, pelvic inflammatory disease, and an increased risk of abnormal pregnancy.

## Pathogenesis of Bacterial Vaginosis Infection



### Complications

- Pelvic inflammatory disease
- post-gynecological surgery infections

### pregnancy outcomes

miscarriage, preterm birth, premature rupture of membranes, chorioamnionitis, neonatal infection, and puerperal infection.

## Diagnostic criteria

Clinical Diagnostic Criteria: Amsel Criteria

Laboratory Gold Standard: Nugent Score and Hay-Ison Criteria

Molecular Diagnostic Techniques

Point-of-Care Testing (POCT) and Emerging Technologies

## Characteristics

In 90% of BV patients, *Gardnerella vaginalis*-dominated biofilms are present. Compared with other vaginal anaerobes, *Gardnerella vaginalis* has greater virulence potential (stronger adhesion, cytotoxicity, and biofilm-forming ability).

*Gardnerella vaginalis* biofilm invasion

Symptoms

Increased thin vaginal discharge with a fishy odor, causing vulvar irritation, dyspareunia, and dysuria. Inflammation signs like redness are usually absent

High rate of missed diagnosis

BV accounts for approximately 11% of healthy women undergoing physical examinations and 36%-60% of patients with vaginal inflammation in gynecological clinics. As the pathogens causing BV are not unique, clinical misdiagnosis is common. 10%-40% of BV patients have no clinical symptoms.

Source: Literature review, Frost & Sullivan analysis

# Clinical Pain Points in Bacterial Vaginosis Treatment

- Bacterial vaginosis (BV), the most common vaginal disease among reproductive-aged women worldwide, poses serious threats to female reproductive health, including increased risks of sexually transmitted infections, genitourinary infections, pelvic inflammatory disease susceptibility, and adverse pregnancy outcomes. Coupled with its high recurrence rate, BV has long been a challenging problem for both clinicians and patients.

## Clinical Pain Points

### High Resistance and Recurrence

#### High Resistance Rates

- Metronidazole resistance: 63.8%
- Clindamycin resistance: 24.1%

#### High recurrence rate

- Metronidazole treatment is 23% at 1 month, 43% at 3 months, and can be as high as 58% at 12 months.
- The short-term recurrence rate (1 and 2 months) of clindamycin cream also reaches 30%-40%.

### Ineffectiveness of Extended Antibacterials Courses

- Prolonged treatment (4–6 months) for recurrent BV may reduce recurrence, but efficacy diminishes after stopping suppressive therapy.
- Extended Antibacterials use **failed to significantly lower recurrence rates** and increased the incidence of vulvovaginal candidiasis (VVC) and other adverse reactions.

### BV Biofilms

- BV polymicrobial biofilms show co-aggregation and metabolic cooperation, enhancing Antibacterials/immune resistance. STI pathogens benefit from interactions with BV biofilms, doubling infection risk from *C. trachomatis*, *M. genitalium*, *N. gonorrhoeae*, *T. vaginalis*, HIV.

## Reasons for Treatment Dilemmas

### Evidence of Sexual Transmission and Its Impact on Recurrence

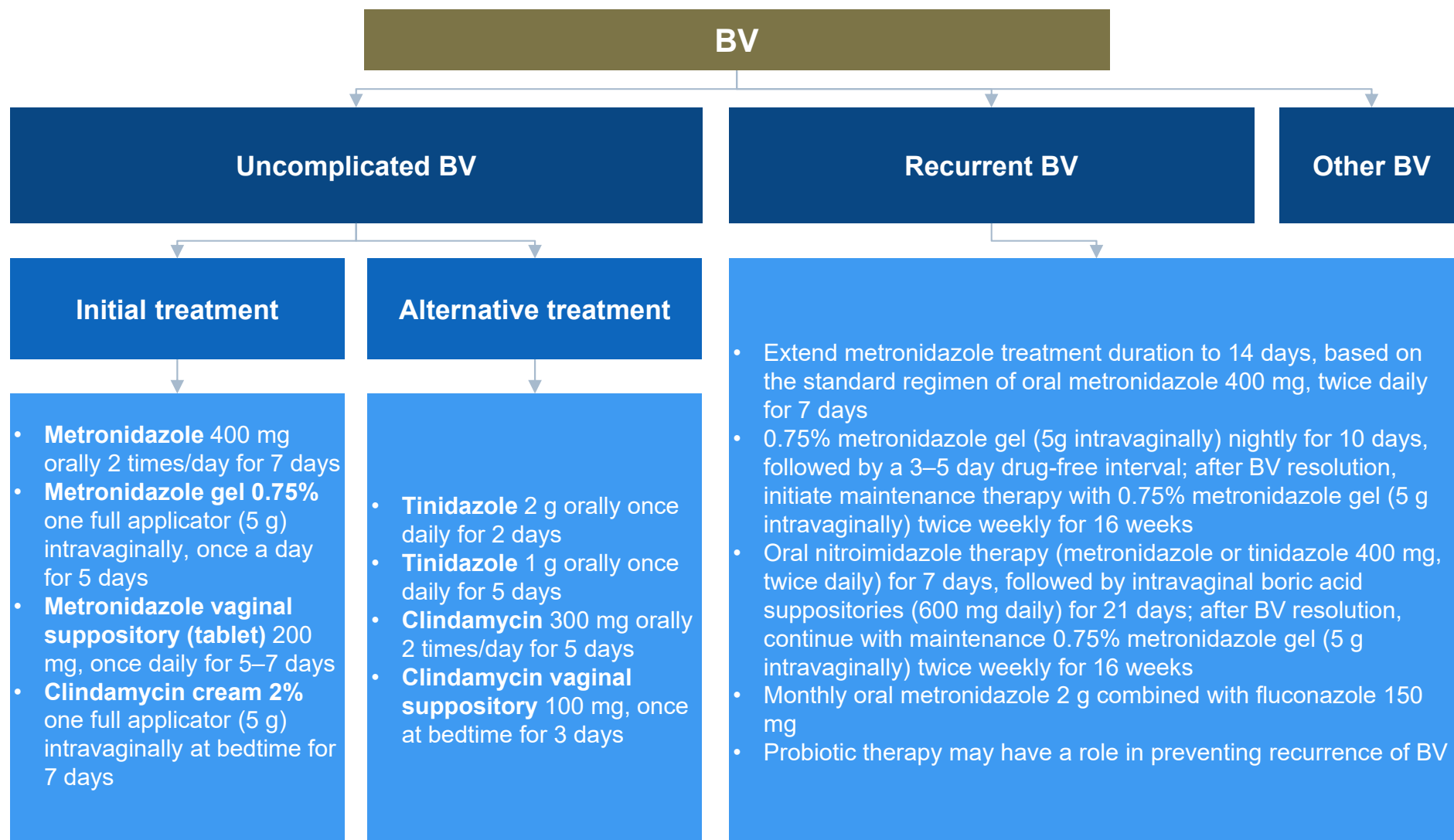
- BV-associated bacteria and biofilms are present in the male urethra/subpreputial space, directly linking male carriage to higher recurrence risk in female partners (untreated male partners double the risk of recurrence)

### Biofilm-Mediated Treatment Failure

- **Biofilm Characteristics:** *Gardnerella vaginalis*-dominated biofilms are found in 90% of BV patients. Biofilm structures protect bacteria from Antibacterials (e.g., metronidazole), enabling post-treatment persistence.

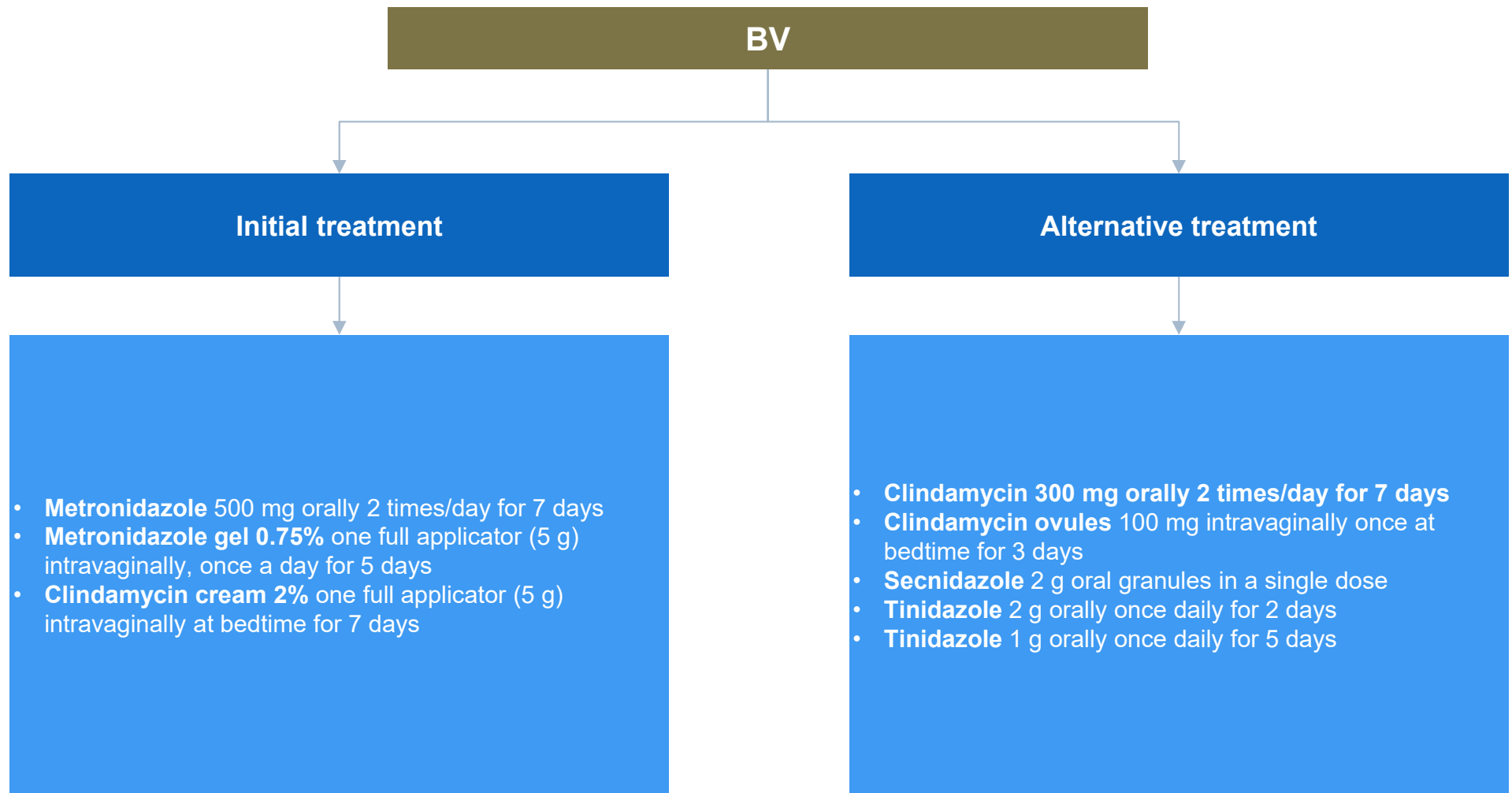
Source: Frost & Sullivan Analysis

# Treatment Paradigm of Bacterial Vaginosis in China



Source : Guidelines for the Diagnosis and Treatment of Bacterial Vaginosis (2021 Revised Edition), Frost & Sullivan analysis

# Treatment Paradigm of Bacterial Vaginosis in US



Source : Sexually Transmitted Infections Treatment Guidelines, 2021, Frost & Sullivan analysis

# NMPA Landscape of Bacterial Vaginitis

## China Marketed Bacterial Vaginitis Drug Competitive Landscape<sup>1-4</sup>



None

## China Bacterial Vaginitis Pipeline<sup>1-4</sup>



Generic Name	Target	Company	Indication	Clinical Stage	First Posted Date
TNP-2198	RNAP/Nitroreductase	TenNor Therapeutics	Bacterial Vaginosis	Phase 1	2024.08

1. Only includes chemical originator, excluding generic drugs
2. Excluding broad-spectrum Antibacterials (e.g., amoxicillin, azithromycin), as they are general-purpose Antibacterials rather than BV-targeted therapies
3. The nature of the sponsor is enterprise
4. Only includes pipelines active within the past three years

Source : NMPA (as of 04/05/2026), Frost & Sullivan analysis

# FDA Landscape of Bacterial Vaginitis(1/2)

## Global Marketed Bacterial Vaginitis Drug Competitive Landscape<sup>1-4</sup>



Generic Name	Brand Name	Target	Company	Indication	Approval Date
Secnidazole	Solosec	DNA	Lupin Pharmaceuticals	Bacterial Vaginosis, Trichomoniasis	2017.09
Astodimer	VivaGel	Envelope glycoprotein gp160	Starpharma	Bacterial Vaginosis, HIV infection	2017.10
Tioconazole/Tinidazole/Lidocaine	Gynomax XL	SCNA, DNA	Exeltis	Candidiasis, Bacterial Vaginosis, Vaginitis	2011.01

## Global Bacterial Vaginitis Pipeline<sup>1-4</sup>



Generic Name	Target	Company	Indication	Drug Type	Clinical Stage	First Posted Date
TOL-463	Dual-action pH regulator + biofilm disruptor	Toltec Pharmaceuticals	Bacterial Vaginosis, Vulvovaginal Candidiasis	Small Molecule Drug	Phase 2	2016.08
PL-18	Multi-target antimicrobial peptide mimics	Protelight Pharmaceuticals Australia	Colpomycosis, Bacterial Vaginosis, Mixed Vaginitis	Small Molecule Drug	Phase 1	2022.04

1. Only includes chemical originator, excluding generic drugs
2. Excluding broad-spectrum Antibacterials (e.g., amoxicillin, azithromycin), as they are general-purpose Antibacterials rather than BV-targeted therapies
3. The nature of the sponsor is enterprise
4. Only includes pipelines active within the past three years

Source : ClinicalTrials (as of 04/05/2026), Frost & Sullivan analysis

# FDA Landscape of Bacterial Vaginitis(2/2)

## Global Bacterial Vaginitis Drug Pipeline<sup>1-4</sup>



Generic Name	Target	Company	Indication	Drug Type	Clinical Stage	First Posted Date
BGY-1601	-	Nexbiome Therapeutics	Bacterial Vaginosis Vulvovaginal Candidiasis	Biologics	Phase 1/2	2024-06-10
BNT331	-	BioNTech	Bacterial Vaginosis	Biologics	Phase 1	2024-06-17

Source : ClinicalTrials (as of 04/05/2026), Frost & Sullivan analysis

# Global Marketed Bacterial Vaginitis Drug Competitive Landscape(off-label)

Drug Class	Representative Drug	Market Launch Year	Major Manufacturer	Typical Susceptibility / Resistance Pattern	Treatment Course Cost & Insurance Coverage
Nitroimidazole	Metronidazole	1960s	Multiple generics	Good activity vs BV anaerobes; resistance/recurrence possible (~60–80% in some studies)	Oral 8–31 USD; widely reimbursed
Lincosamide	Clindamycin	1960s	Multiple generics	Generally high susceptibility (~70–80%+); better coverage vs resistant strains	Oral 10–30 USD; vaginal 20–70 USD; reimbursed
Nitroimidazole	Tinidazole	1970s	Multiple generics	Similar spectrum to metronidazole; variable resistance	Oral 20–100 USD; insurance varies
Nitroimidazole	Secnidazole	2021	Symbiomix Therapeutics	Comparable to metronidazole/tinidazole; activity maintained vs BV bacteria	Single-dose 200–300+ USD; limited insurance coverage
Adjunct/Off-label	Boric Acid (vaginal)	Traditional/OTC	N/A	Not classic antibiotic; used in recurrent BV	Low cost; insurance usually not covered

Source : FDA, NMPA, Frost & Sullivan analysis

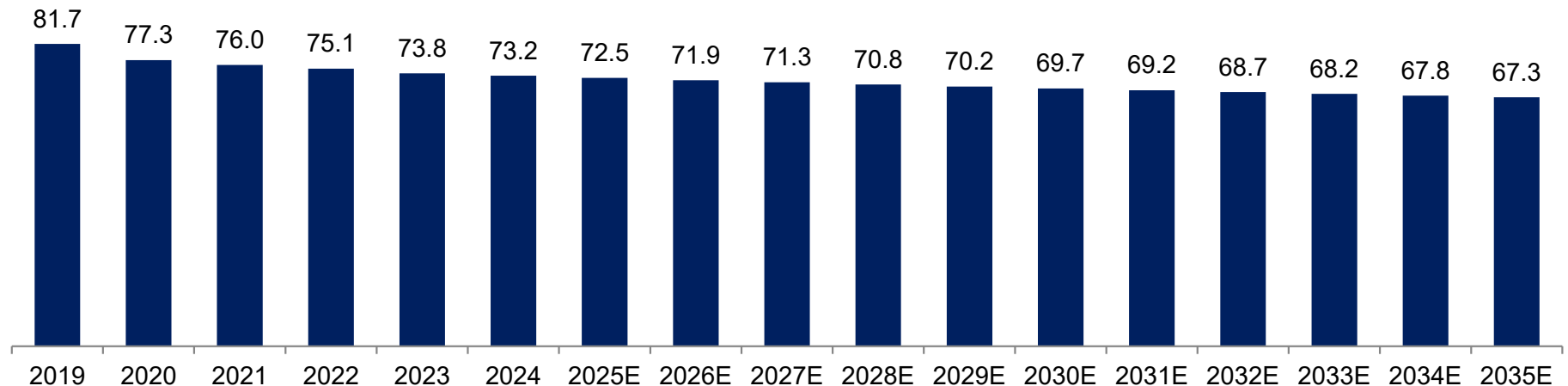
# Incidence of Bacterial Vaginosis in China, 2019-2035E

- Incidence number of bacterial vaginosis in China fluctuated from 81.7 million to 73.2 million in 2019 and 2024. The number is expected to decrease to 69.7 million in 2030 at a CAGR of -0.8% from 2024 to 2030. The number is expected to drop to 67.3 million in 2035, at a CAGR of -0.7%.
- Since bacterial vaginosis (BV) primarily occurs in women of childbearing age, the incidence rate of BV in China has decreased along with the reduction in the number of women of childbearing age in china.

## Incidence of Bacterial Vaginosis in China, 2019-2035E

Unit: Million

Period	CAGR
2019-2024	-2.2%
2024-2030E	-0.8%
2030E-2035E	-0.7%



Source: Literature Review, Frost & Sullivan Analysis

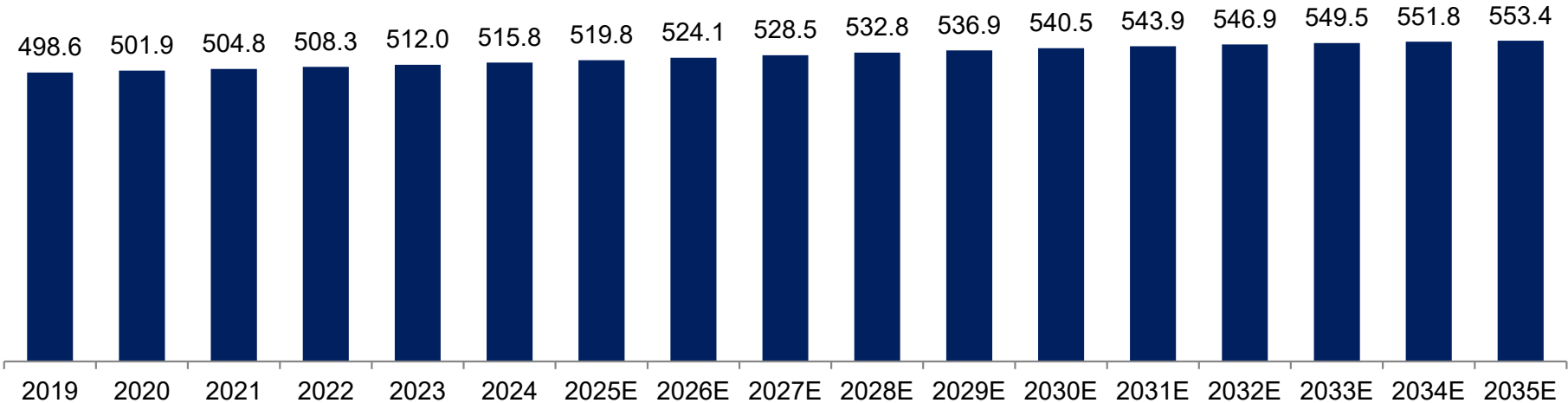
# Global Incidence of Bacterial Vaginosis, 2019-2035E

Global Incidence number of bacterial vaginosis increased from 498.6 million to 515.8 million in 2019 and 2024. The number is expected to grow to 540.5 million in 2030 at a CAGR of 0.8% from 2024 to 2030. The number is expected to grow to 553.4 million in 2035, at a CAGR of 0.5%.

## Global Incidence of Bacterial Vaginosis, 2019-2035E

Unit: Million

Period	CAGR
2019-2024	0.7%
2024-2030E	0.8%
2030E-2035E	0.5%



Source: WHO, Literature Review, Frost & Sullivan Analysis

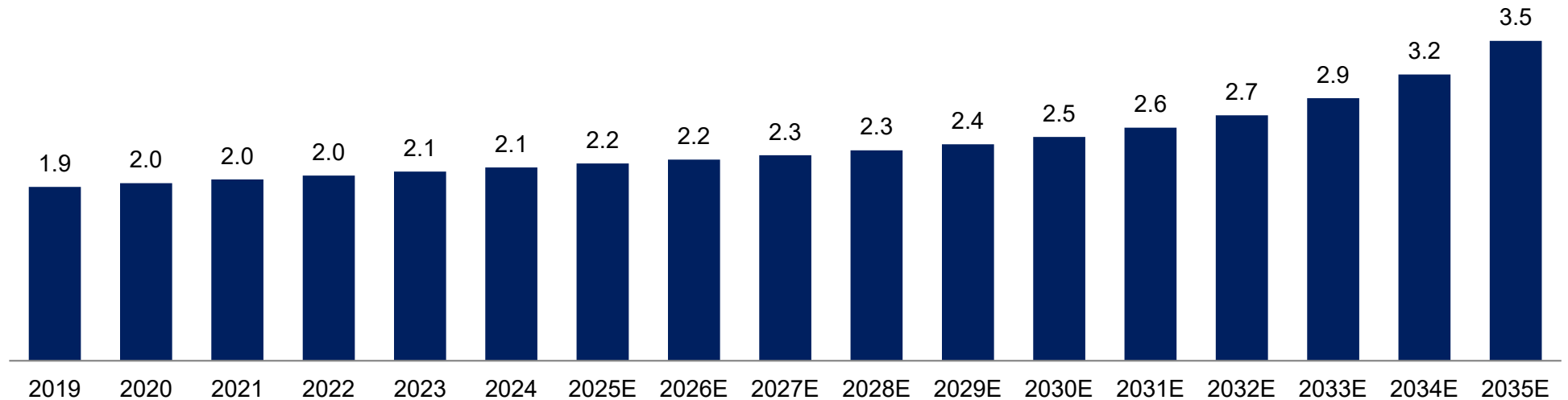
# Global Bacterial Vaginosis Drugs Market Size

- In 2019, the market size was USD1.9 billion. From 2019 to 2024, it grew at a CAGR of 1.6%. In 2024, the market size reached USD2.1 billion. The market size is expected to reach USD2.4 billion in 2029, with a CAGR of 2.2% from 2024 to 2029. The market will further grow to USD3.5 billion in 2035, with a CAGR of 6.2% from 2029 to 2035..

## Global Bacterial Vaginosis Drugs Market Size, 2019-2035E

Unit: Billion USD  
At wholesales price level

Period	CAGR
2019-2024	1.6%
2024-2029E	2.2%
2029E-2035E	6.2%



Source: Frost & Sullivan analysis

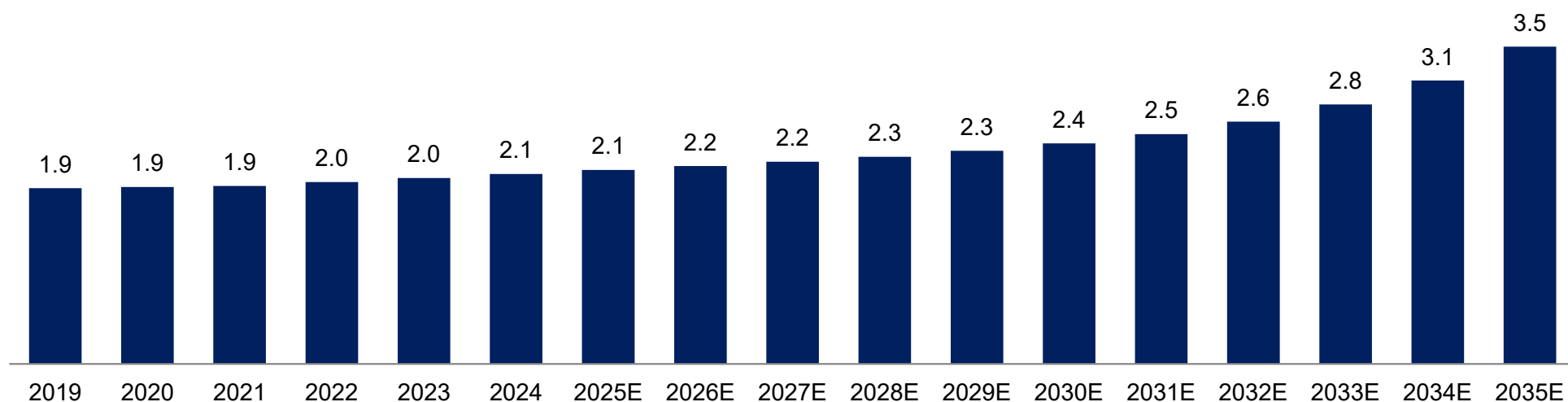
# China Bacterial Vaginosis Drugs Market Size

- In 2019, the market size was RMB1.9 billion. From 2019 to 2024, it grew at a CAGR of 1.6%. In 2024, the market size reached RMB 2.1 billion. The market size is expected to reach RMB2.3 billion in 2029, with a CAGR of 2.3% from 2024 to 2029. The market will further grow to RMB3.5 billion in 2035, with a CAGR of 6.9% from 2029 to 2035.

## China Bacterial Vaginosis Drugs Market Size, 2019-2035E

Unit: Billion RMB  
At ex-factory price level

Period	CAGR
2019-2024	1.6%
2024-2029E	2.3%
2029E-2035E	6.9%



Source: Frost & Sullivan analysis

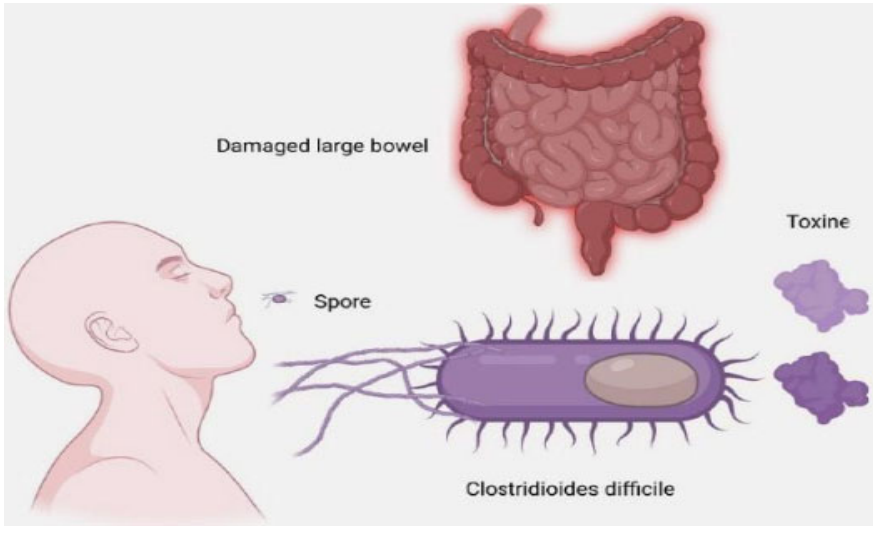
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# Overview of Clostridioides Difficile Infection

- Clostridium difficile (C. difficile) is a Gram-positive, spore-forming, anaerobic bacillus, which is widely distributed in the intestinal tract of humans and animals and in the environment. In the last decade, the frequency and severity of C. difficile infection has been increasing worldwide to become one of the most common hospital-acquired infections.



<b>Risk Factors</b>	<ul style="list-style-type: none"> <li>• <b>Use of Antibacterials :</b> Clindamycin, cephalosporins, and fluoroquinolones</li> <li>• <b>Gastric acid inhibitors :</b> PPI and H2RA therapy</li> <li>• <b>Age :</b> &gt;65 years</li> <li>• <b>Recent stay at a hospital or nursing home</b></li> <li>• <b>Comorbidities :</b> Inflammatory bowel disease, diabetes, leukemia or lymphoma, renal failure, and solid tumors</li> </ul>
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<b>Pathogenesis</b>	<p>The pathogenesis of CDI involves <b>TcdA and TcdB toxins:</b></p> <ul style="list-style-type: none"> <li>• Bind to host cells, undergo endocytosis, and glycosylate Rho/Rac GTPases, disrupting actin cytoskeleton, epithelial barrier, and causing apoptosis/tissue damage.</li> <li>• Triggers vascular permeability, erythrocyte/heme release → diarrhea/colitis.</li> <li>• Some strains produce binary toxin (CDT) to exacerbate cell damage and severity.</li> </ul>
<b>Symptoms</b>	<ul style="list-style-type: none"> <li>• Watery diarrhea as often as 10 to 15 times a day.</li> <li>• Belly cramping and pain, which may be severe.</li> <li>• Fast heart rate.</li> <li>• Loss of fluids, called dehydration.</li> <li>• Fever.</li> <li>• Nausea.</li> <li>• Increased white blood cell count.</li> <li>• Kidney failure.</li> </ul>
<b>Diagnosis Method</b>	<ul style="list-style-type: none"> <li>• Molecular tests</li> <li>• Antigen tests</li> <li>• Toxin tests</li> <li>• Stool cultures</li> </ul>

Source: Literature review, Frost & Sullivan Analysis

# Damage of Clostridioides Difficile Infection

- Considering the high virulence of Clostridioides difficile, the severity of the diseases it induces, its elevated incidence, and the extensive range of risk factors, all of which collectively contribute to increased morbidity and mortality rates, the Centers for Disease Control and Prevention (CDC) has recently re-categorized \*Clostridioides difficile\* as an “urgent threat”.

## Multi-system Effects

- Causes Antibacterials-associated diarrhea (AAD), colitis, and pseudomembranous colitis (PMC), with PMC leading to hemorrhagic diarrhea, severe abdominal pain, pseudomembrane formation, and colonic ulcers.
- Severe cases may progress to fulminant colitis, accompanied by hypotension, multi-organ failure, intestinal obstruction, toxic megacolon, and potential mortality.
- Associated with extraintestinal manifestations (e.g., bacteremia, reactive arthritis) and elevates infection risk in patients with pre-existing conditions like inflammatory bowel disease (IBD).
- Antibacterials use induces gut microbiome dysregulation (e.g., Firmicutes-Bacteroidetes imbalance, reduced butyrate-producing bacteria), disrupts colonization resistance, and increases susceptibility to chronic infection.

## Economic Burden

- Clostridioides difficile has been recognised as a leading cause of healthcare-associated infections (HAIs) and a substantial threat to public health globally. The annual US economic burden is estimated at \$796 million and the burden in European Union (EU) was estimated at €300 million per year .
- Recurrence leads to severe morbidity and healthcare costs, and each recurrence increases

## CDI Complications & Risks

- Prolonged hospital stay, increased risk of sepsis, and need for surgical intervention Septic shock complicated CDI in 34.7% of patients being mechanically ventilated Severely ill patients with CDI, the need for colectomy may arise the procedure carries significant risk of mortality

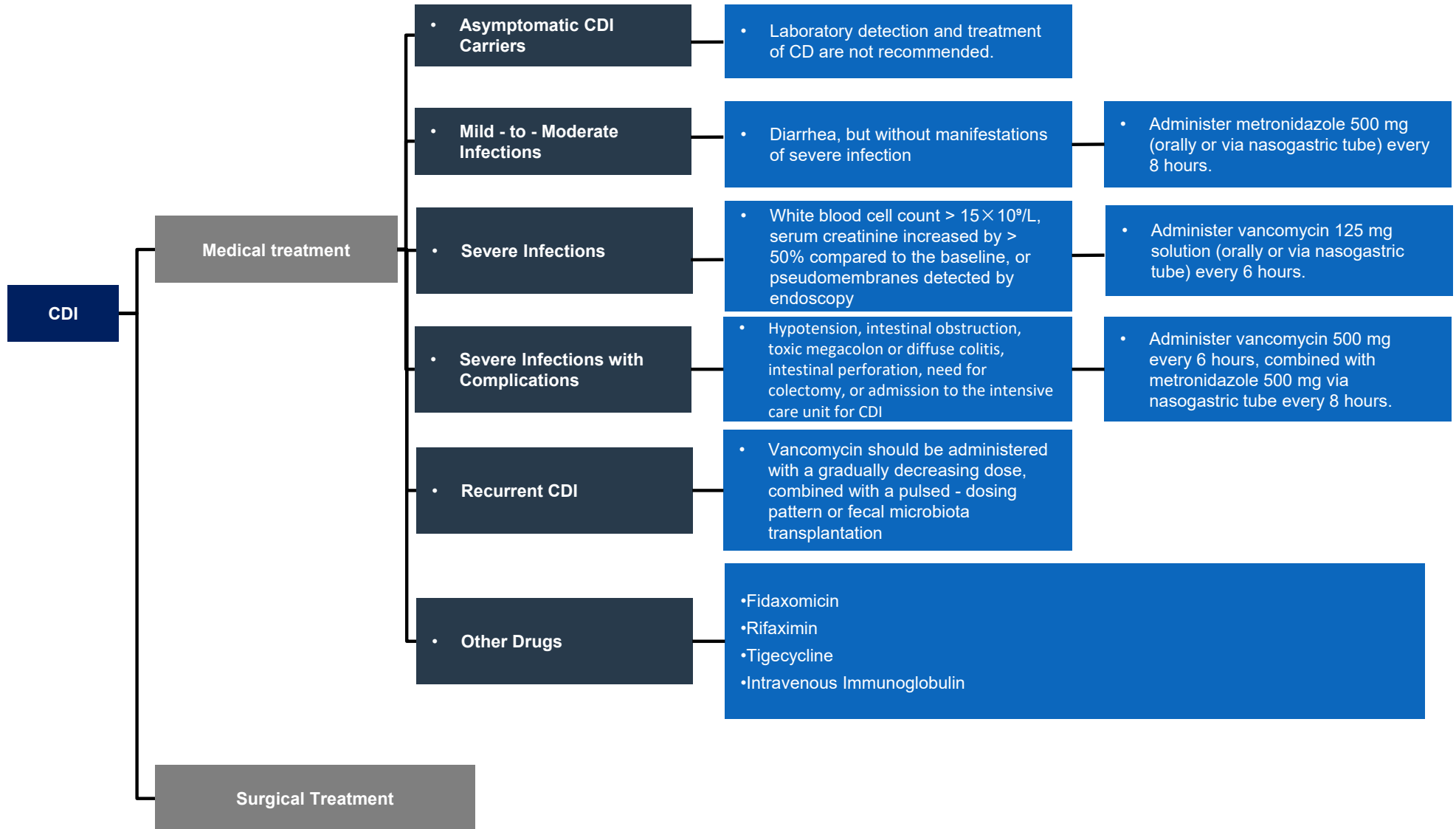
## Impact Scope

- Clinically, Clostridioides difficile infection (CDI) causes approximately 15%-25% of Antibacterials-associated diarrhea (AAD), 50%-75% of Antibacterials-associated colitis, and 95%-100% of pseudomembranous colitis (PMC).

Damage

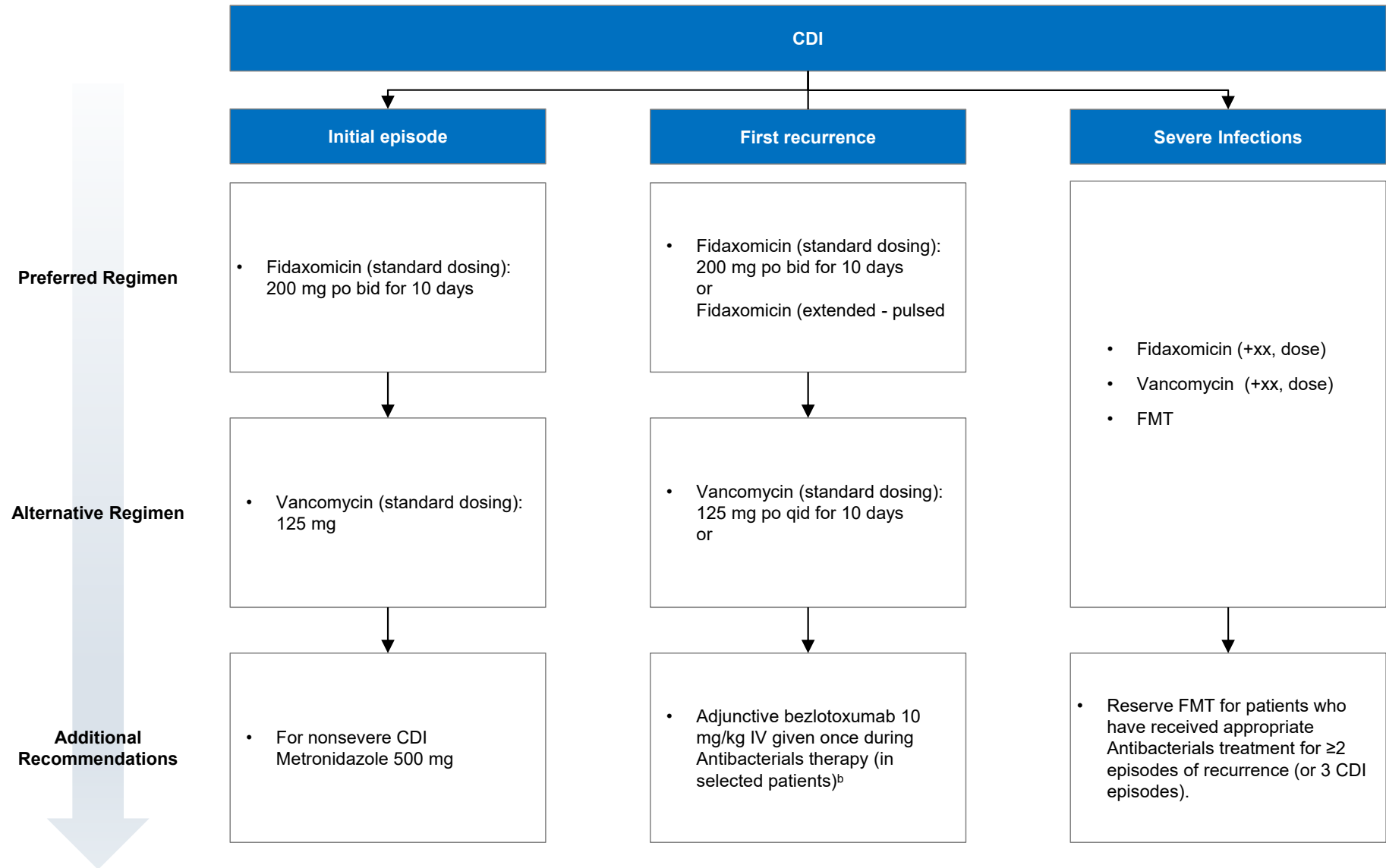
Source: Frost & Sullivan Analysis

# Treatment Paradigm of Clostridioides Difficile Infection in CHINA



Source: 《中国成人艰难梭菌感染诊断和治疗专家共识》，Frost & Sullivan analysis

# Treatment Paradigm of Clostridioides Difficile Infection in US



Source: 《SHEA/IDSA 2021》, Frost & Sullivan analysis

# Unmet needs in the treatment of Clostridioides Difficile infection

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## High recurrence rates despite standard treatment

- Although standard antibiotics such as vancomycin and fidaxomicin can achieve initial symptom resolution in CDI, recurrence remains a major challenge. Up to 20–30% of patients experience a first recurrence, and the risk increases with each subsequent episode. Recurrent CDI is often more difficult to treat and significantly impacts patients' quality of life and healthcare resource utilization.

## Limited long-term solutions for recurrent CDI

- Fecal microbiota transplantation (FMT) has emerged as an effective option for patients with multiple recurrences, restoring gut microbial balance disrupted by antibiotic treatment. However, FMT is still not widely accessible, lacks long-term regulatory standardization, and carries potential risks related to donor screening and transmission of pathogens. Additionally, its mechanism remains only partially understood.

## Need for mechanism-based, targeted antibacterial therapies

- While microbiome-based approaches such as FMT and live biotherapeutic products have shown promise in reducing CDI recurrence, their mechanisms remain incompletely understood and standardization is lacking. There is a clear need for novel antibacterial agents with defined mechanisms of action and low recurrence potential.

Source: Frost & Sullivan Analysis

# NMPA Landscape Small Molecule Drug of Clostridioides difficile Infection

## China Marketed Clostridioides Difficile Infection Small Molecule Drug Competitive Landscape<sup>1-4</sup>



None

## China Clostridioides Difficile Infection Small Molecule Drug Pipeline<sup>1-4</sup>



Generic Name	Target	Company	Indication	Clinical Stage	First Posted Date
TNP-2198	RNAP/Rdx	TenNor Therapeutics	Clostridioides Difficile Infection	Phase 1	2021.11

1. Only includes chemical originator, excluding generic drugs
2. Excluding broad-spectrum Antibacterials (e.g., amoxicillin, azithromycin), as they are general-purpose Antibacterials rather than CDI-targeted therapies
3. The nature of the sponsor is enterprise
4. Only includes pipelines active within the past three years

Source : NMPA (as of 04/05/2026), Frost & Sullivan analysis

# NMPA Landscape Biologics of Clostridioides difficile Infection

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## China Marketed Clostridioides Difficile Infection Biological Drug Competitive Landscape<sup>1-4</sup>



None

## China Clostridioides Difficile Infection Biological Drug Pipeline<sup>1-4</sup>



None

1. Only includes originator, excluding generic drugs
2. Excluding broad-spectrum Antibacterials (e.g., amoxicillin, azithromycin), as they are general-purpose Antibacterials rather than CDI-targeted therapies
3. The nature of the sponsor is enterprise
4. Only includes pipelines active within the past three years

Source : NMPA (as of 04/05/2026), Frost & Sullivan analysis

# Global Marketed CDI Drug Competitive Landscape(off-label)

Drug Class	Representative Drug	Market Launch Year	Major Manufacturer	Typical Susceptibility / Resistance Pattern	Treatment Course Cost & Insurance
Rifamycin antibiotic	Rifaximin	2004	Salix / Bausch Health + generics	Variable activity; resistance possible via rpoB	\$168–\$504/course; usually not covered for CDI
Nitroimidazole antibiotic	Tinidazole	2004	Multiple generics	Similar spectrum to metronidazole; potential cross-resistance	\$30–\$70/course; generally not covered for CDI
Thiazolide antiparasitic	Nitazoxanide	2002	Romark / generics	Broad anaerobic activity; limited CDI data	\$50–\$300/course; generally not covered for CDI
Glycopeptide antibiotic (oral off-label)	Teicoplanin	1988	Sanofi + generics	Good in vitro activity; limited oral clinical use	\$80–\$3,400/course; not covered
Polypeptide antibiotic (historical)	Bacitracin (oral)	1940s	Multiple generics	Historical activity; limited use	<\$100/course; not covered

Source : FDA, NMPA, Frost & Sullivan analysis

# FDA Landscape of Clostridioides Difficile Infection

## Global Marketed Clostridioides Difficile Infection Small Molecule Drug Competitive Landscape<sup>1-4</sup>



None

## Global Clostridioides Difficile Infection Small Molecule Drug Pipeline<sup>1-4</sup>



Generic Name	Target	Company	Indication	Clinical Stage	First Posted Date
DNV3837	DNA topoisomerase	Deinove	Clostridium Difficile	Phase 2	2019.06
REC-3964	UGCG	Recursion Pharmaceuticals	Recurrent Clostridioides Difficile Infection	Phase 2	2024.08
ACX-362E	DNA polymerase III	Acurx Pharmaceuticals	Clostridium Difficile Infection	Phase 2	2020.01

1. Only includes chemical originator, excluding generic drugs
2. Excluding broad-spectrum Antibacterials (e.g., amoxicillin, azithromycin), as they are general-purpose Antibacterials rather than CDI-targeted therapies
3. The nature of the sponsor is enterprise
4. Only includes pipelines active within the past three years

Source : ClinicalTrials (as of 04/05/2026), Frost & Sullivan analysis

# FDA Landscape of Clostridioides Difficile Infection

## Global Marketed Clostridioides Difficile Infection Biological Drug Competitive Landscape<sup>1-4</sup>



Generic Name	Brand Name	Target	Company	Indication	Approval Date
SER-109	Vowst	NA	Seres Therapeutics	Prevention of Recurrence of Clostridioides Difficile Infection	2023.04
RBX2660	Rebyota	NA	Ferring Pharmaceuticals	Prevention of Recurrence of Clostridioides Difficile Infection	2022.11
Bezlotoxumab	Zinplava	TcdB	Merck Sharp & Dohme	Clostridioides Difficile Infection	2016.10

## Global Clostridioides Difficile Infection Biological Drug Pipeline<sup>1-4</sup>



Generic Name	Target	Company	Indication	Clinical Stage	First Posted Date
VE303	-	Vedanta Biosciences	Clostridioides Difficile, Clostridium Difficile Infections, Clostridium Difficile Infection	Phase 3	2024-02-01

1. Only includes biological originator, excluding generic drugs
2. Excluding broad-spectrum Antibacterials (e.g., amoxicillin, azithromycin), as they are general-purpose Antibacterials rather than CDI-targeted therapies
3. The nature of the sponsor is enterprise
4. Only includes pipelines active within the past three years

Source : ClinicalTrials (as of 04/05/2026), Frost & Sullivan analysis

# FDA Landscape of Clostridioides Difficile Infection

## Global Clostridioides Difficile Infection Biological Drug Pipeline<sup>1-4</sup>



Generic Name	Target	Company	Indication	Clinical Stage	First Posted Date
LMN-201	TcdB	Lumen Bioscience	Clostridioides Difficile Infection	Phase 2/ Phase 3	2022-04- 15
MBK-01	CP101	Mikrobiomik Healthcare Company	Recurrent Clostridium Difficile Infection, Primary Clostridium Difficile Infection	Phase 3	2022-01- 20
CP101	-	Finch Research and Development LLC.	Recurrent C. Difficile Infection	Phase 3	2021-12- 09
Egg-derived Polyclonal Antibodies	IM-01	ImmuMed	Clostridium Difficile Infection (CDI)	Phase 2	2019-10- 08

1. Only includes biological originator, excluding generic drugs
2. Excluding broad-spectrum Antibacterials (e.g., amoxicillin, azithromycin), as they are general-purpose Antibacterials rather than CDI-targeted therapies
3. The nature of the sponsor is enterprise
4. Only includes pipelines active within the past three years

Source : ClinicalTrials (as of 04/05/2026), Frost & Sullivan analysis

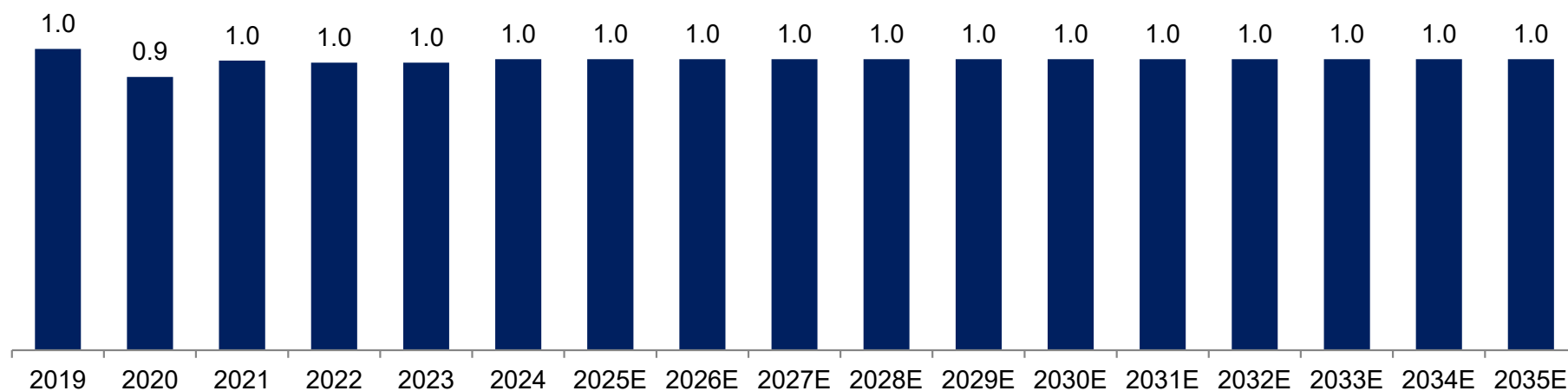
# Incidence of Clostridioides difficile Infection in China, 2019-2035E

- Incidence number of clostridioides difficile infection in China decreased from 1.0 million to 0.9 million from 2019 to 2024 and went up to 1.0 million again in 2030. The number is expected to remain 1.0 million with nearly unchange from 2030 to 2035.
- In 2020, COVID-19 prevention and control measures (strengthening hand hygiene, environmental disinfection, and antibiotic management) temporarily reduced the risk of nosocomial cross-infection. However, some underdiagnosis occurred due to delayed medical treatment, and the number of cases gradually rebounded to the normal level as the epidemic stabilized.

**Incidence of Clostridioides Difficile Infection in China, 2019-2035E**

Unit: Million

Period	CAGR
2019-2024	-0.7%
2024-2030E	0.0%
2030E-2035E	0.0%



Source: Literature Review, Frost & Sullivan Analysis

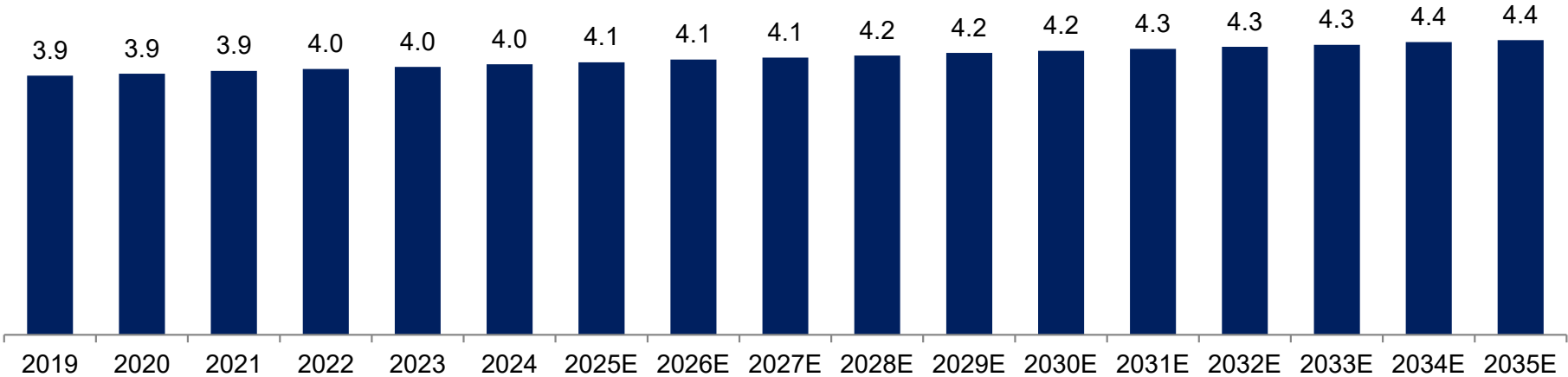
# Global Incidence of Clostridioides Difficile Infection, 2019-2035E

Global Incidence number of clostridioides difficile infection increased from 3.9 million to 4.0 million from 2019 to 2024. The number is expected to grow to 4.2 million in 2030 at a CAGR of 0.8% from 2024 to 2030. The number is expected to grow to 4.4 million in 2035, at a CAGR of 0.7%.

## Global Incidence of Clostridioides Difficile Infection, 2019-2035E

Unit: Million

Period	CAGR
2019-2024	0.9%
2024-2030E	0.8%
2030E-2035E	0.7%



Source: NIH, Literature Review, Frost & Sullivan Analysis

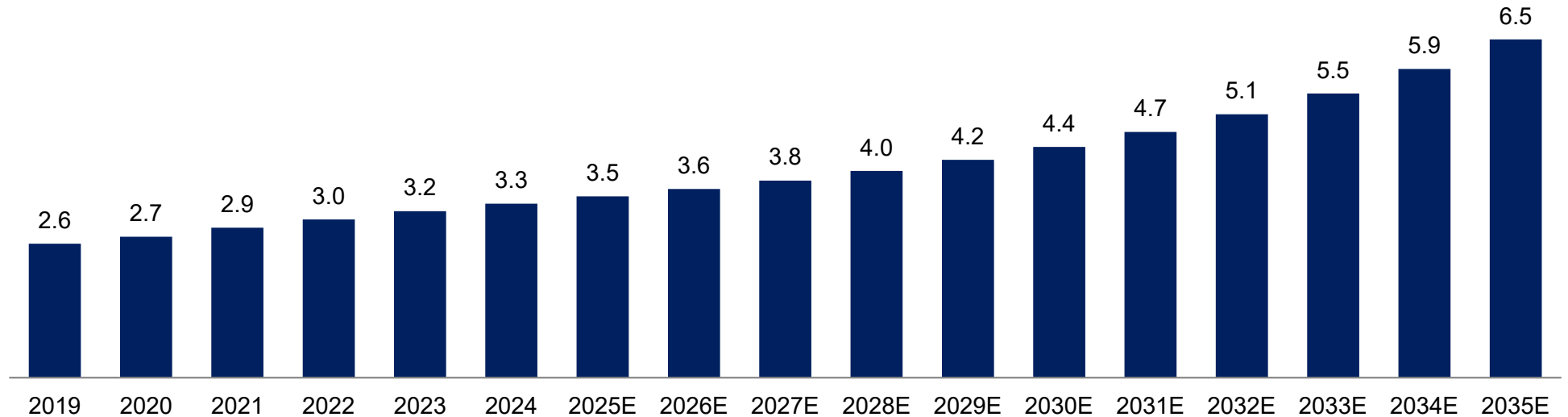
# Global Clostridioides Difficile Infection Drugs Market Size

- In 2019, the market size was USD2.6 billion. From 2019 to 2024, it grew at a CAGR of 5.4%. In 2024, the market size reached USD3.3 billion. The market size is expected to reach USD4.2 billion in 2029, with a CAGR of 4.6% from 2024 to 2029. The market will further grow to USD6.5 billion in 2035, with a CAGR of 7.6% from 2029 to 2035..

**Global Clostridioides Difficile Infection Drugs Market Size, 2019-2035E**

Unit: Billion USD  
At wholesales price level

Period	CAGR
2019-2024	5.4%
2024-2029E	4.6%
2029E-2035E	7.6%



Source: Frost & Sullivan analysis

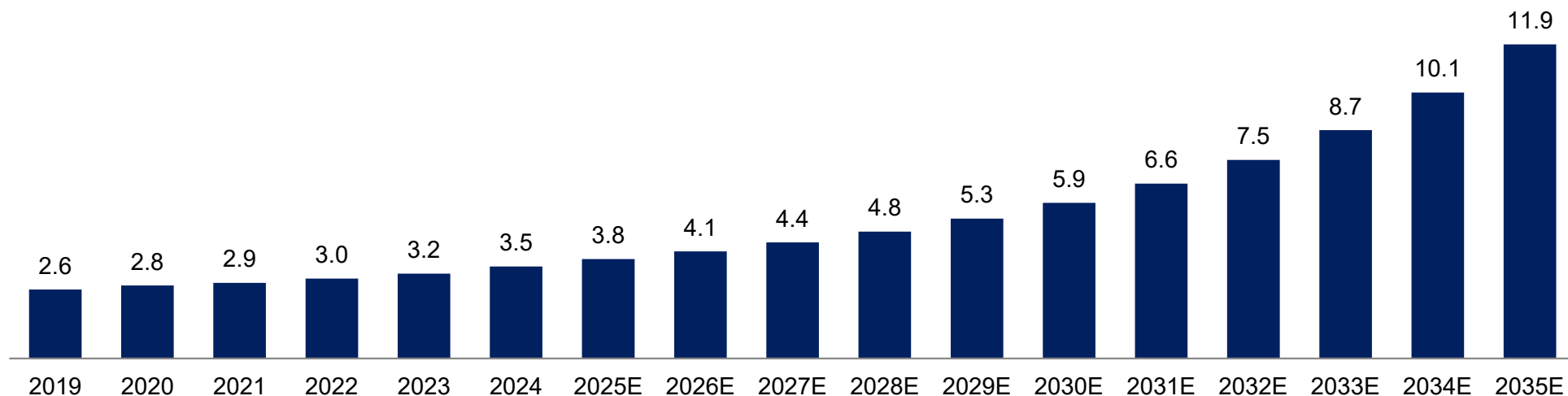
# China Clostridioides Difficile Infection Drugs Market Size

- In 2019, the market size was RMB2.6 billion. From 2019 to 2024, it grew at a CAGR of 1.6%. In 2024, the market size reached RMB 3.5 billion. The market size is expected to reach RMB5.3 billion in 2029, with a CAGR of 8.7% from 2024 to 2029. The market will further grow to RMB11.9 billion in 2035, with a CAGR of 14.4% from 2029 to 2035.

## China Clostridioides Difficile Infection Drugs Market Size, 2019-2035E

Unit: Billion RMB  
At ex-factory price level

Period	CAGR
2019-2024	6.0%
2024-2029E	8.7%
2029E-2035E	14.4%



Source: Frost & Sullivan analysis

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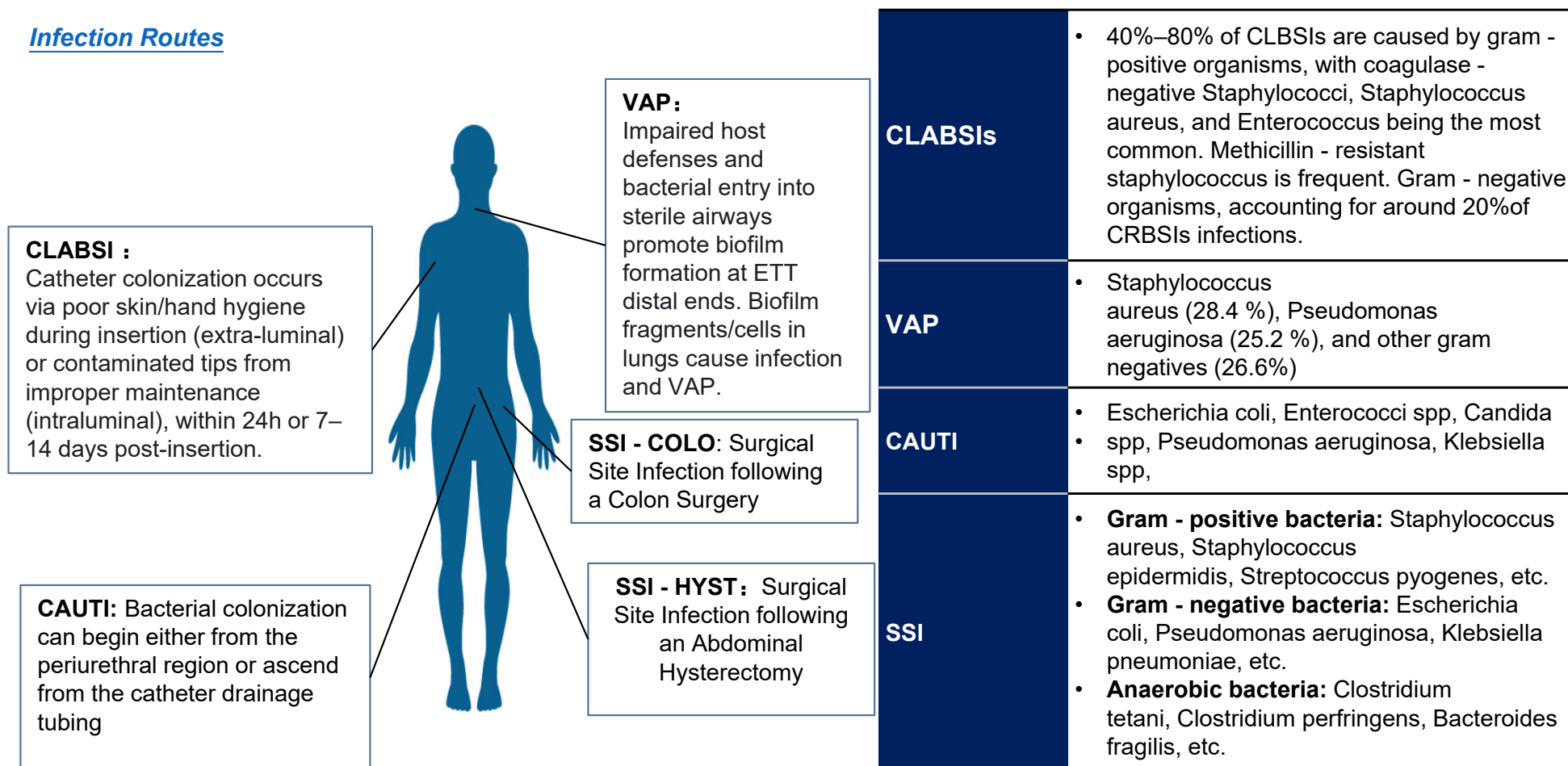
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<b>4.8</b>	Hepatic Encephalopathy
<b>4.9</b>	Irritable Bowel Syndrome
<b>4.10</b>	Diabetic Foot Infection

# Overview of Bacterial Biofilm And Medical Device-Related Infections

- Healthcare-associated infections (HAIs) are a major complication in healthcare and constitute a significant global public health issue. Approximately 60% to 70% of nosocomial infections (NIs) are associated with medical devices. These infections encompass a range of clinical conditions, including catheter-associated urinary tract infections (CAUTIs), Central Line - Associated Bloodstream Infection (**CLABSI**), ventilator-associated pneumonia (VAP), and surgical site infections (SSIs).

## Infection Routes



Source: Catheter-related bloodstream infections caused by Gram-negative bacteria Circulation., Frost & Sullivan Analysis

# Analysis of the Harmfulness of Bacterial Biofilm And Medical Device-Related Infections

- Healthcare-associated infections (HAIs) are a major complication in healthcare and constitute a significant global public health issue. Approximately 60% to 70% of nosocomial infections (NIs) are associated with medical devices. These infections encompass a range of clinical conditions, including catheter-associated urinary tract infections (CAUTIs), Central Line - Associated Bloodstream Infection (**CLABSI**), ventilator-associated pneumonia (VAP), and surgical site infections (SSIs).

## Infection Routes of Medical Devices Infection

- Contamination During Implantation/Insertion
- Extraluminal Contamination (Surface Infections)
- Intraluminal Contamination (Luminal Infections)
- Hematogenous Spread (Secondary Contamination)
- Cross-Contamination in Healthcare Settings
- Host-Related Factors

## Resistance Drivers

- Biofilms on device surfaces resist antimicrobials through multiple mechanisms, exacerbating drug resistance.
- Surface wettability is a critical factor in cell adhesion and the initial formation of biofilms.
- Early monitoring of pathogen attachment enables proactive intervention to prevent chronic infections.
- The delays inherent in traditional detection methods and the high cost of biofilm removal underscore the significance of biofilms as primary virulence factors.

## Pain Points



### Biofilm Resistance

- Biofilms identifiable within 48–72h show 1,000-fold lower Antibacterials sensitivity and immune efficacy, complicating eradication.

### High Medical Costs

- Long-term hospitalization, surgery, and prolonged antimicrobial therapy can lead to extremely high clearance costs.

### Chronic Infection Woes

- Chronic tissue biofilm infections feature high Antibacterials tolerance, immune evasion, and inflammation-induced damage.

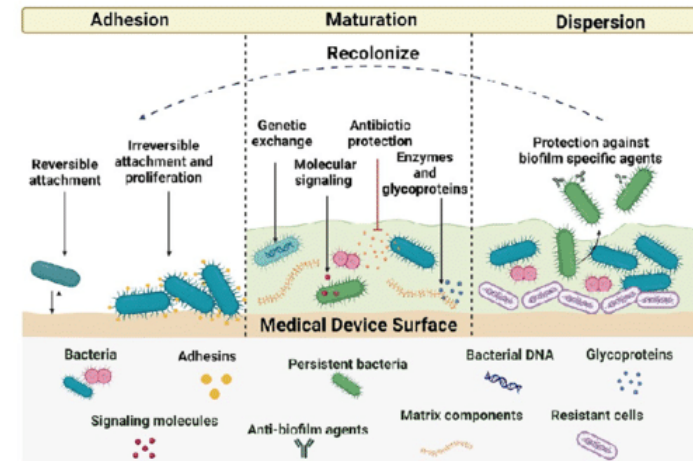
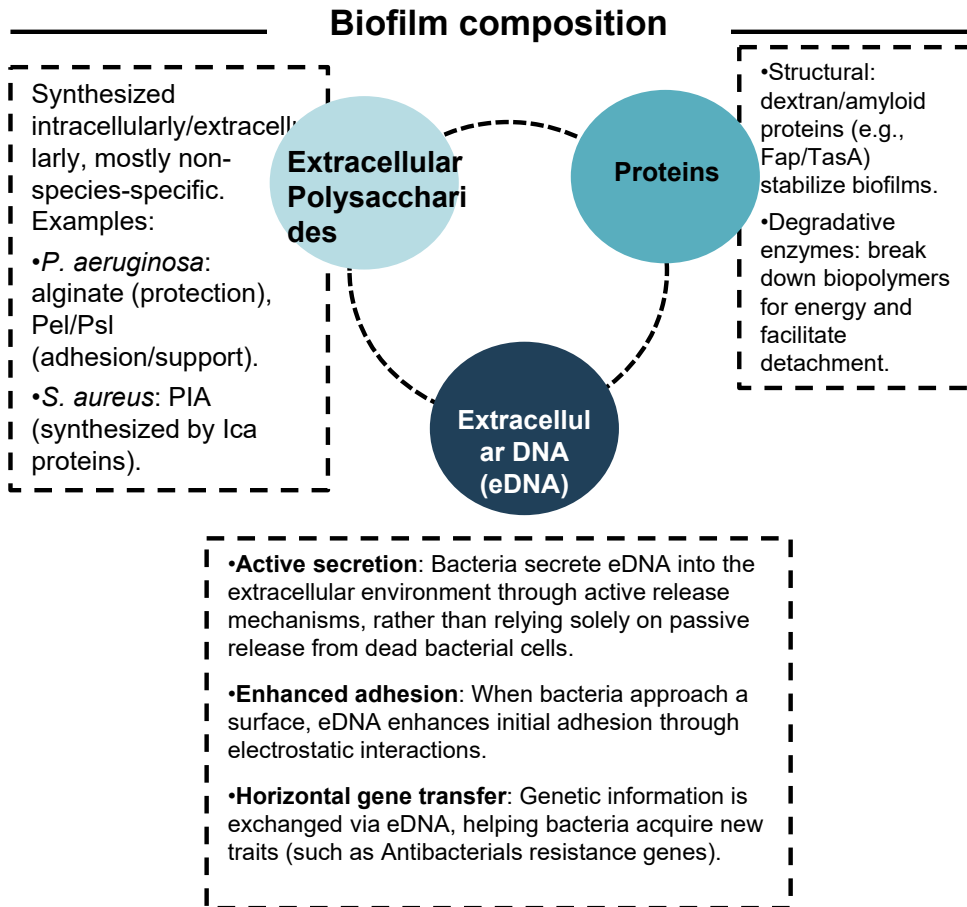
### Device - Related Risks

- Non-removable device infections require lifelong Antibacterials therapy; great vessel/endocardial sources may cause fatal outcomes.
- Removal of the implant may be difficult and sometimes contraindicated due to the patient's underlying comorbidities, thrombocytopenia, immunosuppression, lack of vascular access, and previous surgical interventions.

Source: Literature Review, Frost & Sullivan Analysis

# Overview of Bacterial Biofilm-related Infections

- Due to Antibacterials resistance, the host's immune defense system, and other external pressures, bacterial biofilms have become a significant factor in global health problems. Biofilms are commonly found on the surfaces of hospital devices and body tissues, as well as in industrial settings, food processing units, and natural environments. Nearly all bacteria can form biofilms.



## Drug Resistance Mechanism

Physical Protection by ECM

Restricted Antibacterials Diffusion in Biofilm

Upregulation of Bacterial Efflux Pump Expression

Horizontal Transfer of Resistance Genes

Reduced Metabolism

Source: Literature Review, Frost & Sullivan Analysis

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<b>4.3</b>	Clostridioides Difficile Infection
<b>4.4</b>	Bacterial Biofilm And Medical Device-Related Infections
<b>4.5</b>	<b>Prosthetic Joint Infection</b>
<b>4.6</b>	Left Ventricular Assist Devices
<b>4.7</b>	ABSSSI
<b>4.8</b>	Hepatic Encephalopathy
<b>4.9</b>	Irritable Bowel Syndrome
<b>4.10</b>	Diabetic Foot Infection

# Overview of joint replacement surgery

- Joint replacement surgery is an orthopedic procedure that involves the surgical replacement of a damaged joint with a prosthetic implant to address conditions such as arthritis, joint pathologies, osteoarthritis, and rheumatoid arthritis. The three primary clinical applications of joint arthroplasty are: Total Knee Arthroplasty (TKA), Unicompartmental Knee Arthroplasty (UKA), and Total Hip Arthroplasty (THA), constituting the standard of care for end-stage joint degeneration management.

## Total Knee Arthroplasty(TKA)



## Unicompartmental Knee Arthroplasty(UKA)



## Total Hip Arthroplasty(THA)

	Total Knee Arthroplasty(TKA)	Unicompartmental Knee Arthroplasty(UKA)	Total Hip Arthroplasty(THA)
Indications	<ul style="list-style-type: none"> <li>Indicated for patients with advanced knee osteoarthritis, rheumatoid arthritis, distal femoral lesions, or post-traumatic knee deformities requiring definitive surgical intervention..</li> </ul>	<ul style="list-style-type: none"> <li>Indicated for unicompartmental osteoarthritis, post-traumatic arthritis, or malunited fractures of the tibial condyle or tibial plateau.</li> </ul>	<ul style="list-style-type: none"> <li>Indicated for end-stage hip diseases caused by various factors, including primary or secondary hip osteoarthritis, avascular necrosis of the femoral head, and other degenerative conditions..</li> </ul>
Key Surgical Steps	<ul style="list-style-type: none"> <li>Bone preparation,Component fixation,Patellar management,Articular restoration.</li> </ul>	<ul style="list-style-type: none"> <li>UKA involves a surgical incision, osteotomy of the femoral and tibial surfaces, bone preparation, prosthesis placement, and wound closure.</li> </ul>	<ul style="list-style-type: none"> <li>The procedure includes a posterolateral incision, femoral osteotomy, medullary cavity polishing, prosthesis implantation, hip joint reduction, and wound closure.Hip joint reduction.</li> </ul>
Implant Survivorship	<ul style="list-style-type: none"> <li>Contemporary prostheses demonstrate a 20-year survivorship rate exceeding 80% in registry data.</li> </ul>	<ul style="list-style-type: none"> <li>The prosthesis typically remains functional for 10-20 years postoperatively.</li> </ul>	<ul style="list-style-type: none"> <li>Over 80% of prostheses remain functional after 25 years of follow-up.</li> </ul>
Revision Rates	<ul style="list-style-type: none"> <li>Longitudinal studies report a 7% revision rate at 15-year follow-up, significantly lower than UKA.</li> </ul>	<ul style="list-style-type: none"> <li>Within 10-15 years, the revision rate is approximately 15.</li> </ul>	<ul style="list-style-type: none"> <li>The revision rate varies by age and implant type, with an overall rate of approximately 7% after 10 years.</li> </ul>

Source: Literature Review, Frost & Sullivan Analysis

# Overview of prosthetic joint infection (PJI)

• Prosthetic Joint Infection (PJI) refers to an infection occurring at the site of prosthetic joint implantation that affects both the artificial prosthesis and adjacent periarticular tissues. PJI arises from microbial invasion of the joint space, manifesting as a spectrum of pathophysiological alterations and clinical manifestations through complex interactions among pathogenic microorganisms, implanted biomaterials, and host tissue responses.

<b>Diagnostic Criteria</b>	<b>Definitive Diagnostic Criteria</b>	<p>Meeting any one of the following:</p> <ul style="list-style-type: none"> <li>• Intraoperative cultures from <math>\geq 2</math> distinct periprosthetic tissue/synovial fluid samples yield the same pathogen.</li> <li>• Presence of a fistula communicating with the prosthesis.</li> </ul>
	<b>Suspected Diagnosis Criteria</b>	<p>meeting any three of the following</p> <ul style="list-style-type: none"> <li>• Elevated serum C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR)</li> <li>• Elevated synovial fluid leukocyte count or positive leukocyte esterase test (++)</li> <li>• Increased percentage of neutrophils in synovial fluid</li> <li>• Positive histopathological findings in periprosthetic tissue</li> <li>• Positive bacterial culture from a single specimen</li> </ul>
<b>PJI Classification</b>	<b>Acute PJI</b>	<ul style="list-style-type: none"> <li>• Acute PJI is predominantly caused by high-virulence pathogens and is often characterized by acute symptoms such as joint swelling, pain, and effusion. In the early stages of infection, the bacterial biofilm on the prosthesis is not yet mature, allowing for early intervention to eradicate the pathogens while preserving the prosthesis whenever possible.</li> </ul>
	<b>Chronic PJI</b>	<ul style="list-style-type: none"> <li>• Chronic PJI is typically caused by low-virulence pathogens and presents with prolonged, relatively mild clinical symptoms. However, mature bacterial biofilms have usually formed, often accompanied by bone and soft tissue destruction, necessitating thorough debridement of the infected site and prosthesis exchange.</li> </ul>

Source: Chinese Guidelines for Diagnosis and Treatment of Prosthetic Joint Infection, Frost & Sullivan Analysis

# Pathogen Analysis

- Identification of pathogenic microorganisms cultured from periprosthetic tissue or synovial fluid is a critical diagnostic criterion for PJI. Culture and antimicrobial susceptibility testing results guide the selection of both Antibacterials therapy and surgical intervention strategies. Therefore, every suspected PJI case should undergo thorough microbiological evaluation to definitively identify the causative pathogen(s).

## Pathogen Analysis of PJI

Category	Percentage	Predominant Pathogen	Percentage
Gram-positive bacteria	75%-85%	Staphylococcus epidermidis	35%-65%
		Staphylococcus aureus	20%-40%
		Other Coagulase-Negative Staphylococci	15%-25%
Gram-negative bacteria	10%-15%	-	-
Fungi	~5%	-	-

Source: Chinese Guidelines for Diagnosis and Treatment of Prosthetic Joint Infection, Frost & Sullivan Analysis

# Pathogen Analysis

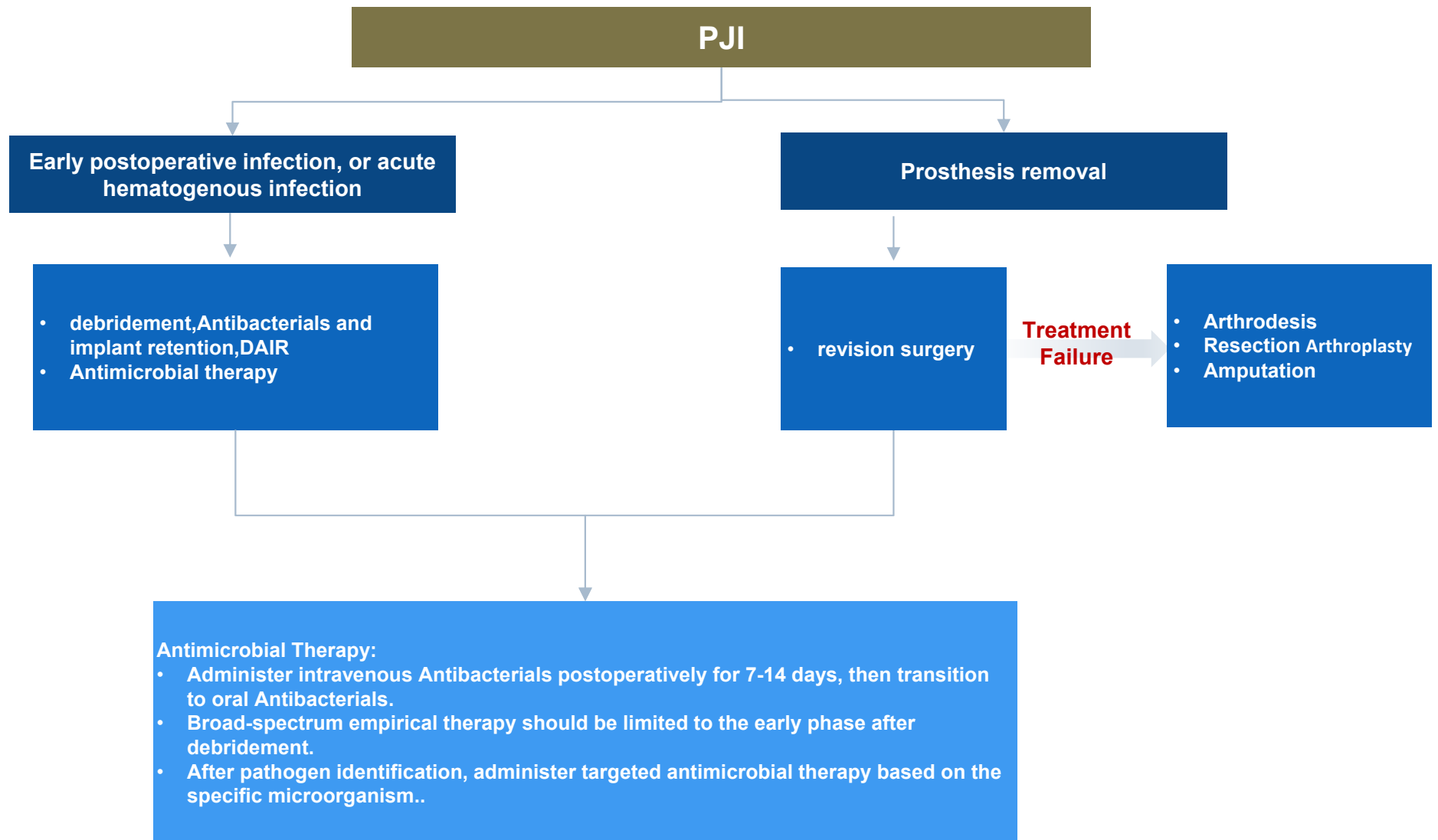
- Identification of pathogenic microorganisms cultured from periprosthetic tissue or synovial fluid is a critical diagnostic criterion for PJI. Culture and antimicrobial susceptibility testing results guide the selection of both Antibacterials therapy and surgical intervention strategies. Therefore, every suspected PJI case should undergo thorough microbiological evaluation to definitively identify the causative pathogen(s).

Resistance Rate Of Different Antibacterial Drugs

Antibacterial Agent	<i>Staphylococcus epidermidis</i> (%)	<i>Staphylococcus aureus</i> (%)
Penicillin G	96.3	100
Oxacillin	81.48	20
Gentamicin	14.29	10
Vancomycin	0	0
Quinupristin/Dalfopristin	0	0
Linezolid	0	0
Tetracycline	7.41	10
Erythromycin	60.71	55
Tigecycline	0	0
Clindamycin	33.33	60
Levofloxacin	32.14	15
Ciprofloxacin	29.63	15
Moxifloxacin	3.7	10
Rifampin	11.11	15.79
Trimethoprim/Sulfamethoxazole	55.56	16.67

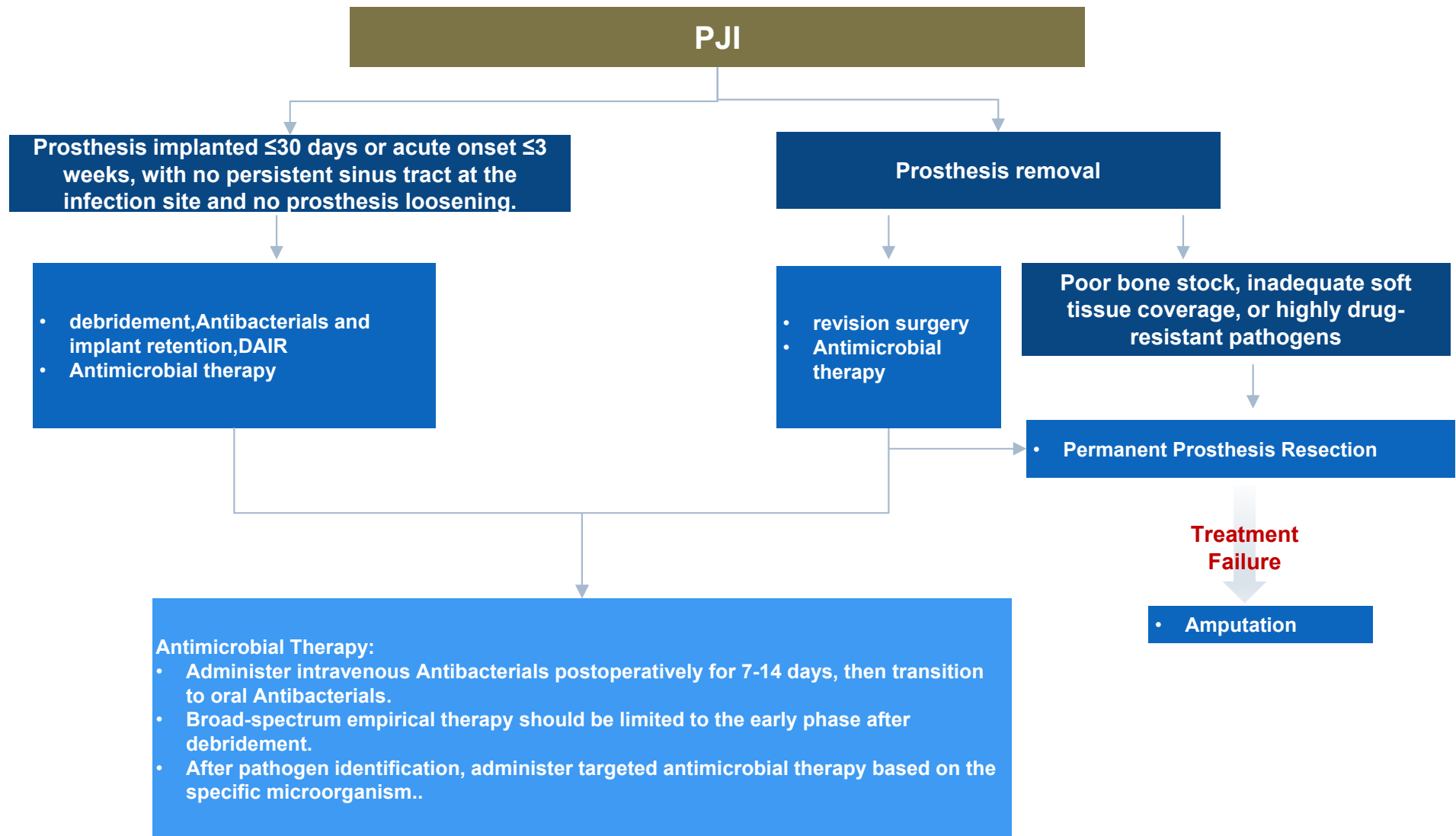
Source: Chinese Guidelines for Diagnosis and Treatment of Prosthetic Joint Infection, Frost & Sullivan Analysis

# Treatment Paradigm of PJI in China



Source: Chinese Guidelines for Diagnosis and Treatment of Prosthetic Joint Infection, Frost & Sullivan Analysis

# Treatment Paradigm of PJI in The US



Source: Diagnosis and management of prosthetic joint infection: clinical practice guidelines by the infectious diseases society of america, Frost & Sullivan Analysis

# Unmet needs in the treatment of PJI

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## Escalating antimicrobial resistance

- The growing prevalence of resistant pathogens, such as methicillin-resistant *Staphylococcus aureus* (MRSA) and multidrug-resistant coagulase-negative staphylococci (CoNS), has significantly limited the effectiveness of standard antibiotic regimens. Treatment options are especially restricted for patients requiring oral therapies or those with contraindications to prolonged intravenous antibiotics. This trend underscores the urgent need for new antimicrobials with novel mechanisms of action.

## Biofilm-driven treatment failure

- Bacterial biofilms formed on the surface of prosthetic joints act as a physical and metabolic barrier to antibiotics, leading to treatment failure and infection recurrence. Most currently approved antibiotics lack sufficient anti-biofilm activity, making it difficult to achieve complete eradication without surgical intervention. This highlights the need for therapies that can penetrate or disrupt biofilms effectively.

## Lack of targeted and less invasive solutions

- Surgical procedures—often staged revisions or complete device removal—remain the mainstay of PJI management, contributing to high patient burden, healthcare costs, and functional loss. Meanwhile, diagnostic delays and culture-negative cases further complicate timely, targeted therapy. There remains a clear unmet need for effective non-surgical treatments, improved diagnostics, and better patient-tailored therapeutic strategies.

Source: Frost & Sullivan Analysis

# NMPA Landscape of Prosthetic Joint Infection

## China Marketed Prosthetic Joint Infection Competitive Landscape<sup>1-4</sup>



None

## China Prosthetic Joint Infection Drug Pipeline<sup>1-5</sup>



Generic Name	Target/MOA	Company	Indication	Clinical Stage	First Posted Date
TNP-2092	RNAP; Bacterial DNA gyrase; DNA topoisomerase	TenNor Therapeutics	Prosthetic Joint Infection	Phase 2	2025.03

1. Only includes chemical originator, excluding generic drugs
2. Excluding broad-spectrum Antibacterials (e.g., amoxicillin, azithromycin), as they are general-purpose Antibacterials rather than PJI-targeted therapies
3. The nature of the sponsor is enterprise
4. Only includes pipelines active within the past three years
5. TNP2092 is currently being prepared for a Phase 3 clinical trial application.

Source : NMPA (as of 04/05/2026), Frost & Sullivan analysis

# FDA Landscape of Prosthetic Joint Infection

## Global Marketed Prosthetic Joint Infection Drug Competitive Landscape<sup>1-4</sup>



None

## Global Prosthetic Joint Infection Drug Pipeline<sup>1-4</sup>



Generic Name	Target/MOA	Company	Indication	Drug Type	Clinical Stage	First Posted Date
TNP-2092	RNAP; Bacterial DNA gyrase; DNA topoisomerase	TenNor Therapeutics	Periprosthetic Joint Infection (PJI)	Small molecule drug	Phase 2	2025.03

1. Only includes small molecule originator, excluding generic drugs
2. Excluding broad-spectrum Antibacterials (e.g., amoxicillin, azithromycin), as they are general-purpose Antibacterials rather than PJI-targeted therapies
3. The nature of the sponsor is enterprise
4. Only includes pipelines active within the past three years

Source : ClinicalTrials (as of 04/05/2026), Frost & Sullivan analysis

# Global Marketed Prosthetic Joint Infection Drug Competitive Landscape(off-label)

Drug Class	Representative Drug	First Marketed / Year	Major Manufacturers	Resistance / Susceptibility	Treatment Course Co (CN)& Insurance Coverage
Glycopeptides	Vancomycin	1980s	Multiple generics (Pfizer origin)	MRSA/MRSE susceptibility: 90–99% globally; vancomycin-intermediate rare (<2%)	RMB 11,000–17,000 per course; reimbursement varies by indication
β-lactams (Anti-staphylococcal)	Cefazolin	1970s	Multiple generics	MSSA susceptibility: >95%	RMB 50–200 per course; widely reimbursed
Carbapenems	Meropenem	1990s	Multiple manufacturers	ESBL-producing Gram-negative susceptibility: 85–95%	RMB 1,500–4,000 per course; usually reimbursed inpatient
Rifamycins	Rifampin	1960s	Multiple generics	Staphylococcal susceptibility >90% initially	RMB 20–100 per course; generally reimbursed, usually in combination
Tetracyclines / Glycylcyclines	Doxycycline / Minocycline / Tigecycline	1960s / 2000s	Multiple / Pfizer (tigecycline)	Staphylococci susceptibility: 70–90%; tigecycline retains activity in >90% MDR strains	RMB 50–8,000 per course; highly agent-dependent, reimbursement varies
Oxazolidinones	Linezolid	2000	Pfizer + generics	linezolid resistance rare (<1–2%)	RMB 625–875 per course; generally reimbursed
Lipopeptides	Daptomycin	2003	Cubist / MSD + generics	MRSA/MRSE susceptibility >95%	RMB 1,000–2,000 per course; reimbursement varies by indication
Fluoroquinolones	Ciprofloxacin / Levofloxacin	1980s / 1990s	Multiple generics	Staphylococci susceptibility 50–70%; Gram-negative 60–80%	RMB 15–100 per course; generally reimbursed
Aminoglycosides	Gentamicin / Amikacin	1960s	Multiple generics	Gram-negative susceptibility 70–90%	RMB 20–200 per course; generally reimbursed inpatient

Source : FDA, NMPA, Frost & Sullivan analysis

# FDA Landscape of Prosthetic Joint Infection

## Global Marketed Helicobacter Pylori Infection Drug Competitive Landscape<sup>1-4</sup>



None

## Global Prosthetic Joint Infection Drug Pipeline<sup>1-4</sup>



Generic Name	Target/MOA	Company	Indication	Drug Type	Clinical Stage	First Posted Date
TNP-2092	RNAP; Bacterial DNA gyrase; DNA topoisomerase	TenNor Therapeutics	Periprosthetic Joint Infection (PJI)	Small molecule drug	Phase 2	2025.03
Icalpurbaug	DNABII	Trellis Bioscience	Prosthetic Joint Infections of Hip, Prosthetic Joint	Biologics	Phase 2	2024.10
Anti-Staphylococcus aureus	S. aureus	PHAXIAM Therapeutics	Hip Prosthesis Infection, Knee Prosthesis Infection	Biologics	Phase 2	2024-09
<b>VT-X7</b>	<b>Drug-Device Combination</b>	<b>Osteal Therapeutics</b>	<b>Prosthetic Joint Infection</b>	<b>Drug-Device Combination</b>	<b>Phase2</b>	<b>2022.10</b>
PLG0206	Protein Based Therapies	Peptilogics	Joint Infection	Biologics	Phase 1	2021.11
TRL1068	DNABII	Trellis Bioscience	Prosthetic Joint Infection	Biologics	Phase 1	2022.02

1. Only includes originator, excluding generic drugs
2. Excluding broad-spectrum Antibacterials (e.g., amoxicillin, azithromycin), as they are general-purpose Antibacterials rather than PJI-targeted therapies
3. The nature of the sponsor is enterprise
4. Only includes pipelines active within the past three years

Source : ClinicalTrials (as of 04/05/2026), Frost & Sullivan analysis

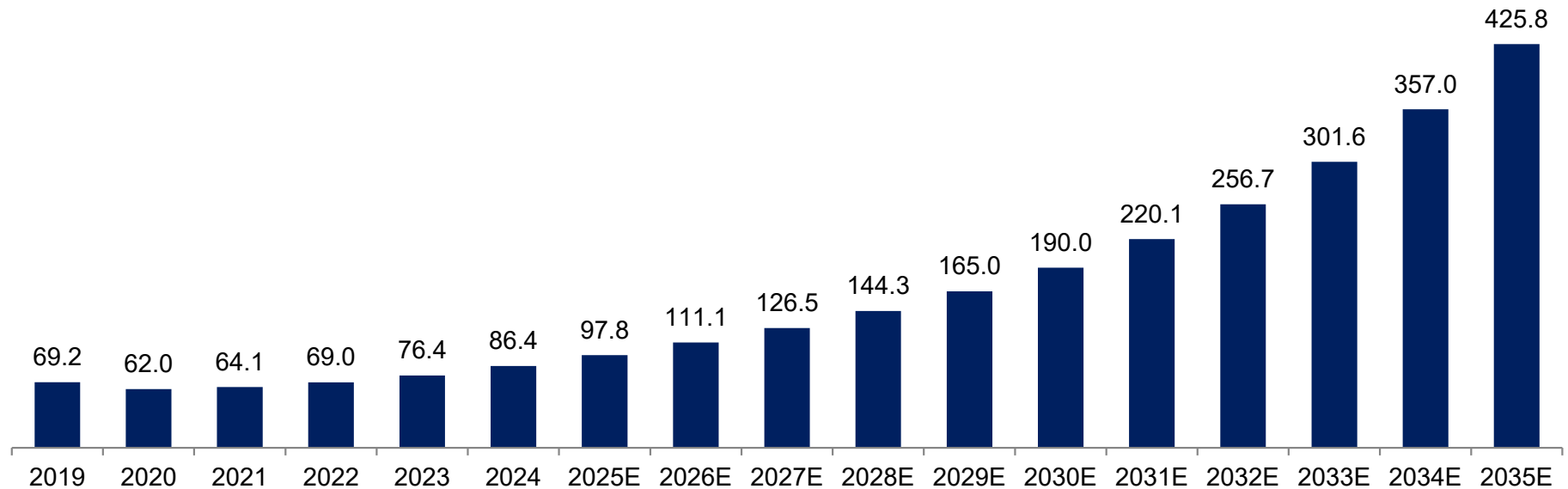
# Global Incidence of Prosthetic Joint Infection, 2019-2035E

- Global Incidence number of Prosthetic joint infection increased from 69.2 thousand to 86.4 thousand in 2019 and 2024. The number is expected to grow to 165.0 million in 2029 at a CAGR of 13.8% from 2024 to 2029. The number is expected to increase to 425.8 million in 2035, at a CAGR of 17.1%.

## Global Incidence of Prosthetic Joint Infection , 2019-2035E

Unit: Thousand

Period	CAGR
2019-2024	4.5%
2024-2029E	13.8%
2029E-2035E	17.1%



Source: Literature Review, Frost & Sullivan Analysis

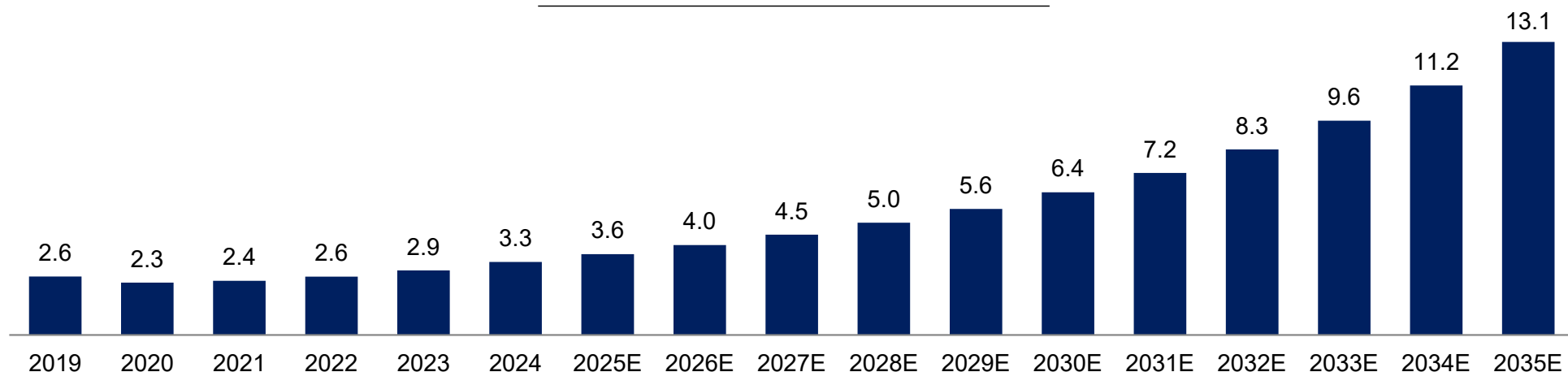
# Global Prosthetic Joint Infection Market Size

- In 2019, the market size was USD2.6 billion. From 2019 to 2024, it grew at a CAGR of 8.6%. In 2024, the market size reached USD3.3 billion. The market size is expected to reach USD5.6 billion in 2029, with a CAGR of 11.6% from 2024 to 2029. The market will further grow to USD13.1 billion in 2035, with a CAGR of 14.6% from 2029 to 2035..

## Global Prosthetic Joint Infection Drugs Market Size, 2019-2035E

Unit: Billion USD  
At wholesales price level

Period	CAGR
2019-2024	8.6%
2024-2029E	11.6%
2029E-2035E	14.6%



NOTE: The market comprises the drug and surgical treatment segments.  
Source: Frost & Sullivan analysis

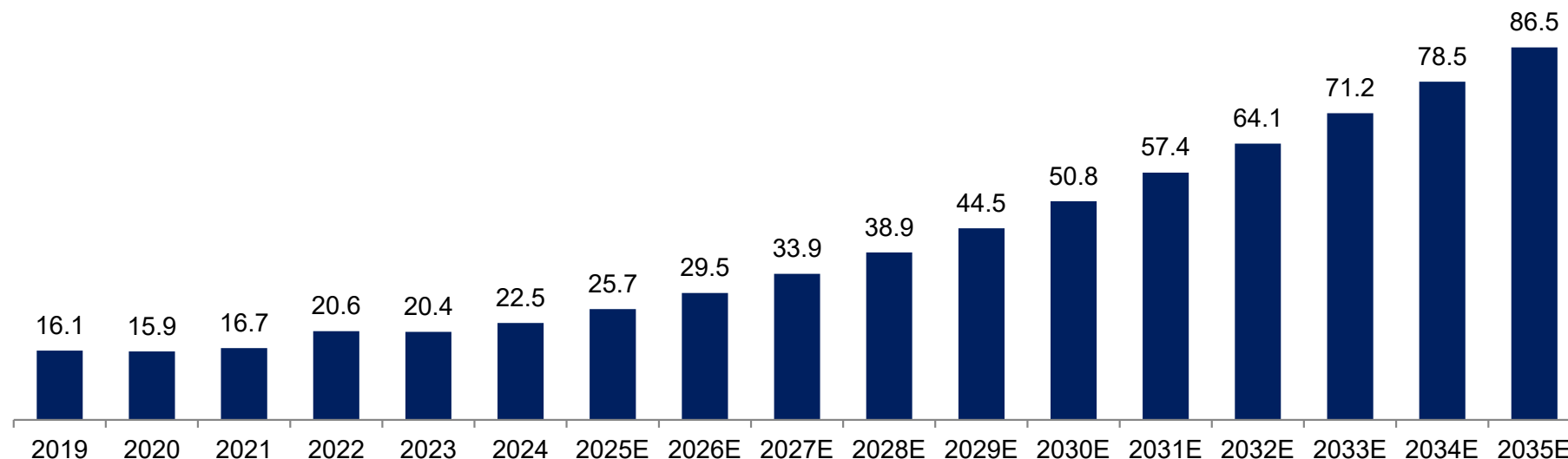
# Incidence of Prosthetic Joint Infection in China, 2019-2035E

- Incidence number of Prosthetic joint infection in China increased from 16.1 thousand to 22.5 thousand in 2019 and 2024. The number is expected to grow to 44.5 thousand in 2029 at a CAGR of 14.6% from 2024 to 2029. The number is expected to increase to 86.5 thousand in 2035, at a CAGR of 11.7%.

## Incidence of Prosthetic Joint Infection in China, 2019-2035E

Unit: Thousand

Period	CAGR
2019-2024	6.9%
2024-2029E	14.6%
2029E-2035E	11.7%



Source: Literature Review, Frost & Sullivan Analysis

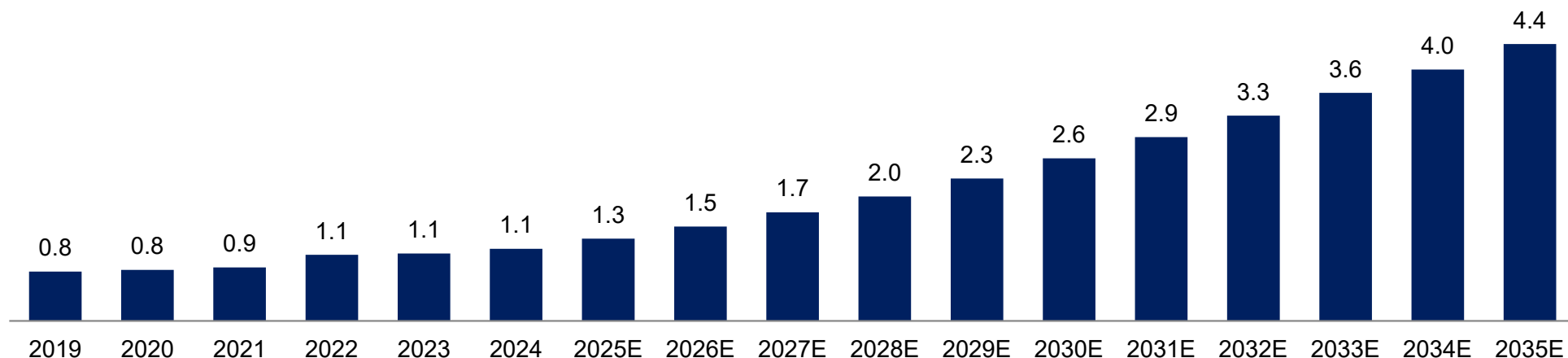
# China Prosthetic Joint Infection Market Size

- In 2019, the market size was RMB0.8 billion. From 2019 to 2024, it grew at a CAGR of 6.9%. In 2024, the market size reached RMB 1.1 billion. The market size is expected to reach RMB2.3 billion in 2029, with a CAGR of 14.6% from 2024 to 2029. The market will further grow to RMB4.4 billion in 2035, with a CAGR of 12.0% from 2029 to 2035.

## China Prosthetic Joint Infection Drugs Market Size, 2019-2035E

Unit: Billion RMB  
At ex-factory price level

Period	CAGR
2019-2024	9.0%
2024-2029E	14.6%
2029E-2035E	12.0%



*NOTE: The market comprises the drug and surgical treatment segments.  
Source: Frost & Sullivan analysis*

# Prosthetic Joint Infection Drugs Market Size

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- Prophylactic use of antibacterial agents in periprosthetic joint replacement typically lasts 1–2 weeks, with drug-related expenses estimated at approximately US \$1,000 to 2,000 in the U.S. and RMB 6,000 to 10,000 in China. In contrast, treatment of established periprosthetic joint infections involves 3–6 months of antimicrobial therapy, with drug-related expenses estimated at US \$60,000 to 105,000 in the U.S. and RMB 60,000 to 90,000 in China.

Source: Frost & Sullivan analysis

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# Overview of Left Ventricular Assist Devices

- Left ventricular assist devices (LVADs) are indicated for patients with heart failure
- **LVAD:** Each LVAD comprises internal components (inflow cannula, implantable pump, outflow graft) hidden within the patient and external parts (drive-line, controller, energy source), where the smartphone-sized controller offers diagnostics and alarms, and the energy source—either batteries (up to 17 hours) or AC power—connects to it.
- **LVAD Surgery Process:**
  - Preparation:** Before surgery, patients undergo extensive evaluations, including imaging, blood tests, and consultations with a multidisciplinary team. This ensures they are suitable candidates for the procedure.
  - Surgical Procedure:** During the surgery:
    - ❑ A median sternotomy (incision along the breastbone) is performed to access the heart.
    - ❑ The LVAD pump is implanted and connected to the heart's left ventricle and the aorta.
    - ❑ Tubing is routed through the skin to connect the pump to the external controller and power source.
  - Postoperative Care:** Patients are monitored in the intensive care unit (ICU) for the first few days. They remain hospitalized for 2-4 weeks on average to ensure the device is functioning properly and to learn how to manage it.

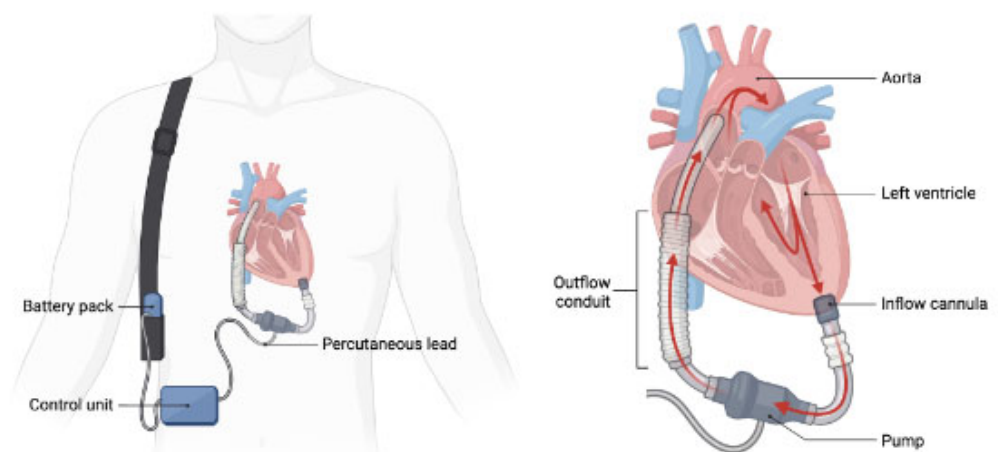
## Complications

- **Infections:** The external components of the device increase the risk of infection at the drive-line site.
- **Blood Clots:** Clots can form in the pump, leading to stroke or pump malfunction.
- **Bleeding:** Anticoagulant medications, necessary to prevent clots, can increase the risk of bleeding.
- **Device Malfunction:** Mechanical issues, though rare, may require surgical intervention or device replacement.

Source: Literature Research, Frost & Sullivan Analysis

## Left Ventricular Assist Device (LVAD)

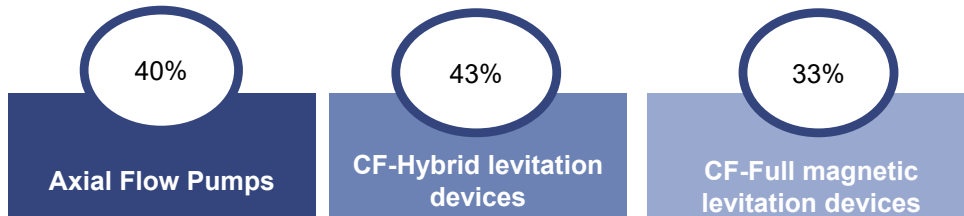
The LVAD pumps blood into the aorta and then supplied to the body



# Overview of Left Ventricular Assist Devices

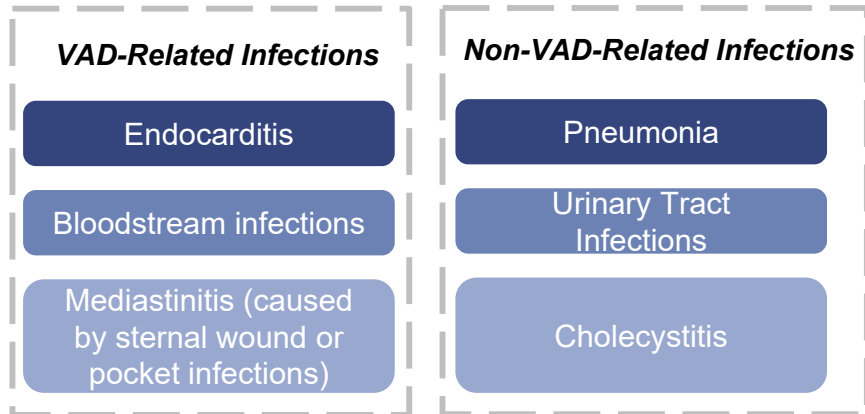
- As more devices have been implanted, LVAD infections, which are associated with substantial morbidity and mortality, have become an increasingly important problem. The definitive treatment, removing the device, is often not feasible, thus making LVAD infections a devastating complication for affected patients.
- 22% overall infection rate of LVADs per year and a one-year mortality 5.6 times greater in patients with infections

## Characteristics



- During the first-year follow-up after LVAD implantation, severe infections occurred in 40% of patients with axial flow pumps, 43% with CF-Hybrid levitation devices, and 33% with CF-Full magnetic levitation devices.

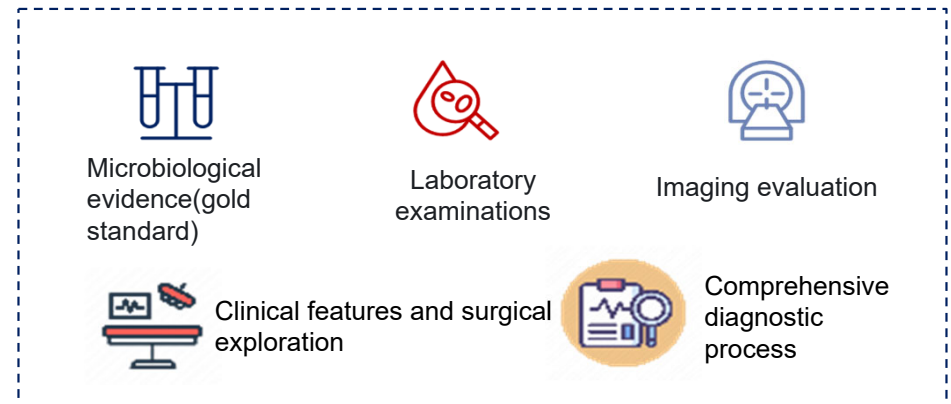
## Infection Type



## Infection Mechanisms :

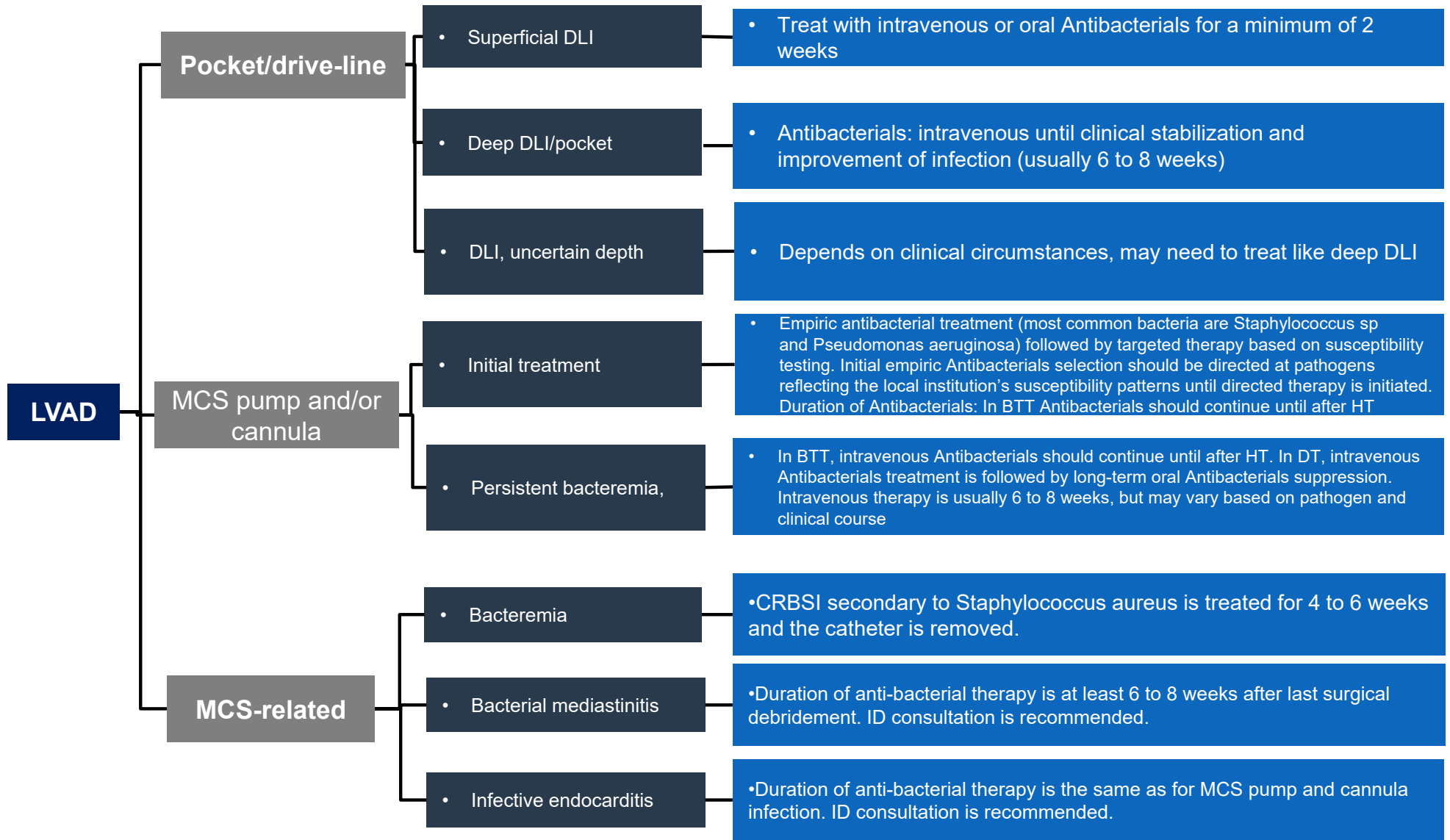
- Surgery - related infections:** During surgery, the pump, pump pocket, and other infected sites (such as the heart and mediastinum) can be infected due to bloodstream seeding or microbial contamination, including infective endocarditis, mediastinitis, pump/cannula infections, and pump pocket infections.
- Biofilm - related infections:** Biofilms are likely to form at the exit site of the driveline, leading to driveline infections. In the driveline tissue tunnel, biofilms can disperse, causing bloodstream infections, or migrate, resulting in ascending tunnel infections.

## Diagnostic criteria



Source: Prospective, multicenter study of ventricular assist device infections. Circulation. Frost & Sullivan analysis

# Treatment Paradigm of Left Ventricular Assist Devices Infection



NOTE: BTT: Bridge to Transplant, DLI: Drive-Line Infection, HT: Heart Transplant

Source: ISHLT, Frost & Sullivan analysis

# Unmet needs in the treatment of LVAD infection

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## Multidrug resistance and limited antimicrobial options

- Patients with LVAD infections often face infections caused by multidrug-resistant organisms, including MRSA, VRE, and resistant Gram-negative bacilli. Recurrent exposure to broad-spectrum antibiotics during hospitalization contributes to selection pressure and rising resistance. Treatment is further complicated by the limited availability of oral antibiotics with activity against key pathogens, making long-term outpatient management difficult.

## Biofilm formation and incomplete eradication

- LVAD components, especially the driveline and pump housing, are prone to biofilm formation, which shields pathogens from both the host immune system and antibiotic penetration. Most conventional antimicrobials are ineffective against mature biofilms, leading to persistent or recurrent infections despite prolonged treatment courses. There is a clear need for agents or adjunctive therapies that can disrupt or prevent biofilm development on device surfaces.

## Lack of device-sparing strategies and diagnostic challenges

- Currently, LVAD infections often require device exchange or even heart transplantation when medical therapy fails. However, reoperation carries significant risk, particularly in frail patients. Moreover, differentiating between superficial driveline infections and deeper pump-related infections remains difficult due to limitations in imaging and culture techniques. Less invasive, more targeted treatment strategies and better diagnostics are urgently needed to improve outcomes.

Source: Frost & Sullivan Analysis

# Global Marketed LVADI Drug Competitive Landscape(off-label)

Drug Class	Representative Drug	Major Manufacturer	Clinical Use (LVADI)	Remarks (Off-label Use)	Treatment Course (CN) & Insurance Coverage
Glycopeptide	Vancomycin (IV)	Multiple generics	First-line MRSA / Gram+ LVADI (acute phase)	Standard IV backbone; device-infection practice	RMB 11,000–17,000 per course; reimbursed; varies by indication
Lipopeptide	Daptomycin (IV)	Merck / generics	MRSA bacteremia / deep infection	Alternative to vancomycin; salvage therapy	RMB 7,000–20,000 per course; reimbursed; varies by indication
Broad $\beta$ -lactam	Piperacillin–tazobactam (IV)	Multiple generics	Empiric polymicrobial / Gram– coverage	Initial broad-spectrum bridge	RMB 300–1,500 per week; usually reimbursed inpatient
	Cefiderocol	Shionogi	Complicated UTI, hospital-acquired pneumonia	Siderophore cephalosporin; "Trojan horse" antibiotic	~RMB 10,000–20,000 per course; reimbursed; varies
	Ceftaroline fosamil	Takeda/AstraZeneca	Complicated skin infections	Fifth-generation cephalosporin	~RMB 5,000–10,000 per course
Rifamycin (Adjunct)	Rifampin (PO/IV)	Multiple generics	Biofilm-active combination therapy	Generally in combination	RMB 20–100 per day; generally reimbursed
Oxazolidinone	Linezolid (PO)	Pfizer / generics	Oral step-down / suppressive therapy (SAT)	Common long-term suppression option	RMB 1,800–2,600 per month; reimbursed; varies
	Tedizolid	Merck & Co	Complicated skin infections	May have better safety profile than linezolid	~RMB 1,500–2,500 per course; reimbursed; varies
Tetracycline	Doxycycline (PO)	Multiple generics	Chronic oral suppressive therapy	Frequently used SAT agent	RMB 20–80 per day; generally reimbursed
Fluoroquinolone	Levofloxacin (PO)	Multiple generics	Gram– suppressive therapy	Used when susceptible	RMB 30–120 per day; generally reimbursed
Novel Topoisomerase Inhibitor	Gepotidacin	GSK	Uncomplicated UTI caused by E. coli	First-in-class oral antibiotic; inhibits bacterial DNA replication	Not available

Source: Frost & Sullivan Analysis

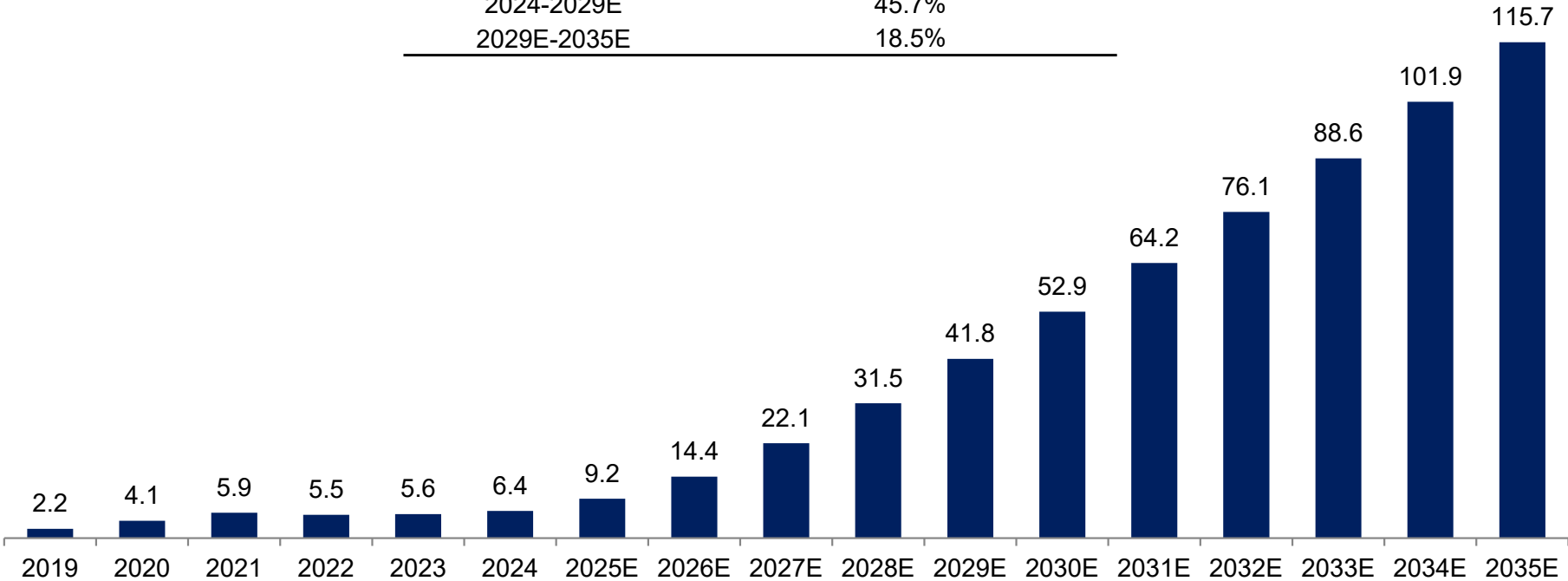
# Global Left Ventricular Assist Device Infections

Global Incidence number of left ventricular assist device infections increased from 2.2 Thousand to 6.4 thousand in 2019 and 2024. The number is expected to grow to 41.8 Thousand in 2029 at a CAGR of 45.7% from 2024 to 2029. The number is expected to increase to 115.7 Thousand in 2035.

Global Left Ventricular Assist Device Infections , 2019-2035E

Unit: Thousand

Period	CAGR
2019-2024	23.8%
2024-2029E	45.7%
2029E-2035E	18.5%



Source: Literature Review, Frost & Sullivan Analysis

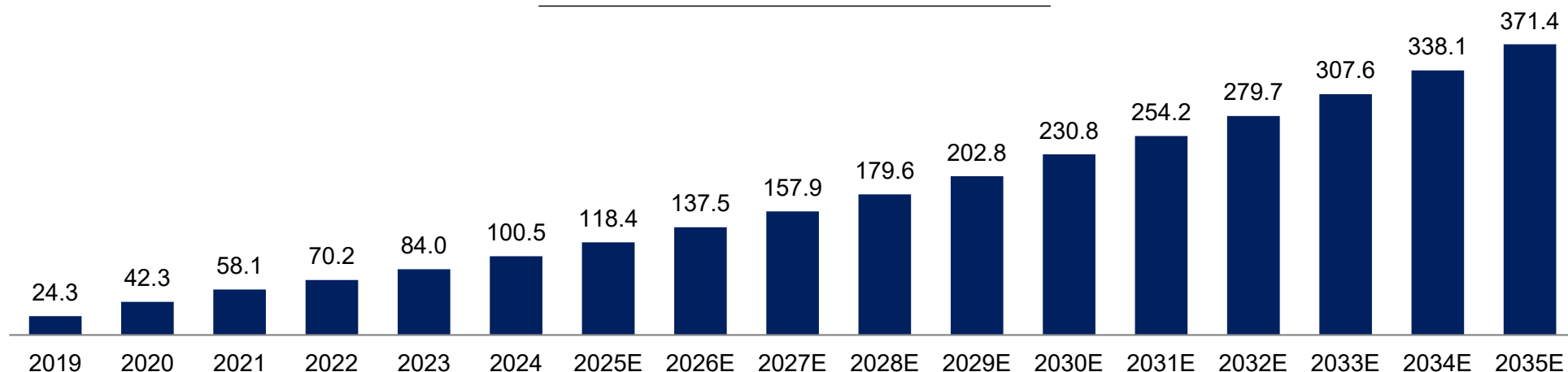
# Global Left Ventricular Assist Device Infections Drugs Market Size

- In 2019, the market size was USD24.3 million. From 2019 to 2024, it grew at a CAGR of 32.9%. In 2024, the market size reached USD100.5 million. The market size is expected to reach USD202.8 million in 2029, with a CAGR of 15.1% from 2024 to 2029. The market will further grow to USD371.4 million in 2035, with a CAGR of 10.6% from 2029 to 2035.

## Global Left Ventricular Assist Device Infections Drugs Market Size, 2019-2035E

Unit: Million USD  
At wholesales price level

Period	CAGR
2019-2024	32.9%
2024-2029E	15.1%
2029E-2035E	10.6%



The sum of global indication-specific antibiotic markets may exceed the total antibiotic market size, as revenues are not strictly separable by indication and combination therapies have been taken into account.

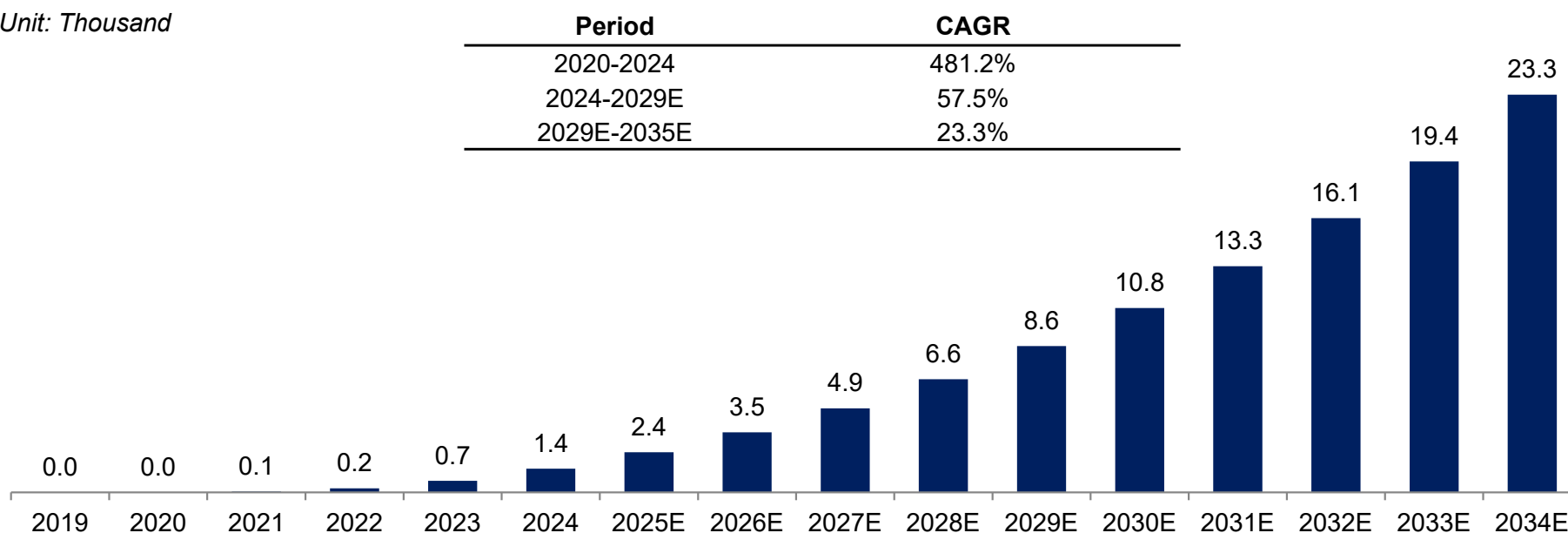
Source: Frost & Sullivan analysis

# Left Ventricular Assist Device Infections in China

- The cumulative patients of left ventricular assist device (LVAD) infections in China rose from 0.0 thousand to 1.4 thousand (2024). It is projected to grow to 8.6 thousand by 2029 (CAGR 57.5%, 2024–2029) and further to 15.4 thousand by 2035 (CAGR 23.3%, 2029–2035). The incidence of LVAD infections is fundamentally determined by two interconnected factors: the total number of LVAD implantations performed and the infection rate associated with each device. This trend stems from two core drivers: **growing LVAD implantation volumes** and **persistent pathogen-related infection risks**.
- **Implantation Volume Drivers:**
- LVAD implantation in China expands via domestic innovators and multinational players: Domestic manufacturers: companies like Suzhou Tongxin, Aerospace Taisheng, and Shenzhen CoreMed Medical scale up adoption of products. Multinational Players: Entities like Abbott complement market growth with established technologies, widening LVAD availability across hospitals.
- **Pathogen-Specific Infection Risks:**
- LVAD infections are driven by persistent pathogens: Pathogens responsible for LVAD infections primarily consist of **Gram-positive bacteria** (e.g., *Staphylococcus aureus*, coagulase-negative staphylococci) and **Gram-negative bacteria** (including *Pseudomonas spp.*).

## Left Ventricular Assist Device Infections in China, 2019-2035E

Unit: Thousand



Source: Literature Review, Frost & Sullivan Analysis

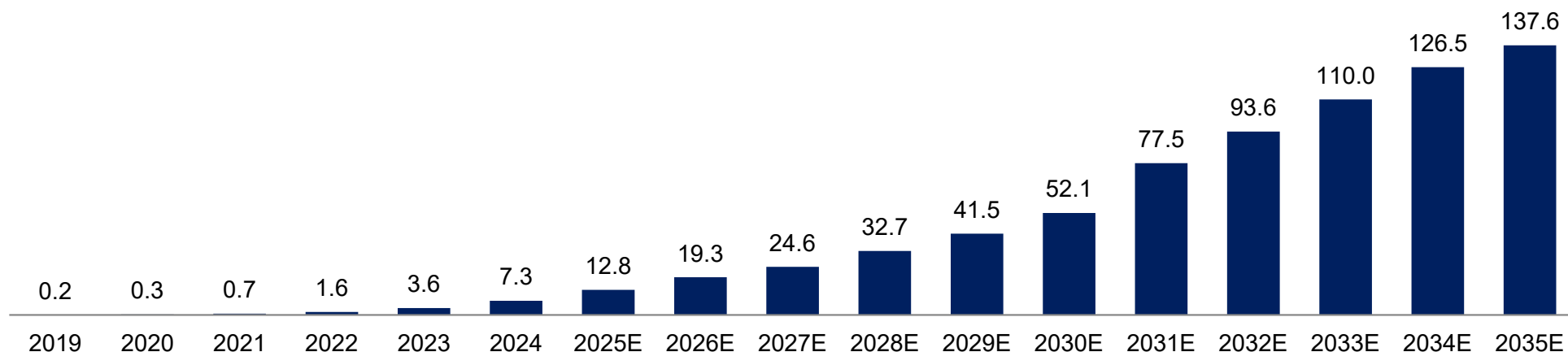
# China Left Ventricular Assist Device Drugs Market Size

- In 2019, the market size was RMB0.2 million. From 2019 to 2024, it grew at a CAGR of 105.5%. In 2024, the market size reached RMB7.3 million. The market size is expected to reach RMB41.5 thousand in 2029, with a CAGR of 41.6% from 2024 to 2029. The market will further grow to RMB137.6 million in 2035, with a CAGR of 22.1% from 2029 to 2035.

## China Left Ventricular Assist Device Infections Drugs Market Size, 2019-2035E

Unit: Million RMB  
At ex-factory price level

Period	CAGR
2019-2024	105.5%
2024-2029E	41.6%
2029E-2035E	22.1%



The sum of China's indication-specific antibiotic markets may exceed the total antibiotic market size, as revenues are not strictly separable by indication and combination therapies have been taken into account.

Source: Frost & Sullivan analysis

# Prosthetic Joint Infection Drugs Market Size

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- For LVAD-associated infection prophylaxis, perioperative antibiotic regimens typically last for 2 to 3 weeks, involving both intravenous and oral administration. For established LVAD infections, antibiotic treatment—including long-term intravenous and oral courses—generally extends for 3 to 6 months, depending on infection severity and response. Drug-related expenses in such cases are estimated at roughly US \$60,000-70,000 in the U.S. and RMB 60,000–90,000 in China.

Source: Frost & Sullivan analysis

# Advantages of TNP-2198

Dimension	TNP-2198	Standard Regimen (BQT)
Mechanism of Action	An unbreakable antibody–drug conjugate covalently links rifamycin and nitroimidazole pharmacophores through a stable linker, thereby simultaneously targeting RNA polymerase and nitroreductase-mediated DNA damage, achieving synergistic bactericidal activity against <i>Helicobacter pylori</i> .	Multi-drug combination: PPI + bismuth + two antibiotics (e.g., clarithromycin + metronidazole, or amoxicillin + tetracycline)
Bactericidal Characteristics	TNP-2198 is intended to replace part of existing antibiotics due to rising drug resistance in patients, in combination with amoxicillin (rather in compete with amoxicillin) and PPI for <i>H. pylori</i> treatment;	Different pharmacokinetics across drugs; requires multiple agents to cover different targets
Eradication Rate	The triple therapy (RTT) based on China's first-in-class antibacterial drug Rifasutenizol (TNP-2198) achieves a 92.0% (92.0% (95% CI: 88.7-94.6)) eradication rate in treatment-naive patients.	80–90% (depending on drug resistance rate, compliance and regional variations)
Eradication rate against multidrug-resistant strains	89.9% (95% CI: 83.0-94.7)	81.2% (95% CI: 74.0-87.1)
Safety Profile	The rifasutenizol combination was reported to have lower incidences of TEAEs and Grade $\geq 3$ adverse events compared with the BQT control group (EVEREST-HP)  Diarrhea (~7%) and nausea (~6%), No serious adverse events related to the drug were reported.	$\geq 10\%$ AE  Diarrhea (>20%)

Source: Frost & Sullivan analysis

# Comparison between Multi-targeting and Non-multi-targeting Conjugated Antibiotics

Feature / Indicator	Tenor Multi-Targeting Conjugated Antibiotics	Non-Multi-Targeting Conjugated Antibiotics	Advantages / Limitations (Qualitative)
Spectrum of Activity	Broad, targets multiple bacterial pathways simultaneously	Narrower, often single-target or limited spectrum	Multi-targeting allows coverage of diverse pathogens; non-multi-targeting may miss resistant strains
Efficacy	High, effective against resistant and multi-drug resistant strains	Moderate; efficacy may decline with resistance	Multi-targeting improves efficacy in difficult-to-treat infections; conventional antibiotics can be limited by existing resistance
Drug Resistance	Reduced risk due to simultaneous targeting of multiple pathways	Higher risk; bacteria may develop resistance more rapidly	Multi-targeting may slow resistance emergence; non-multi-targeting requires combination therapy for similar effect
Route of Application	Primarily intravenous or targeted delivery	Oral or intravenous depending on molecule	Multi-targeting molecules may require controlled delivery; non-multi-targeting often easier for outpatient use
Safety	Favorable; lower off-target effects due to targeted design	Established safety profile, but systemic side effects may be higher	Multi-targeting reduces collateral toxicity; conventional antibiotics may affect normal flora
Cost	Higher due to innovative technology and development	Generally lower; generics widely available	Multi-targeting is more expensive but addresses unmet needs; non-multi-targeting is cost-effective but limited by resistance
Patient Adherence	Moderate; intravenous or hospital-based administration may affect adherence	Higher for oral antibiotics; convenient dosing	Multi-targeting may require supervised administration; oral antibiotics easier for self-administration

Source: Frost & Sullivan analysis

# Advantages of TNP-2198

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Clinical results show that TNP-2198 combined with amoxicillin and rabeprazole achieves eradication rates of approximately **91-94%** in both treatment-naïve patients and antibiotic-resistant strains, overall surpassing BQT (approximately **87-90%**). In Phase III studies (EVEREST-HP), eradication rates reached up to **92%**. TNP-2198 also demonstrates a favorable safety profile, with adverse event rates comparable to or lower than those of BQT.

*Source: Frost & Sullivan analysis*

## Detailed information of antibiotics for the indications of TNP-2092

Indication	Drug Name	Developer	Target / Mechanism of Action	Treatment Duration	Clinical Status / Notes
<b>H. pylori infection</b>	Clarithromycin	Abbott / Various	Macrolide; inhibits bacterial protein synthesis	7–14 days	Part of standard triple therapy
	Amoxicillin	Beecham/GSK	Beta-lactam; inhibits bacterial cell wall synthesis	7–14 days	Used in combination regimens
	Metronidazole	Roche	Nitroimidazole; inhibits DNA synthesis	7–14 days	Component of quadruple therapy
<b>Bacterial Vaginosis (BV)</b>	Metronidazole	Roche	Nitroimidazole; inhibits DNA synthesis	5–7 days	First-line therapy
	Clindamycin (oral / topical)	Upjohn/Pfizer	Lincosamide; inhibits protein synthesis	5–7 days	Alternative therapy; topical forms common
<b>ABSSSI</b>	Oritavancin	InterMune/Targanta Therapeutics	Lipoglycopeptide; inhibits cell wall synthesis	Single dose / 1–3 days	Innovative small molecule; approved for MRSA
	Dalbavancin	Allergan / Durata	Lipoglycopeptide; inhibits cell wall synthesis	Single dose / 1–2 weeks	Approved for ABSSSI; targets resistant Gram-positive
<b>CDI</b>	Vancomycin	Eli Lilly	Glycopeptide; inhibits cell wall synthesis	10–14 days	Standard therapy
	Fidaxomicin	Optimer Pharmaceuticals/Pfizer	Macrolide; RNA polymerase inhibitor	10 days	Targets recurrence; innovative antibiotic

Source: Frost & Sullivan analysis

## Detailed information of antibiotics for the indications of TNP-2092

Indication	Drug Name	Developer	Target / Mechanism of Action	Treatment Duration	Clinical Status / Notes
<b>HE</b>	Rifaximin	Salix Pharmaceuticals	Rifamycin derivative; inhibits bacterial RNA synthesis	Long-term maintenance	Standard care for recurrent HE
	Lactulose	Duphar / Hospira	Non-absorbable disaccharide; reduces ammonia	Long-term	Widely used
<b>PJI</b>	Vancomycin	Eli Lilly	Glycopeptide; inhibits cell wall synthesis	7–14 days	Targets MRSA and Gram-positive bacteria
	Linezolid	Pfizer / Various	Oxazolidinone; inhibits protein synthesis	10–14 days	For resistant infections
	Daptomycin	Cubist / Various	Lipopeptide; disrupts cell membrane	7–14 days	Hospital-administered for resistant Gram-positive infections
<b>IBS-D</b>	Rifaximin	Salix Pharmaceuticals	Rifamycin derivative; inhibits bacterial RNA synthesis	10–14 days	Targets gut microbiota; symptom relief
<b>Diabetic Foot Infection</b>	Piperacillin-Tazobactam	Pfizer / Various	Beta-lactam + beta-lactamase inhibitor	7–14 days	Broad-spectrum coverage
	Vancomycin	Eli Lilly	Glycopeptide; inhibits cell wall synthesis	7–14 days	MRSA coverage
	Linezolid	Pfizer / Various	Oxazolidinone; inhibits protein synthesis	10–14 days	For resistant infections

Source: Frost & Sullivan analysis

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# Pain Points in ABSSSI Treatment

- MRSA, driven by the *mecA* gene, causes a major resistance crisis with cross-transmitted CA-MRSA and HA-MRSA raising infection rates in communities and hospitals, while gram-negative infections add complexity via multiple pathogens and broad-spectrum needs. Traditional  $\beta$ -lactam Antibacterials fail against MRSA; second-line drugs (e.g., vancomycin, linezolid) face issues like nephrotoxicity, high costs, and resistance, and conventional oral options have onset/tissue penetration limits.

## MRSA-Driven Resistance Crisis

The resistance in MRSA is primarily based on the acquisition of the *mecA* gene, which encodes a novel penicillin-binding protein (PBP) called PBP2a.

• Cross-transmission of CA-MRSA and HA-MRSA has led to MRSA accounting for over 50% of community-acquired infections and even higher rates in hospital settings

## 1 Epidemic Trends

## Challenges from Gram-Negative Bacteria

3

• Complex wounds (e.g., perianal infections, diabetic foot ulcers) often involve *Escherichia coli* and *Pseudomonas aeruginosa*, necessitating broad-spectrum Antibacterials (e.g., piperacillin-tazobactam) and further exacerbating resistance pressures.

## Treatment Limitations

2

Traditional  $\beta$ -lactam Antibacterials (e.g., penicillins, cephalosporins) are ineffective against MRSA, requiring reliance on second-line drugs like vancomycin and linezolid. However, these drugs are associated with nephrotoxicity, high costs, and resistance warnings

1

## Clinical Challenges

### Spread of drug resistance

- The detection rate of methicillin-resistant *Staphylococcus aureus* (MRSA) is > 40%. Traditional  $\beta$ -lactam Antibacterials are ineffective.
- Vancomycin requires intravenous injection, leading to poor compliance in outpatient treatment.

### Lagging therapeutic effect

- For conventional oral Antibacterials, it takes 2 - 4 hours for the blood drug concentration to reach its peak, resulting in a delay in the control of severe infections.
- Insufficient tissue penetration leads to poor therapeutic effects in deep-seated infections (such as diabetic foot).

### Safety concerns

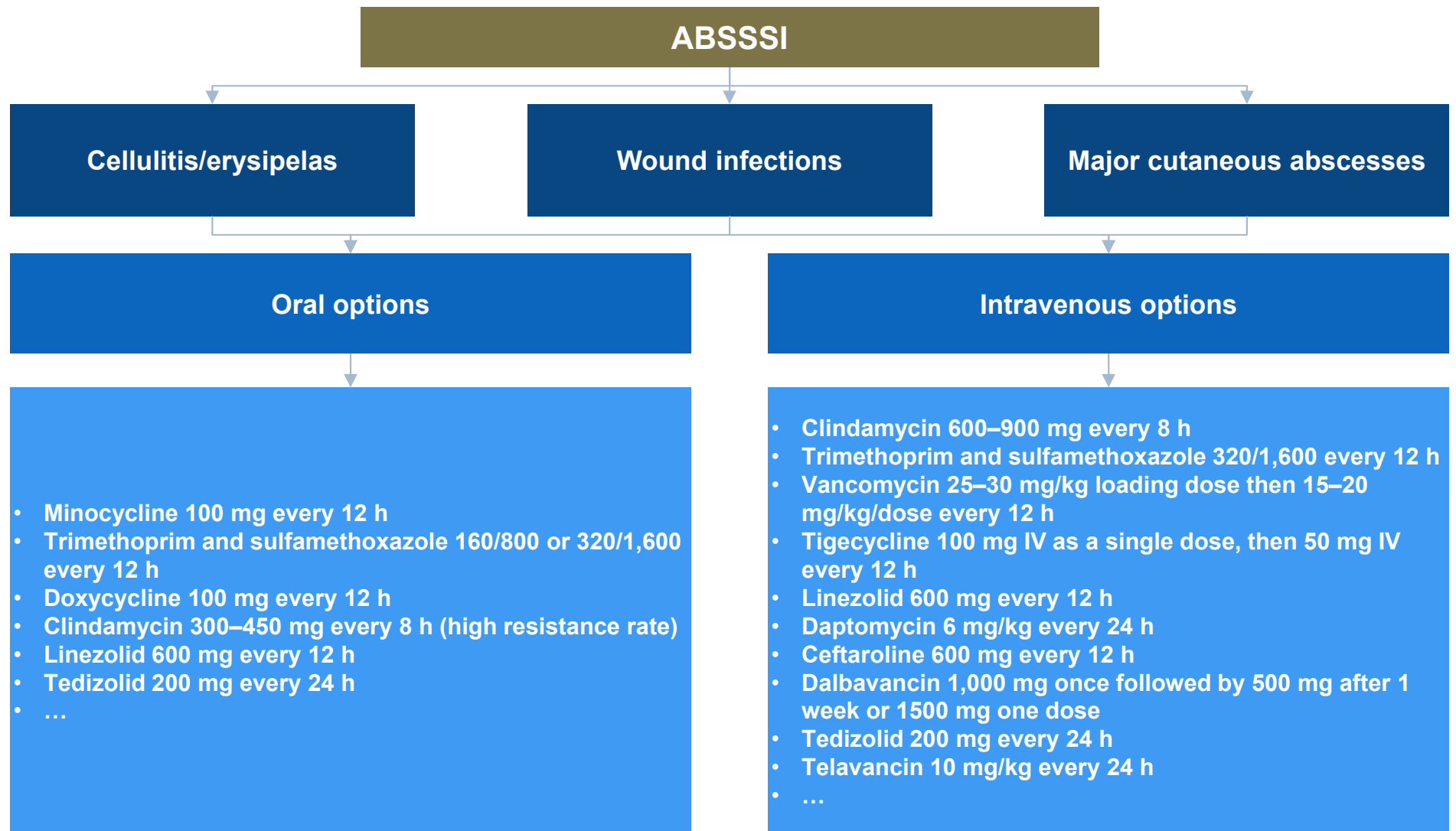
- Linezolid has a risk of bone marrow suppression (the incidence of thrombocytopenia is > 10%).
- There is a risk of inducing 5-HT syndrome during long-term treatment.

### ABSSSI with implant-related infection

- Medical implants like central venous catheters complicate ABSSSI treatment. Bacterial biofilms reduce antibiotic penetration by >50%, forcing extended IV therapy (14-28 days) that worsens patient adherence
- Keeping catheters requires anti-biofilm drugs (e.g., daptomycin-rifampin). However, this raises both costs and resistance risks.

Source: Literature Review, Frost & Sullivan Analysis

# Treatment Paradigm of ABSSSI

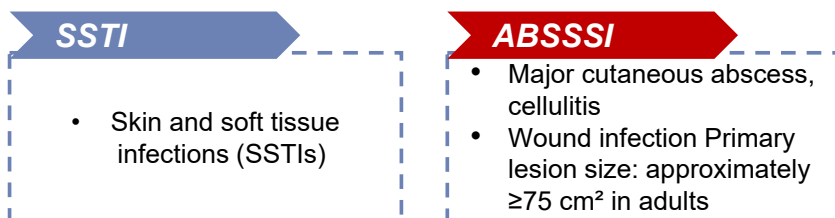


Source : WSES/GAIS/WSIS/SIS-E/AAST global clinical pathways for patients with skin and soft tissue infections, Frost & Sullivan analysis

# Overview of ABSSSI

- Acute bacterial skin and skin structure infections (ABSSSI) refer to a range of infections involving the skin and its underlying soft tissues, typically caused by bacteria. These infections can vary in severity and are characterized by local inflammation, redness, increased skin temperature, and sometimes purulent discharge. Common pathogens causing ABSSSI include *Staphylococcus aureus* (including methicillin-resistant *Staphylococcus aureus*/MRSA), *Streptococcus pyogenes*, and other Gram-positive and Gram-negative bacteria.

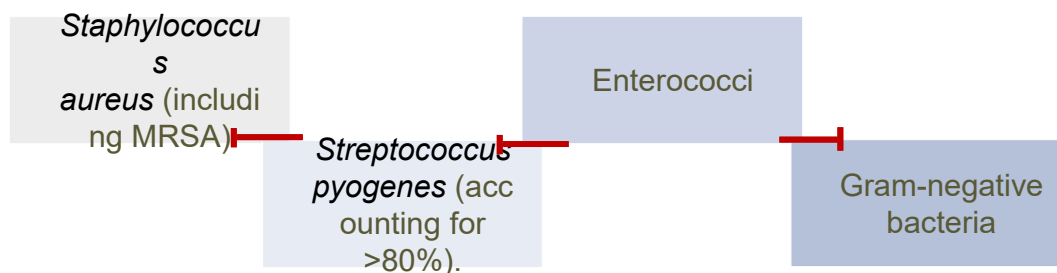
## 1 Definition



### Infection Sources

- Community-acquired:** Common in healthy populations, associated with trauma, tinea pedis, venous insufficiency, etc.
- Hospital-acquired:** More frequent in immunosuppressed patients, those with hospitalization history, or venous catheterization, with high MRSA risk.

## 2 Severe complications and common pathogens



### Complications of ABSSSI

- Vascular Diseases:** Peripheral vascular disease, Congestive heart disease
- Organ Dysfunction:** Renal disease, Chronic obstructive pulmonary disease (COPD) or respiratory diseases
- Malignant Tumors**

## 3 Pathophysiology of ABSSSI

- The cause of ABSSSI usually stems from a compromise to the skin barrier. A second although much less common route for infection is hematogenous spread to tissue

Source: Literature Review, Frost & Sullivan Analysis

# NMPA Landscape of ABSSSI

## China Marketed ABSSSI Competitive Landscape<sup>1-4</sup>



Generic Name	Brand Name	Target	Company	Indication	Approval Date
Omadacycline Tosilate	NUZYRA	30S Ribosomal Subunit	ZaiLab	ABSSSI	2021.12
MRX1	Contezolid	50S Ribosomal Subunit	MicuRx Pharmaceuticals	ABSSSI	2021.06

## China ABSSSI Drug Pipeline<sup>1-4</sup>



Generic Name	Target	Company	Indication	Drug Type	Clinical Stage	First Posted Date
MRX4	50S Ribosomal Subunit	MicuRx Pharmaceuticals	ABSSSI	Small molecule drug	NDA	2025.06
TNP-2092	RNAP; Bacterial DNA gyrase; DNA topoisomerase	TenNor Therapeutics	ABSSSI	Small molecule drug	Phase 2 Completed	2022.06
9MW1411	$\alpha$ -Toxin	Mabwell (Shanghai) Bioscience	ABSSSI	Biologics	Phase 2	2021.11

1. Only includes chemical originator, excluding generic drugs
2. Excluding broad-spectrum Antibacterials (e.g., amoxicillin, azithromycin), as they are general-purpose Antibacterials rather than ABSSSI-targeted therapies
3. The nature of the sponsor is enterprise
4. Only includes pipelines active within the past three years

NOTE: MRX4-201\*

Source : NMPA (as of 04/05/2026), Frost & Sullivan analysis

# FDA Landscape of ABSSSI

## Global Marketed ABSSSI Drug Competitive Landscape<sup>1-4</sup>



Generic Name	Brand Name	Target	Company	Indication	Approval Date
Ceftobiprole Medocartil Sodium	ZEVTERA	PBP	ISTX	ABSSSI	2024-04
Omadacycline Tosilate	NUZYRA	30S Ribosomal Subunit	Paratek Pharma	ABSSSI	2021.12

## Global ABSSSI Drug Pipeline<sup>1-4</sup>



Generic Name (Identifier)	Target	Company	Indication	Study Location	Clinical Stage	First Posted Date
MRX-4	50S Ribosomal Subunit	MicuRx Pharmaceuticals	ABSSSI	MRCT <sup>2</sup>	NDA <sup>3</sup>	2025.05.20
Rifaquinizone (TNP-2092 injection) <sup>1</sup>	RNAP; DNA gyrase; DNA topoisomerase IV	The Company	ABSSSI	China	Phase II	2024.06.02
				U.S.	Phase II	2019.05.28

1. Only includes chemical originator,

Source : ClinicalTrials (as of 04/05/2026), Frost & Sullivan analysis

# Global Marketed ABSSSI Drug Competitive Landscape(off-label)

Drug Class	Representative Drug	Market Launch Year	Major Manufacturer	Typical Susceptibility / Resistance Pattern	Treatment Course Cost (CN) & Insurance Coverage	Treatment Course Cost (US) & Insurance Coverage
Glycopeptide antibiotics (lipoglycopeptide subclass)	Vancomycin	1958	Multiple generics	MRSA susceptibility >95%; MIC creep 5–15%	RMB 4,000-4,500; generally covered	300–800 USD; widely reimbursed
	Oritavancin	2014	Novartis	Potent activity against Gram-positive pathogens including MRSA	Not available in China/ not reimbursed	~US\$3,500–4,000/course; reimbursement varies
	Dalbavancin	2014	AbbVie	Potent activity against Gram-positive pathogens including MRSA	Not available	\$3,000–\$5,000/course
Lipopeptide	Colistin (Polymyxin E)	1960s	Multiple generics	Mainly Gram-negative; sometimes used off-label for polymicrobial ABSSSI in resistant infections	RMB 400–4,000/course; usually not covered for ABSSSI	\$200–\$1,000/course; usually not covered for ABSSSI
	Daptomycin	2003	Cubist / Astellas	MRSA susceptibility >99%; resistance <1%	RMB 1,000–2,000; reimbursement varies by indication	3,000–6,000 USD; reimbursed by indication

Source :FDA, NMPA, Frost & Sullivan analysis

# Global Marketed ABSSSI Drug Competitive Landscape(off-label)

Drug Class	Representative Drug	Market Launch Year	Major Manufacturer	Typical Susceptibility / Resistance Pattern	Treatment Course Cost (CN) & Insurance Coverage	Treatment Course Cost (US) & Insurance Coverage
Fluoroquinolone	Ciprofloxacin / Levofloxacin	1987 / 1996	Multiple generics	Active vs Gram-negative and some Gram-positive; ABSSSI off-label	RMB 15–50/course; usually covered for labeled infections	\$50–\$500/course; usually covered for labeled infections
Oxazolidinones	Linezolid	2000	Pfizer	Strong activity against Gram-positive pathogens including MRSA; resistance remains relatively low	RMB 625–875/course; generally reimbursed	US\$ 5,300–7,500/course; reimbursement varies
Tetracyclines	Minocycline / Doxycycline	Multiple generics	Multiple generics	Active against some CA-MRSA isolates; resistance varies by region	RMB 30–120/course; generally reimbursed	US\$ 10–60/course; generally covered
Sulfonamides	Trimethoprim / sulfamethoxazole	Multiple generics	Multiple generics	Active against many CA-MRSA isolates; limited streptococcal coverage	RMB 10–20/course; generally reimbursed	US\$ 50–75/course; generally covered
Other Antibacterials	Tigecycline	2005	Pfizer	Broad-spectrum activity; generally reserved for selected patients	RMB 400–1,200/course; hospital use primarily	US\$ 200–2,800/course; reimbursement varies

Source :FDA, NMPA, Frost & Sullivan analysis

# FDA Landscape of ABSSSI

Drug Class	Representative Drug	Market Launch Year	Major Manufacturer	Typical Susceptibility / Resistance Pattern	Treatment course cost (CN, post-NRDL / reimbursed basis)	Treatment Course Cost & Insurance Coverage
Aminomethylcycline (tetracycline class)	NUZYRA (omadacycline)	2018 (US)	Zai Lab (Greater China); Paratek (originator)	Broad Gram-positive activity incl. MRSA; coverage of atypicals; retains activity against many tetracycline-resistant strains	~RMB 4,800–7,200 / course	~3,000–5,000 USD per course (US); limited reimbursement
Oxazolidinone	Centezolid	2021 (China)	MicuRx Pharmaceuticals	Potent Gram-positive coverage incl. MRSA; comparable efficacy to linezolid with improved hematologic safety; lower myelosuppression risk	~RMB 2,700–5,400 / course	Mid-to-high hospital IV cost; limited NRDL coverage

1. Only includes chemical originator,

Source : FDA, NMPA (as of 04/05/2026), Frost & Sullivan analysis

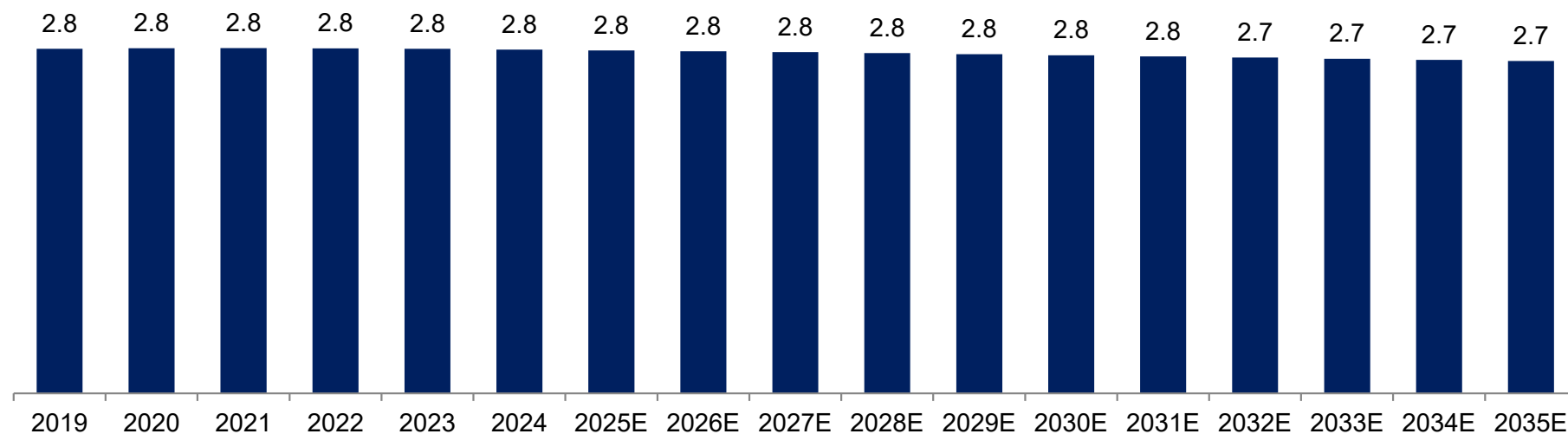
# Incidence of Acute Bacterial Skin and Skin Structure Infection in China, 2019-2035E

- Incidence number of acute bacterial skin and skin structure infection in China remained nearly unchanged from 2019 to 2024. The number is expected to decrease to 2.8 million in 2030 at a CAGR of  $-0.3\%$  from 2024 to 2030. The number is expected to reduce to 2.7 million in 2035, at a CAGR of  $-0.3\%$ .
- The 《Clinical Application Classification Catalog of Antibacterial Drugs》 was released in 2023. The overuse of empirical broad-spectrum antibiotics has decreased, and the risk of severe infections induced by drug-resistant bacteria has been reduced.

## Incidence of Acute Bacterial Skin and Skin Structure Infection in China, 2019-2035E

Unit: Million

Period	CAGR
2019-2024	0.0%
2024-2030E	-0.3%
2030E-2035E	-0.3%



Source: Literature Review, Frost & Sullivan Analysis

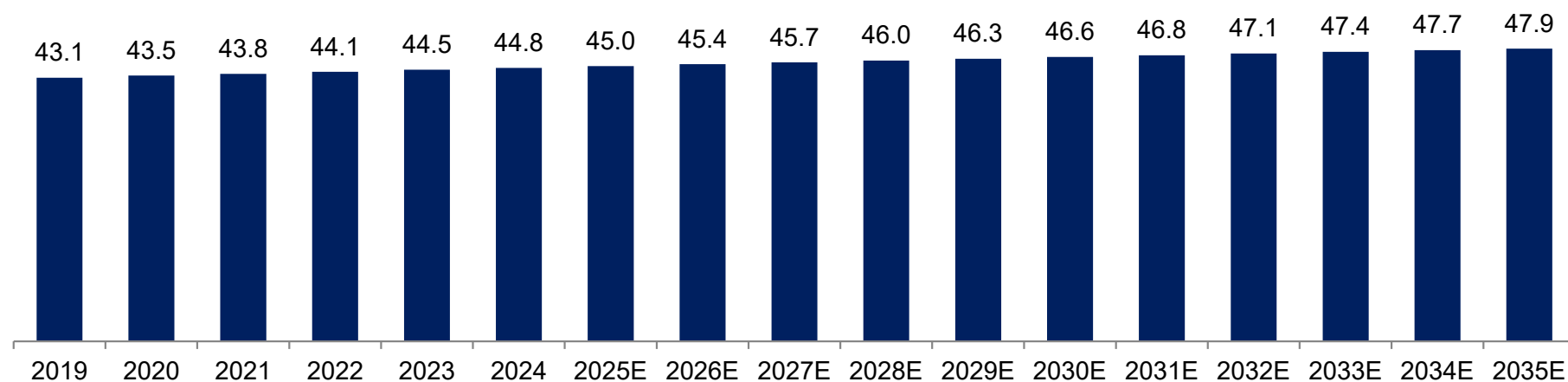
# Global Incidence of Acute Bacterial Skin and Skin Structure Infection, 2019-2035E

- From 2019 to 2024, global incidence of ABSSSI increased from 43.1 million to 44.8 million, with a CAGR of approximately 0.7%. This steady upward trend is projected to continue, reaching 46.6 million by 2030 (CAGR: 0.6%) and 47.9 million by 2035 (CAGR: 0.6%).

## Global Incidence of Acute Bacterial Skin and Skin Structure Infection, 2019-2035E

Unit: Million

Period	CAGR
2019-2024	0.7%
2024-2030E	0.7%
2030E-2035E	0.6%



Source: Literature Review, Frost & Sullivan Analysis

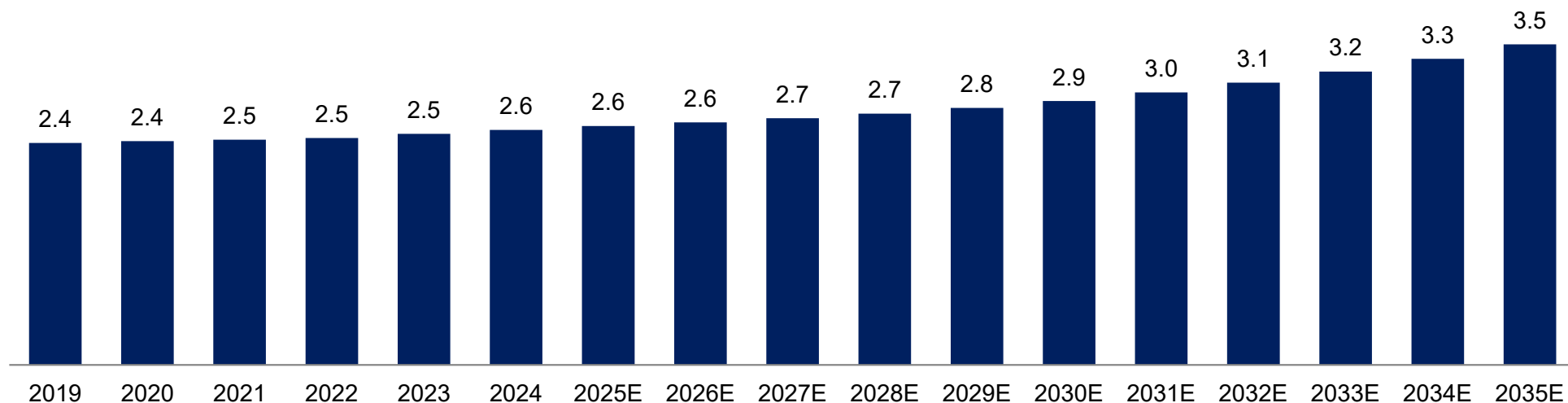
# Global ABSSSI Drugs Market Size

- In 2019, the market size was USD2.4 billion. From 2019 to 2024, it grew at a CAGR of 1.2%. In 2024, the market size reached USD2.6 billion. The market size is expected to reach USD2.8 billion in 2029, with a CAGR of 1.8% from 2024 to 2029. The market will further grow to USD3.5 billion in 2035, with a CAGR of 3.8% from 2029 to 2035..

## Global ABSSSI Drugs Market Size, 2019-2035E

Unit: Billion USD  
At wholesales price level

Period	CAGR
2019-2024	1.2%
2024-2029E	1.8%
2029E-2035E	3.8%



Source: Frost & Sullivan analysis

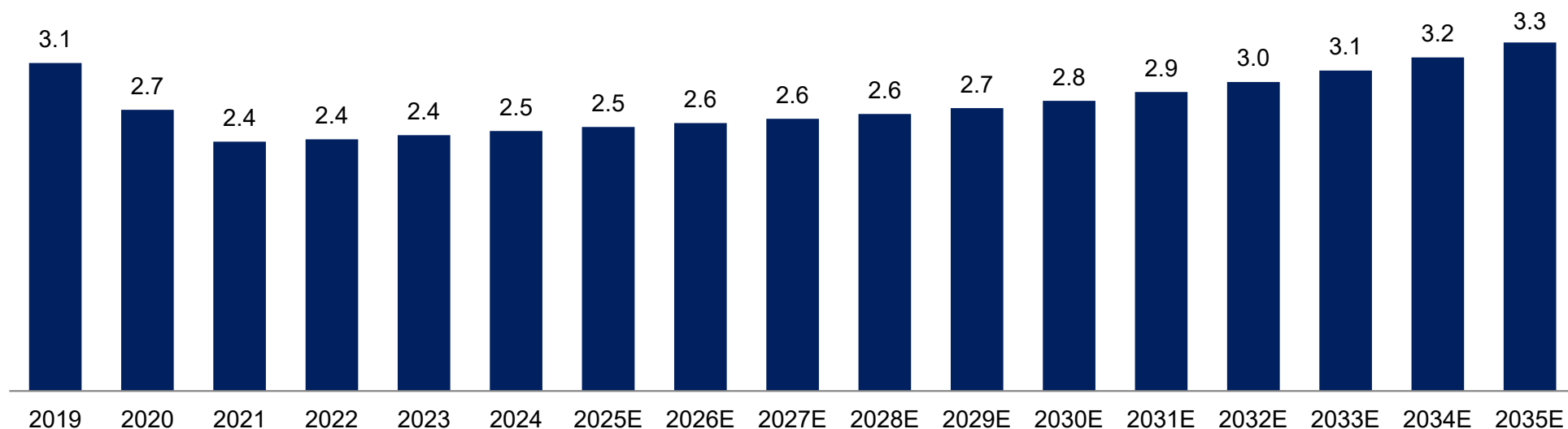
# China ABSSSI Drugs Market Size

- In 2019, the market size was RMB3.1 billion. From 2019 to 2024, it grew at a CAGR of -4.5%. In 2024, the market size reached RMB 2.5 billion. The market size is expected to reach RMB2.7 billion in 2029, with a CAGR of 1.7% from 2024 to 2029. The market will further grow to RMB3.3 billion in 2035, with a CAGR of 3.5% from 2029 to 2035.

## China ABSSSI Drugs Market Size, 2019-2035E

Unit: Billion RMB  
At ex-factory price level

Period	CAGR
2019-2024	-4.5%
2024-2029E	1.7%
2029E-2035E	3.5%



Source: Frost & Sullivan analysis

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<b>4.10</b>	Diabetic Foot Infection



# Overview of Hepatic Encephalopathy

- Hepatic encephalopathy (HE), affecting up to 28% of cirrhosis patients and occurring up to 10 years post-diagnosis, manifests with neuropsychiatric symptoms (from mild mental changes to coma) and neuromuscular signs, often in severe liver failure. It stems from reduced hepatic detoxification capacity, allowing bowel-derived toxins to accumulate. Astrocytes, particularly Alzheimer type II cells, play a key role in its pathogenesis.

## Ammonia-Driven Pathway

### Gastrointestinal Ammonia Production:

Dietary protein is broken down by colonic bacteria and mucosal enzymes in the gut, releasing ammonia absorbed into the portal circulation.

### Normal Hepatic Ammonia Metabolism:

In the liver, ammonia is converted to urea via the urea cycle, maintaining normal serum levels.

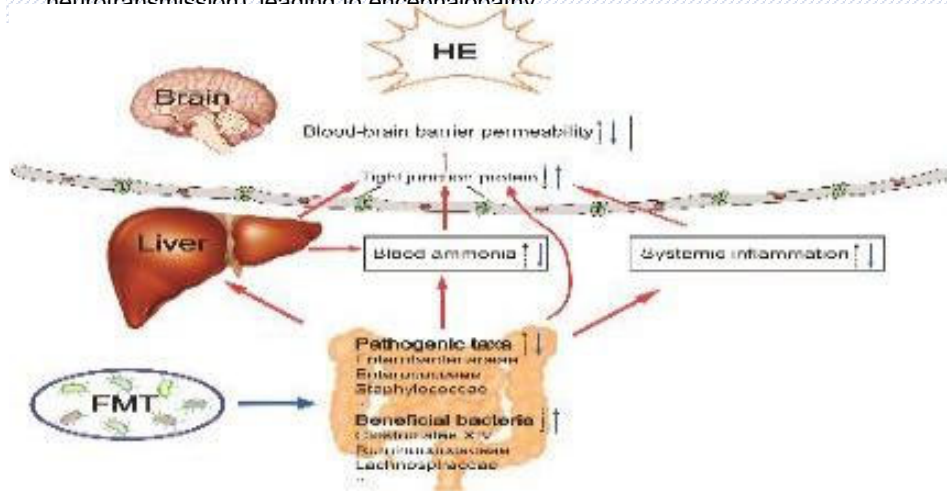
### Impaired Ammonia Clearance:

Liver failure reduces urea cycle efficiency.

Portosystemic shunting allows ammonia to bypass the liver into systemic circulation.

### Hyperammonemia and Neurotoxicity:

Ammonia crosses the blood-brain barrier, disrupting neuronal function (e.g., excitatory neurotransmission), leading to encephalopathy.



Source: Literature Review, Frost & Sullivan Analysis

## Predisposing Factors

### Nitrogen Products

- Gastrointestinal bleeding
- Hyperammonemia
- Constipation
- High - protein diet
- H. pylori infection
- Uremia

### Metabolic Imbalances

- Hypokalemia
- Alkalosis
- Hypoxia
- Hyponatremia
- Hyperkalemia
- Dehydration

### Drugs

- Opiates
- Benzodiazepines
- Diuretics
- Sedatives
- Phenol

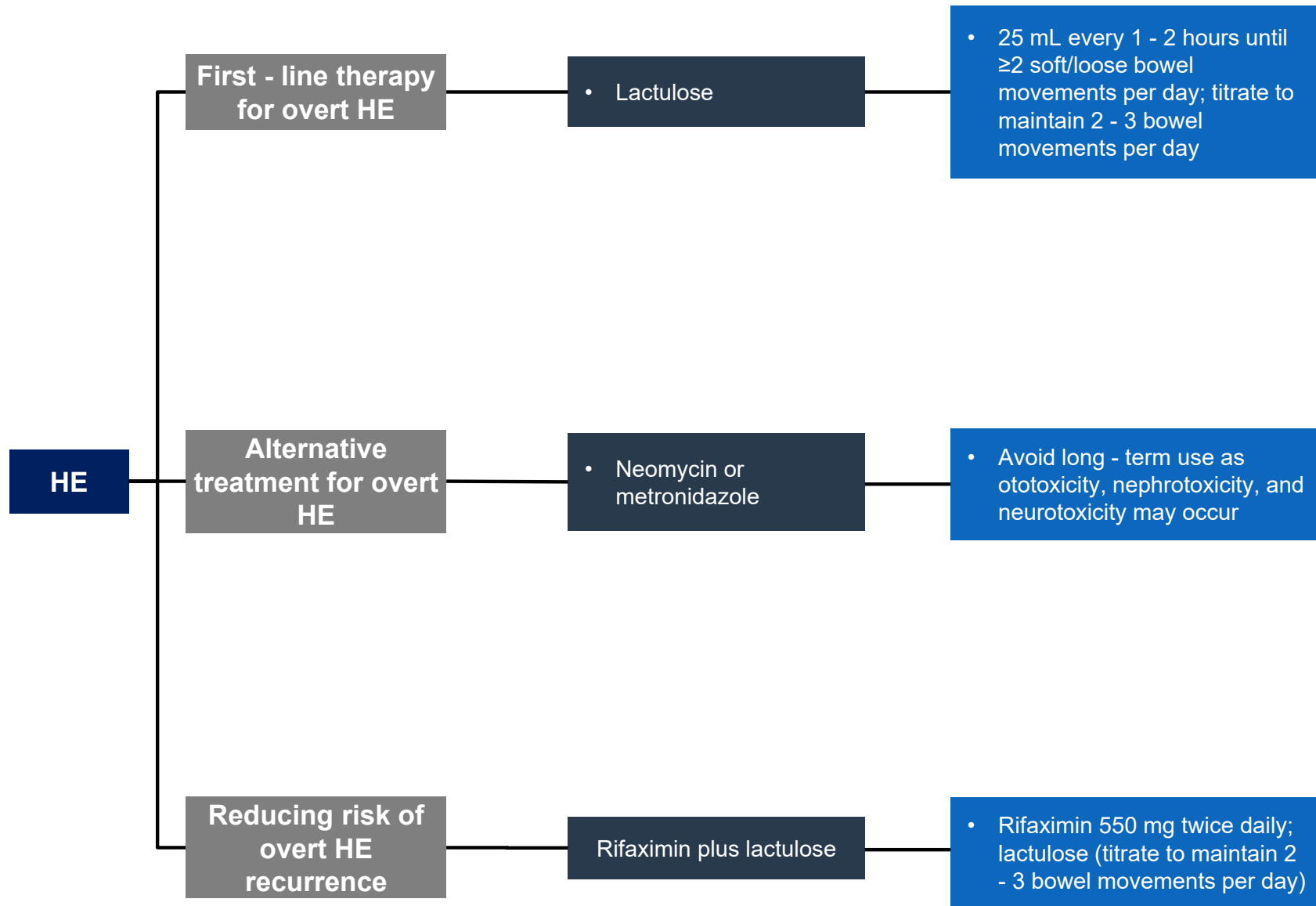
## CLINICAL MANIFESTATIONS

Minor Coordination Issues

Asterixis

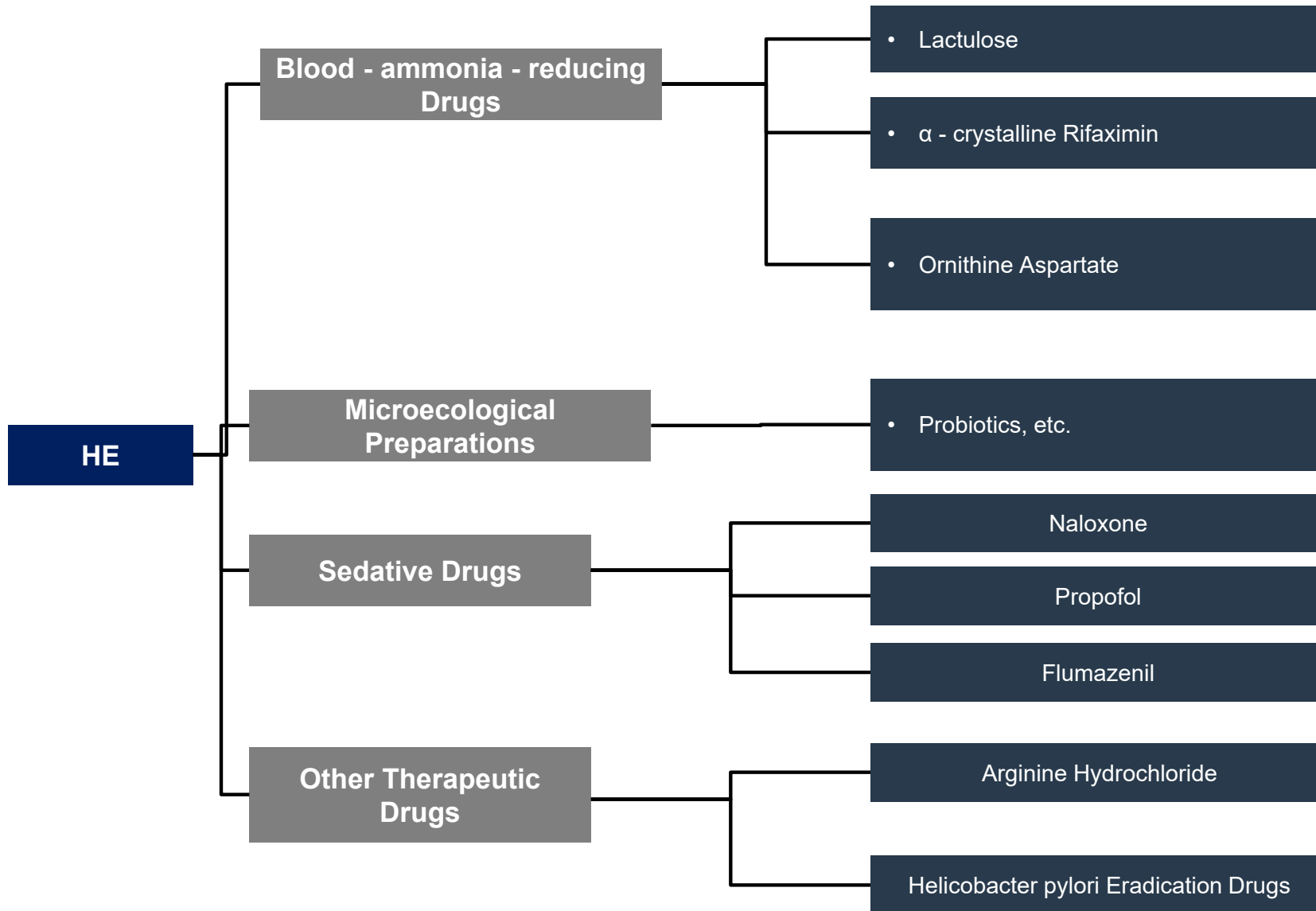


# Treatment Paradigm of Hepatic Encephalopathy in US



Source: EASL, Frost & Sullivan analysis

# Treatment Paradigm of Hepatic Encephalopathy in CHINA



Source: 肝硬化肝性脑病诊疗指南 (2024 年版), Frost & Sullivan analysis

# Unmet needs in the treatment of HE

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## Gap in the treatment of refractory cases

- Existing drugs (such as lactulose and rifaximin) have poor response in some patients with refractory hepatic encephalopathy (HE), especially those with severe cirrhosis and multi-organ dysfunction. There is a lack of innovative therapies with faster onset and stronger targeting, making it difficult to effectively reverse neurocognitive impairment.

## Limited means for recurrence prevention

- For patients with recurrent HE, existing long-term prevention regimens (such as lactulose combined with rifaximin) still have problems such as poor compliance and cumulative side effects. Moreover, there is a lack of precise prevention strategies based on individual patient risk stratification (such as intestinal flora characteristics and ammonia metabolism levels), making it difficult to reduce the recurrence rate.

## Insufficient early diagnosis and monitoring tools

- The diagnosis of HE relies on clinical symptoms and blood ammonia testing, lacking specific biomarkers (such as cerebrospinal fluid neurotransmitters and intestinal flora metabolites) or rapid detection technologies. Primary medical institutions find it difficult to implement early screening and dynamic monitoring, which often leads to delayed treatment.

Source: Frost & Sullivan Analysis

# NMPA Landscape of HE

## China Marketed HE Competitive Landscape<sup>1-4</sup>



Generic Name	Brand Name	Target	Company	Indication	Approval Date
RIFAXIMIN	XIFAXAN	DdRp, NR112	Salix Pharmaceuticals	HE	2002.12

## China HE Drug Pipeline<sup>1-4</sup>



Generic Name	Target	Company	Indication	Drug Type	Clinical Stage	First Posted Date
NONE						

1. Only includes chemical originator, excluding generic drugs
2. Excluding broad-spectrum Antibacterials (e.g., amoxicillin, azithromycin), as they are general-purpose Antibacterials rather than ABSSSI-targeted therapies
3. The nature of the sponsor is enterprise
4. Only includes pipelines active within the past three years

Source : NMPA, CDE (04/05/2026), Frost & Sullivan analysis

# FDA Landscape of HE

## Global Marketed HE Drug Competitive Landscape<sup>1-4</sup>



Generic Name	Brand Name	Target	Company	Indication	Approval Date
RIFAXIMIN	XIFAXAN	DdRp, NR112	Salix Pharmaceuticals	HE	2004-05

## Global HE Drug Pipeline<sup>1-4</sup>



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3. The nature of the sponsor is enterprise
4. Only includes pipelines active within the past three years
5. Source : FDA, Clinicaltrials (04/05/2026), Frost & Sullivan analysis

# Global Marketed HE Drug Competitive Landscape(off-label)

Drug Class	Representative Drug	Launch Year	Major Manufacturer	Clinical Use	Resistance / Sensitivity	Remarks (Off-label Use)	Treatment Course Cost (CN) & Insurance Coverage	Treatment Course Cost (US) & Insurance Coverage
Non-absorbable disaccharide (laxative)	Lactulose	1960s (early clinical use)	Multiple generics worldwide	First-line ammonia reduction; used in overt and minimal HE	No resistance; mainly tolerance issues (bloating, diarrhea)	Also used for mild HE and constipation management	RMB 30–150 per month; generally reimbursed	~20–100 USD
Amino acid / ammonia metabolism modulator	L-Ornithine-L-Aspartate (LOLA)	1980–1990s	Merz Pharmaceuticals (some markets)	Adjunct ammonia-lowering therapy; mild-moderate HE or combined with lactulose	Not applicable	Used for ammonia reduction and supporting nitrogen metabolism	RMB 200–2,000 per course/month; formulation-dependent	Not commercially standardized in the U.S
Nutritional modulator (supportive)	Branched-Chain Amino Acids (BCAA)	1970–1980s	Multiple nutrition supplement companies	Amino acid/nitrogen support, especially in malnourished patients	Not applicable	Primarily adjunct therapy, not first-line	RMB 100–500 per month	~50–150 USD
Probiotics (microbiome support)	Various probiotic preparations	OTC	Multiple brands	Mild HE or constipation; gut microbiome modulation	Non-antibiotic, no resistance	Mainly for long-term supportive care	RMB 50–200 per month	~15–40 USD

NOTE: Rifaximin is currently established as a first-line therapeutic agent for hepatic encephalopathy.

Source: Frost & Sullivan Analysis

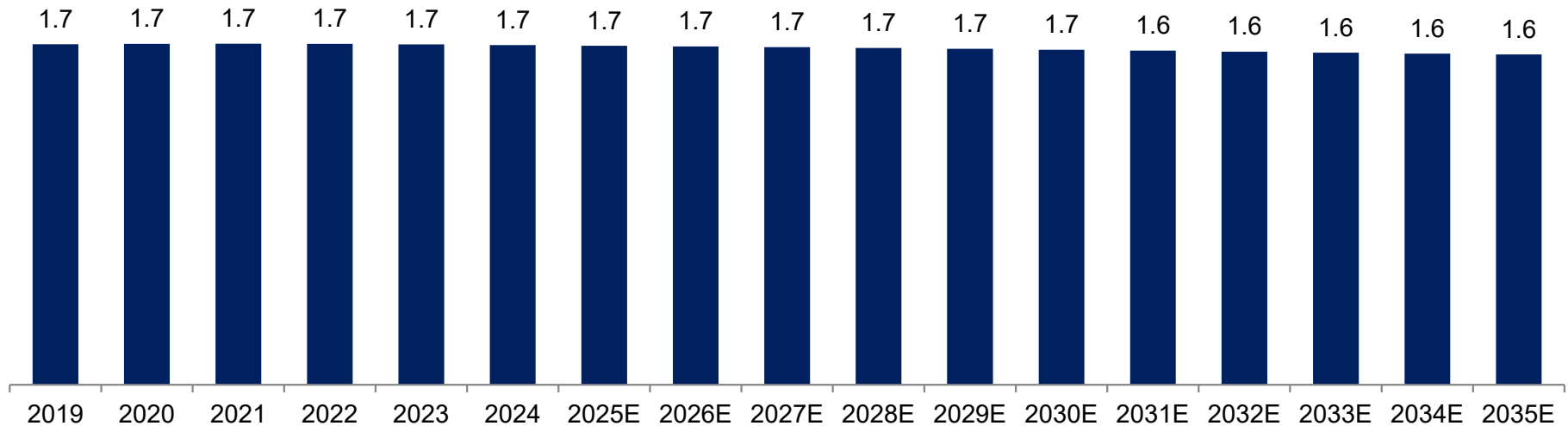
# Incidence of Hepatic Encephalopathy in China, 2019-2035E

- Incidence number of hepatic encephalopathy in China remained nearly unchanged from 2019 to 2024. The number is expected to reduce to 1.6 million in 2035, at a CAGR of -0.3%.
- The expected decline in the prevalence of hepatitis B and hepatitis C will significantly reduce the risk of viral hepatitis progressing to cirrhosis, thereby reducing the triggers of hepatic encephalopathy at the source.

## Incidence of Hepatic Encephalopathy in China, 2019-2035E

Unit: Million

Period	CAGR
2019-2024	0.0%
2024-2030E	-0.2%
2030E-2035E	-0.3%



Source: Literature Review, Chinese Guidelines on the Management of Hepatic Encephalopathy in Cirrhosis (2024), Frost & Sullivan Analysis

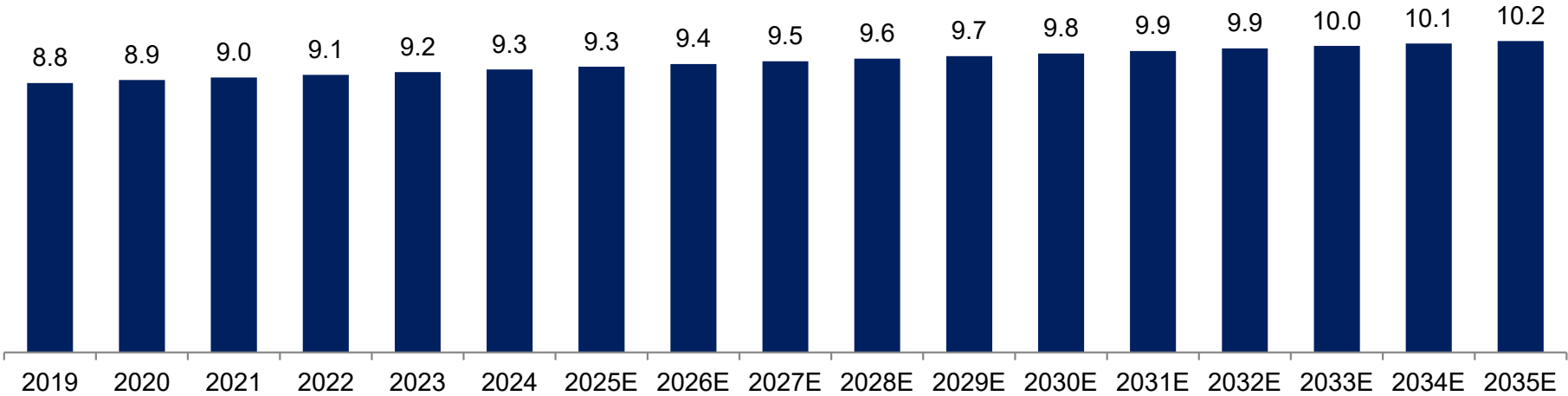
# Global Incidence of Hepatic Encephalopathy, 2019-2035E

• Global Incidence number of hepatic encephalopathy infection increased from 8.8 million to 9.3 million from 2019 to 2024. The number is expected to grow to 9.8 million in 2030 at a CAGR of 0.9% from 2024 to 2030. The number is expected to grow to 10.2 million in 2035, at a CAGR of 0.8%.

## Global Incidence of Hepatic Encephalopathy , 2019-2035E

Unit: Million

Period	CAGR
2019-2024	1.0%
2024-2030E	0.9%
2030E-2035E	0.8%



Source: Literature Review, WHO, Frost & Sullivan Analysis

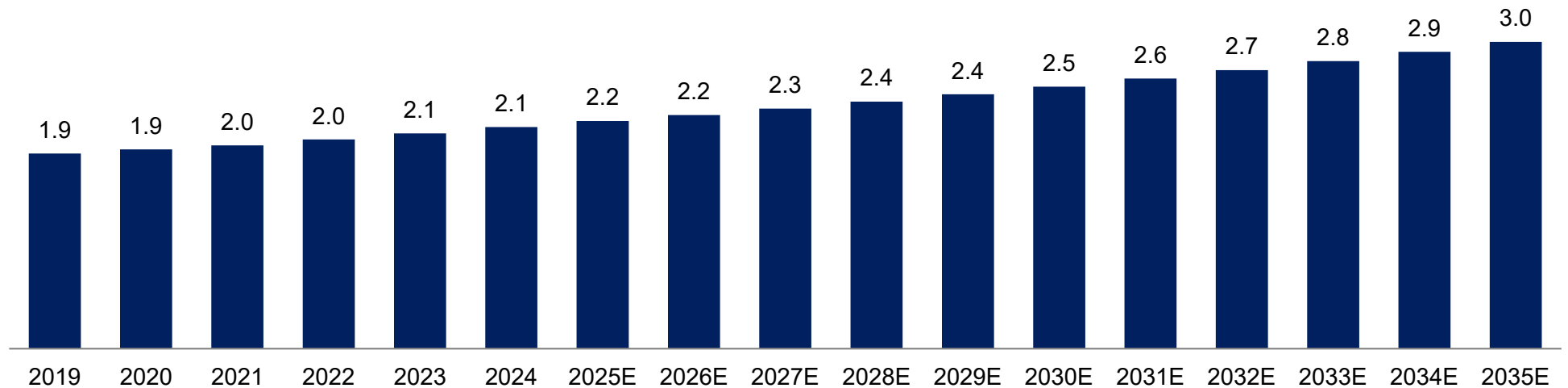
# Global Hepatic Encephalopathy Drugs Market Size

- In 2019, the market size was USD1.9 billion. From 2019 to 2024, it grew at a CAGR of 2.6%. In 2024, the market size reached USD2.1 billion. The market size is expected to reach USD2.4 billion in 2029, with a CAGR of 2.8% from 2024 to 2029. The market will further grow to USD3.0 billion in 2035, with a CAGR of 3.2% from 2029 to 2035..

## Global Hepatic Encephalopathy Drugs Market Size, 2019-2035E

Unit: Billion USD  
At wholesales price level

Period	CAGR
2019-2024	2.6%
2024-2029E	2.8%
2029E-2035E	3.2%



Source: Frost & Sullivan analysis

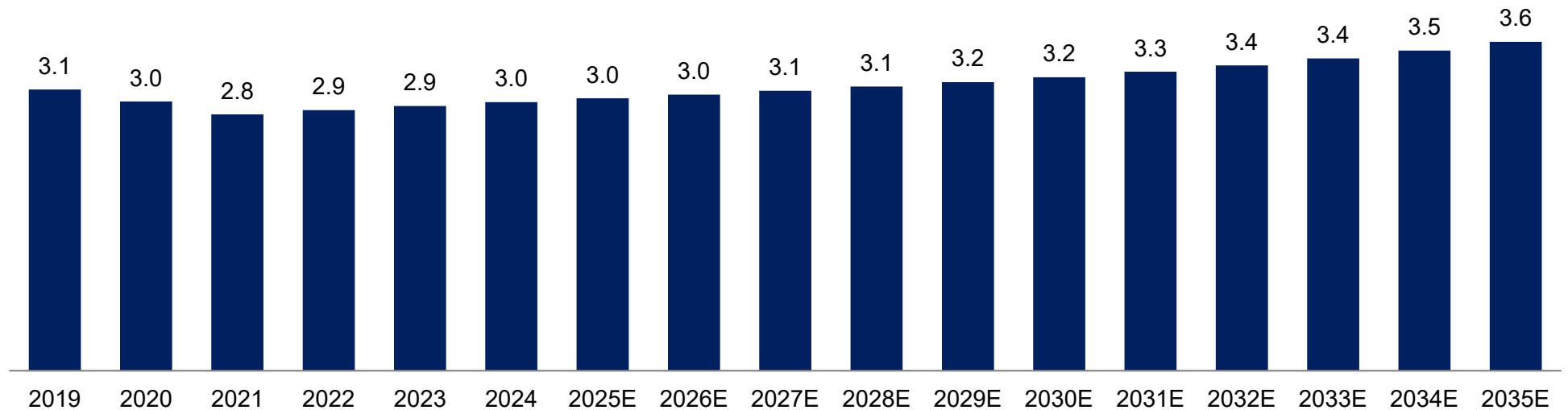
# China Hepatic Encephalopathy Drugs Market Size

- In 2019, the market size was RMB3.1 billion. From 2019 to 2024, it grew at a CAGR of -0.9%. In 2024, the market size reached RMB 3.0 billion. The market size is expected to reach RMB3.2 billion in 2029, with a CAGR of -1.4% from 2024 to 2029. The market will further grow to RMB3.6 billion in 2035, with a CAGR of 2.2% from 2029 to 2035.

## China Hepatic Encephalopathy Drugs Market Size, 2019-2035E

Unit: Billion RMB  
At ex-factory price level

Period	CAGR
2019-2024	-0.9%
2024-2029E	-1.4%
2029E-2035E	2.2%



Source: Frost & Sullivan analysis

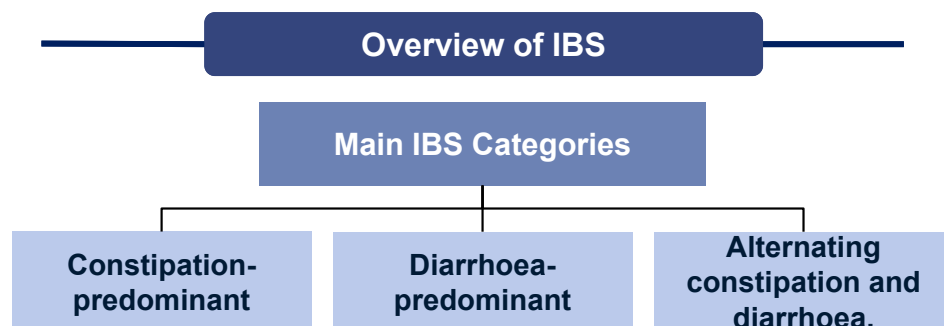
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<b>4.6</b>	Left Ventricular Assist Devices
<b>4.7</b>	ABSSSI
<b>4.8</b>	Hepatic Encephalopathy
<b>4.9</b>	<b>Irritable Bowel Syndrome</b>
<b>4.10</b>	Diabetic Foot Infection

# Overview of Irritable Bowel Syndrome

- Irritable bowel syndrome (IBS) is the most prevalent disorder of brain-gut interaction, affecting 5% to 10% of the general population worldwide. Current symptom criteria restrict diagnosis to recurrent abdominal pain associated with changes in bowel habits, but most patients also report non-painful abdominal discomfort, associated mental illnesses (anxiety and depression), and other visceral and somatic pain-related symptoms.



## key Triggers :

- Infection:** Post-gastroenteritis symptoms persist after pathogen clearance.
- Food Intolerance:** Poorly absorbed carbohydrates (e.g., FODMAPs like fructose, lactose, sorbitol) are common dietary triggers.
- Emotional Stress:** Anxiety or stress affects bowel nerves in susceptible individuals.
- Brain-Gut Dysregulation:** Also called "visceral hypersensitivity," impairing gut-brain signaling.
- Medications:** Antibacterials, antacids, and painkillers may cause constipation or diarrhea.

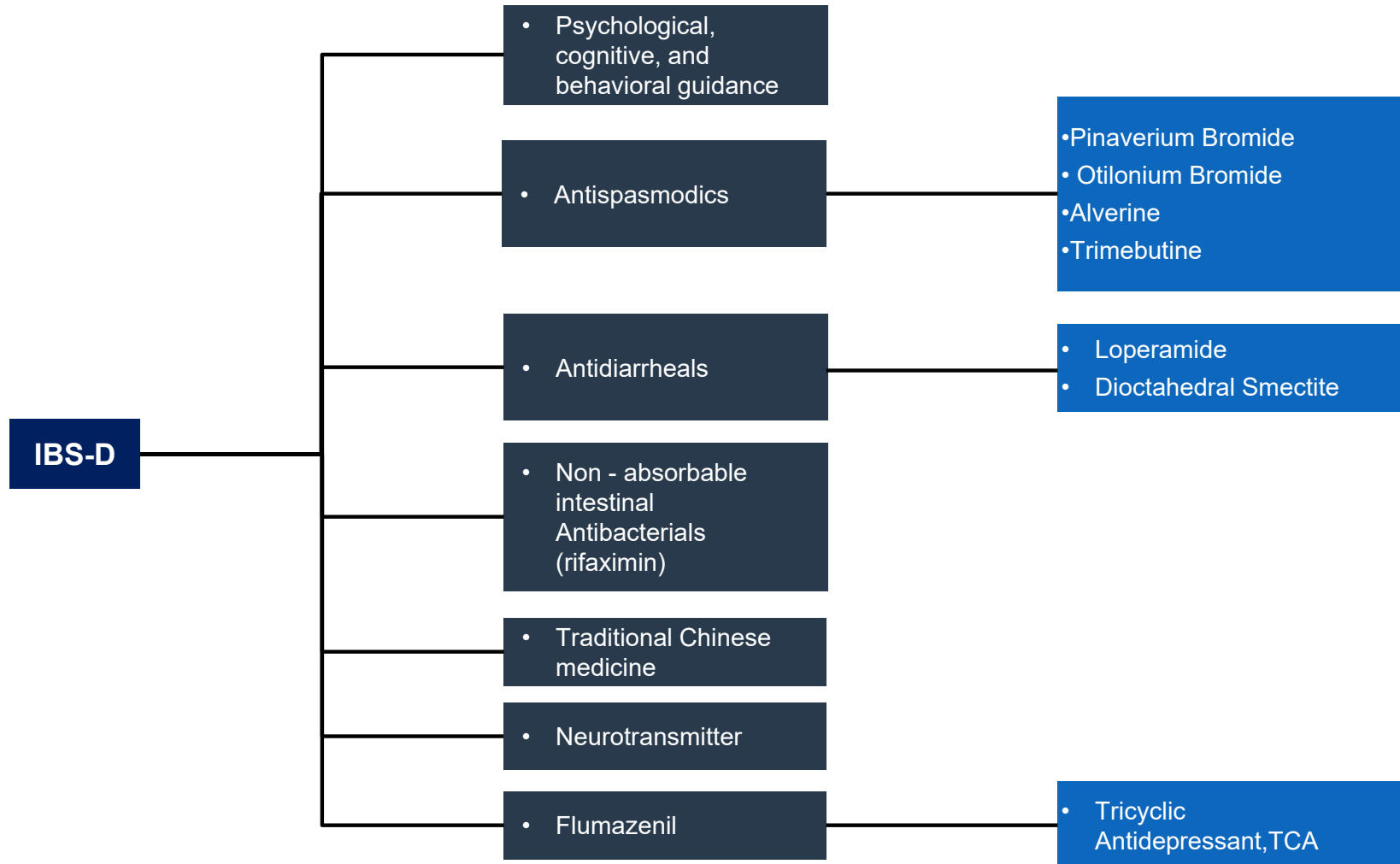
Source: Literature Review, Frost & Sullivan Analysis

## Gut Microbiota in IBS Diarrhea and Pain

### Mechanisms :

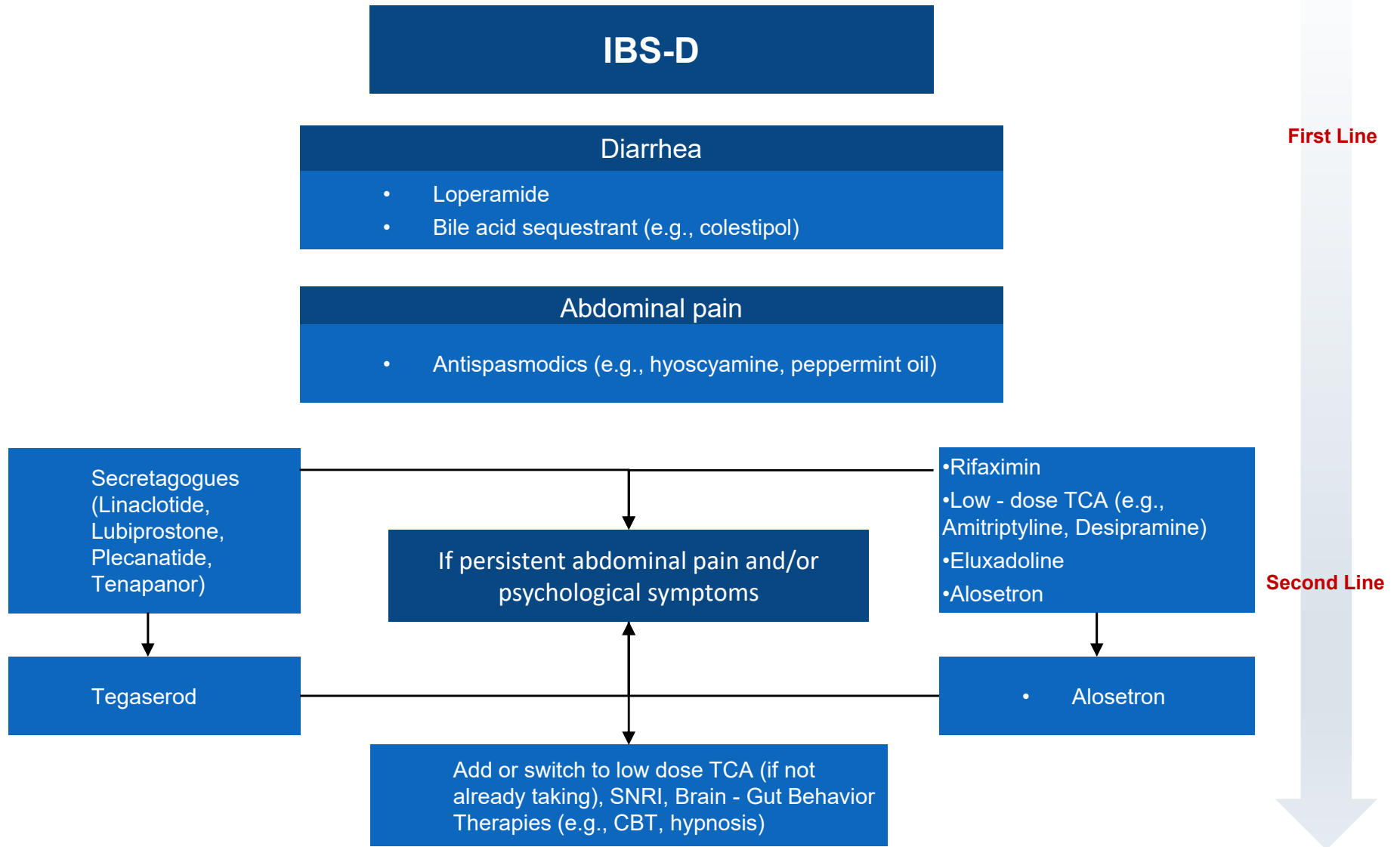
- Fecal supernatant from irritable bowel syndrome with diarrhea patients (IBS-D FS) upregulates serotonin (5-HT) levels and downregulates serotonin reuptake transporter (SERT) expression in the mouse colon.
- This effect is dependent on mast cell regulation via the COX-PGE<sub>2</sub> pathway, as IBS-D FS fails to downregulate SERT expression in mast cell-deficient mice.
- Lipopolysaccharide (LPS) in IBS-D FS, synergizing with trypsin, stimulates mucosal mast cell COX-2 expression, releasing prostaglandin E<sub>2</sub> (PGE<sub>2</sub>), which downregulates SERT and increases 5-HT levels.
- Dysregulation of the intestinal mucosal SERT-5-HT pathway is a key mechanism underlying diarrhea and visceral hypersensitivity induced by IBS-D FS in mice.

# Treatment Paradigm of Irritable Bowel Syndrome in CHINA



Source: 《2020年中国肠易激综合征专家共识意见》, Frost & Sullivan analysis

# Treatment Paradigm of Irritable Bowel Syndrome in US



Source: AGA, Literature Review, Frost & Sullivan Analysis

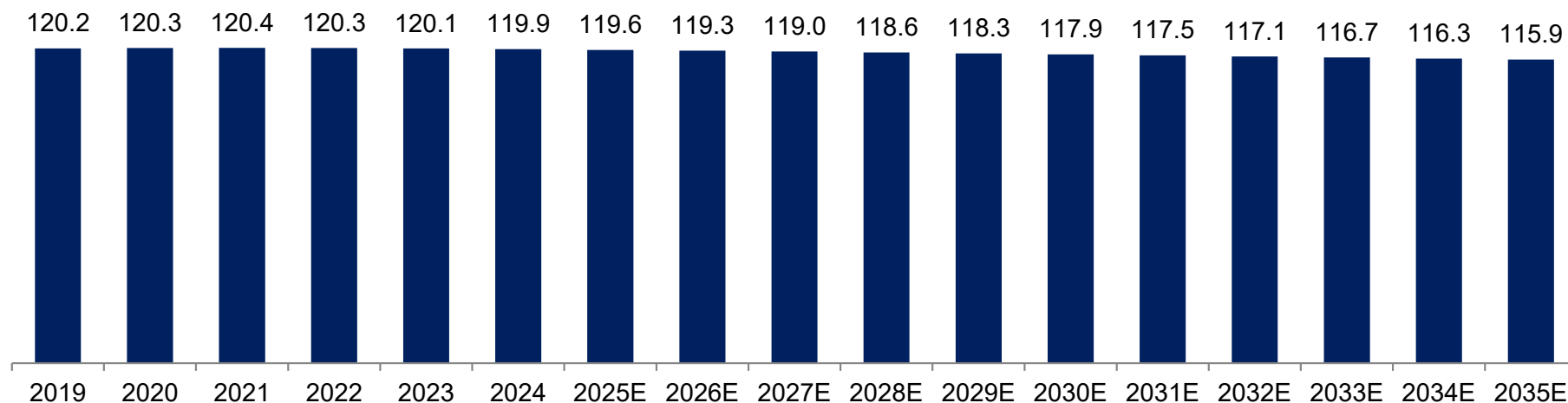
# Incidence of Irritable Bowel Syndrome-diarrhea Predominant in China, 2019-2035E

- Incidence number of irritable bowel syndrome-diarrhea predominant in China fluctuated with a slight change from 2019 to 2024. The number is expected to decrease to 117.9 million in 2030 at a CAGR of  $-0.3\%$  from 2024 to 2030. The number is expected to reduce to 115.9 million in 2035, at a CAGR of  $-0.3\%$ .
- Due to the overall expected decline in China's population, coupled with the current popularization of the Rome IV criteria at the primary level and the stabilization of combined gastrointestinal and psychiatric diagnosis and treatment, the expected number of patients with IBS-D is showing a downward trend.

## Incidence of Irritable Bowel Syndrome-diarrhoea Predominant in China, 2019-2035E

Unit: Million

Period	CAGR
2019-2024	0.0%
2024-2030E	-0.3%
2030E-2035E	-0.3%



Source: 2020 Chinese Expert Consensus on Irritable Bowel Syndrome, Literature Review, Frost & Sullivan Analysis

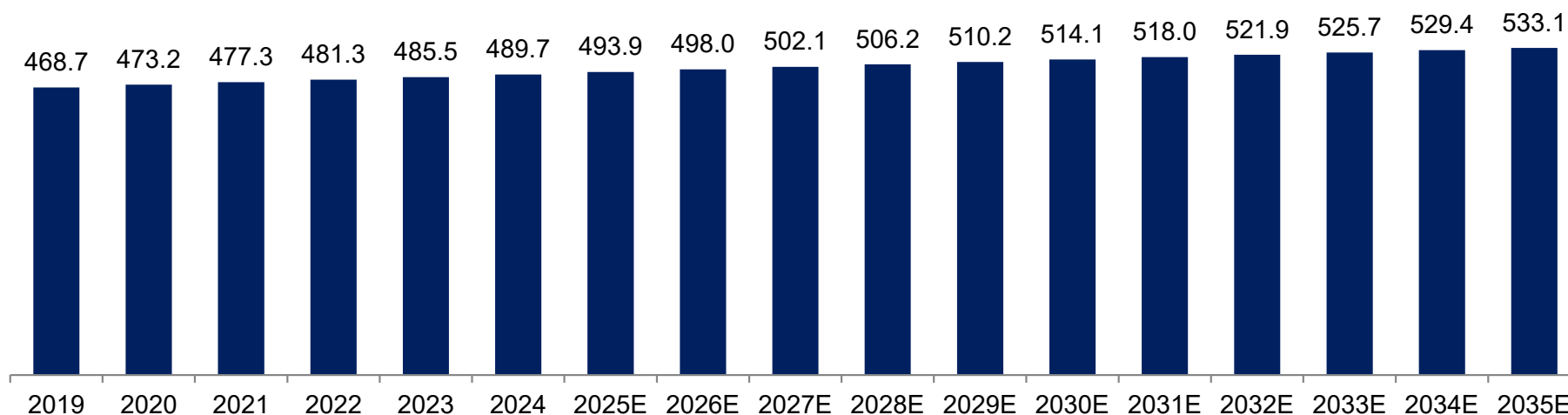
# Global Incidence of Irritable Bowel Syndrome-diarrhea Predominant, 2019-2035E

- From 2019 to 2024, global incidence number of irritable bowel syndrome-diarrhoea predominant increased from 468.7 million to 489.7 million, representing a CAGR of 0.87%. This upward trend is expected to continue at a gradually slowing pace, with a CAGR of 0.8% from 2024 to 2030 and 0.7% from 2030 to 2035.

## Global Incidence of Irritable Bowel Syndrome-diarrhoea Predominant, 2019-2035E

Unit: Million

Period	CAGR
2019-2024	0.9%
2024-2030E	0.8%
2030E-2035E	0.7%



Source: 2020 Chinese Expert Consensus on Irritable Bowel Syndrome, Literature Review, Frost & Sullivan Analysis

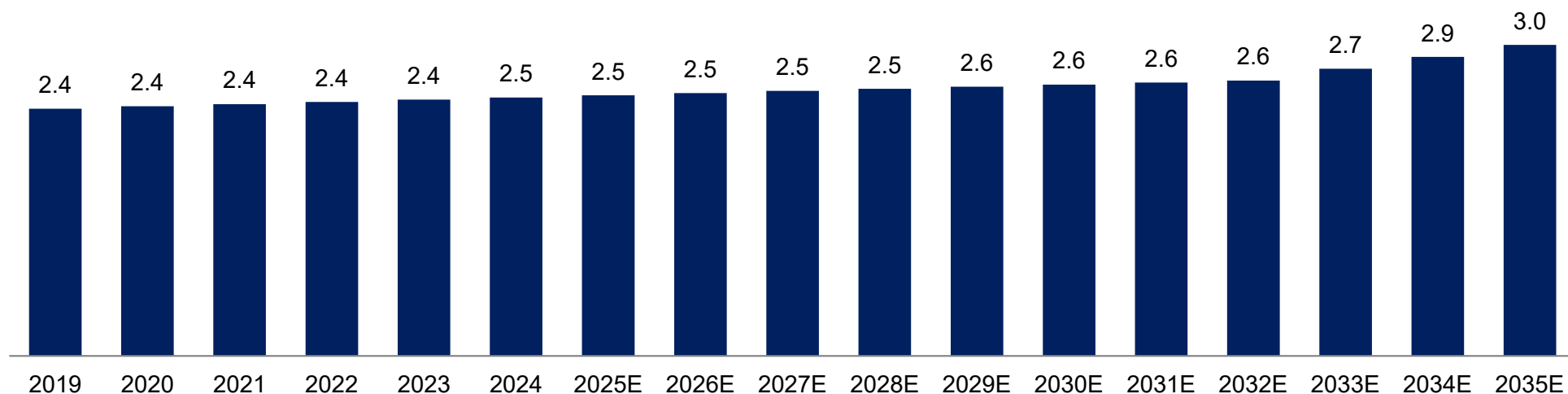
# Global Irritable Bowel Syndrome-diarrhea Predominant Drugs Market Size

- In 2019, the market size was USD2.4 billion. From 2019 to 2024, it grew at a CAGR of 0.9%. In 2024, the market size reached USD2.5 billion. The market size is expected to reach USD2.6 billion in 2029, with a CAGR of 0.8% from 2024 to 2029. The market will further grow to USD3.0 billion in 2035, with a CAGR of 2.4% from 2029 to 2035..

## Global Irritable Bowel Syndrome-diarrhea Predominant Drugs Market Size, 2019-2035E

Unit: Billion USD  
At wholesales price level

Period	CAGR
2019-2024	0.9%
2024-2029E	0.8%
2029E-2035E	2.4%



Source: Frost & Sullivan analysis

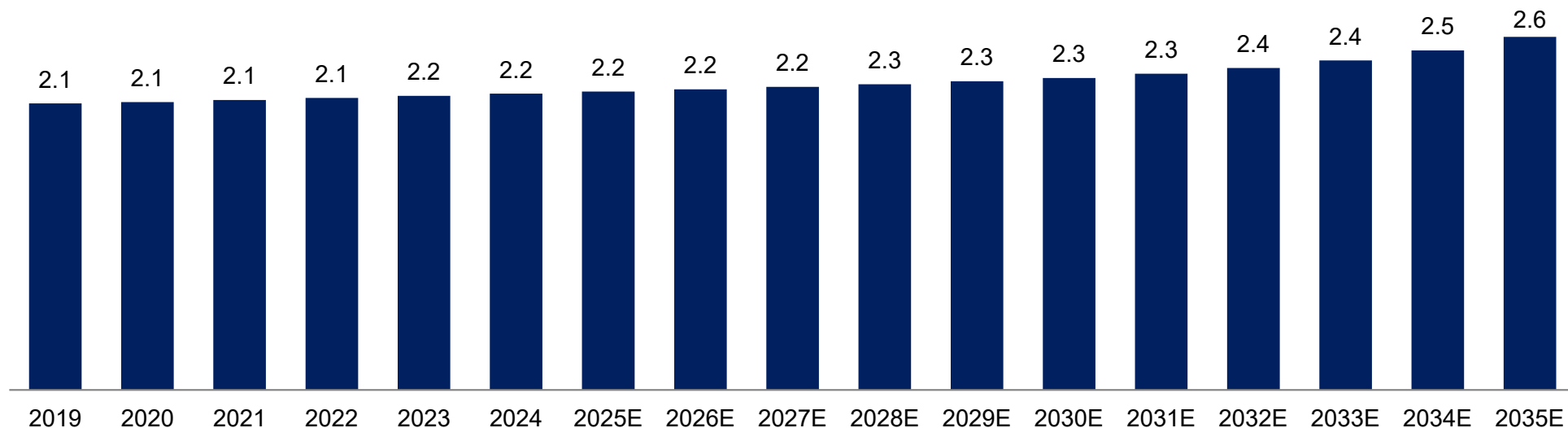
# China Irritable Bowel Syndrome-diarrhea Predominant Drugs Market Size

- In 2019, the market size was RMB2.1 billion. From 2019 to 2024, it grew at a CAGR of 0.7%. In 2024, the market size reached RMB 2.2 billion. The market size is expected to reach RMB2.3 billion in 2029, with a CAGR of 0.8% from 2024 to 2029. The market will further grow to RMB2.6 billion in 2035, with a CAGR of 2.3% from 2029 to 2035.

## China Irritable Bowel Syndrome-diarrhea Predominant Drugs Market Size, 2019-2035E

Unit: Billion RMB  
At ex-factory price level

Period	CAGR
2019-2024	0.7%
2024-2029E	0.8%
2029E-2035E	2.3%



Source: Frost & Sullivan analysis

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<b>4.9</b>	Irritable Bowel Syndrome
<b>4.10</b>	<b>Diabetic Foot Infection</b>

# Overview of Diabetic Foot infection

- The prevalence of diabetic foot in diabetic patients is 4%-10%. It refers to foot infections, ulcers, or tissue destruction caused by diabetes, often accompanied by lower limb neuropathy and/or peripheral arterial disease, including musculoskeletal lesions leading to foot deformities. As one of the chronic complications causing disability and death in diabetic patients, over 85% of those with foot ulcers will undergo amputation. Diabetic foot requires attention due to its high treatment costs and poor prognosis.

## Risk Factors of Diabetic Foot

### Peripheral Neuropathy

- 1
  - Impairing distal blood flow and nerve function → sensory loss → undetected skin injuries → infection.
  - Restricting joint mobility → high pressure in weight-bearing areas → skin damage and inflammation-induced autolysis.

### Peripheral Arterial Disease

- 2

90% of amputations due to diabetic foot ulcers are related to lower limb vascular diseases.

### Infection

- 3

The damages caused by peripheral neuropathy and peripheral arterial disease can easily lead to local wound infections in diabetic patients. Although infection is not the main cause of diabetic foot ulcers, it is a crucial factor that slows down wound healing in such patients

### Symptoms of Diabetic Foot

- Diabetic Neuropathy
- Skin Changes
- Toenail Issues
- Ulcers and Infections
- Other Symptoms

## Mechanism of Diabetic Foot

Wound healing is a complex process involving inflammatory, proliferative, and remodeling phases. Disruption of any phase via cell/factor dysfunction may cause ischemia-reperfusion injury and non-healing wounds.

- **Elevated Oxidative Stress** The high-glucose microenvironment disrupts redox reactions, affecting all stages of wound healing.
- **Chronic Inflammation** Excessive inflammation in diabetic wounds prolongs the transition from the inflammatory to proliferative phase. Proteases degrade the extracellular matrix, sustaining inflammatory cascades and impairing healing.
- **Impaired Angiogenesis** Insufficient or dysfunctional new blood vessel formation is a key factor delaying healing in diabetic foot ulcers, primarily affecting the proliferative phase.

## Complications of Diabetic Foot

- Sepsis
- Osteomyelitis
- Gangrene
- Necrosis
- Amputation
- Foot Deformities

Source: Frost & Sullivan Analysis

# Treatment Paradigm of Diabetic Foot infection in China

## Diabetic Foot

### No infection or mild superficial tissue infection

- No Antibacterials are needed, or empirically oral Antibacterials against Gram-positive cocci (GPC) are administered for 7-10 days, and the changes in the wound surface are observed.

### Moderate or severe infections, or deep tissue infections

#### Initial Empirical Antibacterials Selection

##### •Acute/non-Antibacterials-pretreated wounds

- **Protocol:** Narrow-spectrum Antibacterials against Gram-positive cocci (GPC).

##### •Chronic/Antibacterials-pretreated wounds

- **Protocol:** Intravenous broad-spectrum Antibacterials covering GNB (especially drug-resistant *Pseudomonas aeruginosa*) and anaerobes. Antifungal therapy may be added for some cases (e.g., third-generation cephalosporins combined with anti-anaerobic and antifungal agents for ischemic infected feet).

## Antibacterials Regimen Selection

Chinese DF etiology-based recommended regimens (based on resistance data):

- GPB infections:** Linezolid, Vancomycin, Teicoplanin.
- GNB infections:** Piperacillin/Tazobactam, Amikacin, Meropenem, Imipenem.

Source: 《中国糖尿病足诊治临床路径(2023版)》; Literature Review, Frost & Sullivan Analysis

# Treatment Paradigm of Diabetic Foot in US

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Source: 《中国糖尿病足诊治临床路径(2023版)》; Literature Review, Frost & Sullivan Analysis

# NMPA Landscape of Diabetic Foot Infection

## China Marketed Diabetic Foot Infection Drug Competitive Landscape<sup>1-4</sup>



None

## China Diabetic Foot Infection Drug Pipeline<sup>1-4</sup>



Generic Name	Target/MOA	Company	Indication	Drug Type	Clinical Stage	First Posted Date
MRX-4	50S Ribosomal Subunit	MicuRx Pharmaceuticals	Diabetic Foot Infection	Small molecule drugs	Phase 3	2022.07
TP-102	Bacteriophage cocktail	Technophage	Diabetic Foot Infection	Biologics	Phase 2	2023.07
TNP-2092	RNAP; Bacterial DNA gyrase; DNA topoisomerase	TenNor Therapeutics	Diabetic Foot Infection	Small molecule drugs	IND received	2023.12

1. Only includes originator, excluding generic drugs
2. Excluding broad-spectrum Antibacterials (e.g., amoxicillin, azithromycin), as they are general-purpose Antibacterials rather than DFI-targeted therapies
3. The nature of the sponsor is enterprise
4. Only includes pipelines active within the past three years

Source : NMPA (as of 04/05/2026), Frost & Sullivan analysis

# FDA Landscape of Diabetic Foot Infection

## Global Marketed Diabetic Foot Infection Drug Competitive Landscape<sup>1-4</sup>



None

## Global Diabetic Foot Infection Drug Pipeline<sup>1-4</sup>



Generic Name	Target	Company	Indication	Clinical Stage	First Posted Date
MRX-4	50S Ribosomal Subunit	MicuRx Pharmaceuticals	Diabetic Foot Infection	Phase 3	2022-07-25

1. Only includes chemical originator, excluding generic drugs
2. Excluding broad-spectrum Antibacterials (e.g., amoxicillin, azithromycin), as they are general-purpose Antibacterials rather than DFI-targeted therapies
3. The nature of the sponsor is enterprise
4. Only includes pipelines active within the past three years

Source : ClinicalTrials (as of 04/05/2026), Frost & Sullivan analysis

# Global Marketed Diabetic Foot Infection Drug Competitive Landscape(off label)

Drug Class	Representative Drug	First Marketed Year	Major Manufacturer	Resistance / Susceptibility	Treatment Course Treatment Course Cost & Insurance Coverage
$\beta$ -lactam/ $\beta$ -lactamase inhibitor	Piperacillin/tazobactam	1993	Wyeth / multiple generics	High susceptibility for Enterobacteriaceae; resistance >50% in some regions	200–600 USD; usually reimbursed
Carbapenems	Ertapenem	2001	Merck	High susceptibility for Enterobacteriaceae; ineffective against Pseudomonas	400–1,000 USD; reimbursed for inpatient use
Fluoroquinolones	Levofloxacin	1993	Multiple manufacturers	Resistance 20–30% in some regions	100–400 USD; widely reimbursed
Fluoroquinolones	Moxifloxacin	1990s	Multiple manufacturers	Rising resistance trends	200–500 USD; insurance coverage common
Anti-MRSA / Gram-positive coverage	Vancomycin	1958	Eli Lilly / multiple generics	Most S. aureus / Enterococcus highly susceptible; occasional intermediate resistance	300–800 USD; widely reimbursed
Anti-MRSA / Gram-positive coverage	Linezolid	2000	Pharmacia & Upjohn	Global resistance <0.2%	1,500–3,000 USD; usually reimbursed, IV/PO dependent

*NOTE: DFI Off-Label Use: Indicates that the drug is not officially approved by FDA/NMPA/EMA specifically for diabetic foot infections, but is widely used in clinical practice.*

*Source : Literature Review, Frost & Sullivan analysis*

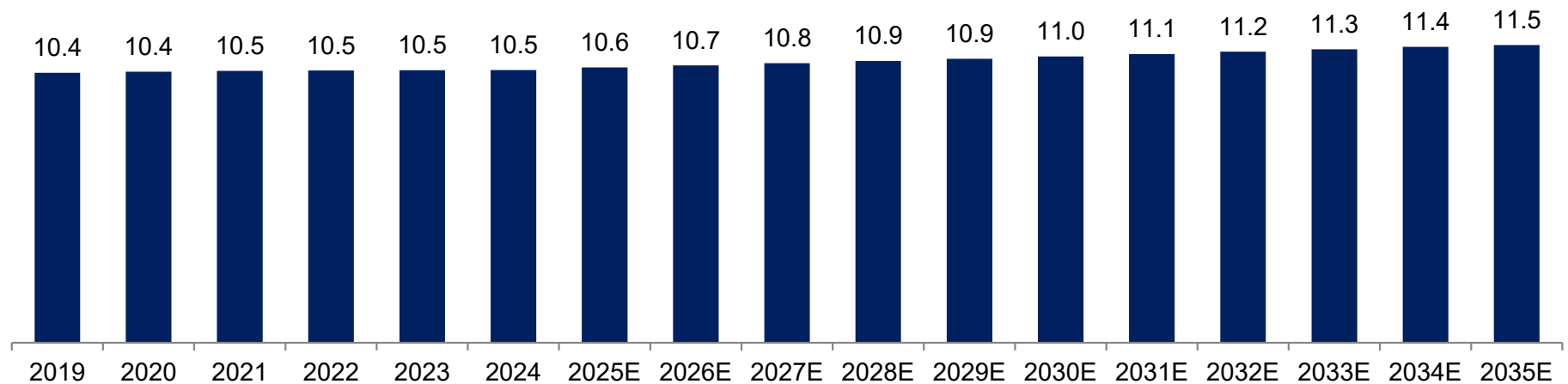
# Incidence of Diabetic Foot Infection in China, 2019-2035E

- Incidence number of diabetic foot infection in China increased slightly from 10.4 million in 2019 to 10.5 million in 2024. The number is expected to increase to 11.0 million in 2030 at a CAGR of 0.8% from 2024 to 2030. The number is expected to grow to 11.5 million in 2035, at a CAGR of 0.8%.

## Incidence of Diabetic Foot Infection in China, 2019-2035E

Unit: Million

Period	CAGR
2019-2024	0.2%
2024-2030E	0.8%
2030E-2035E	0.8%



Source: Literature Review, Frost & Sullivan Analysis

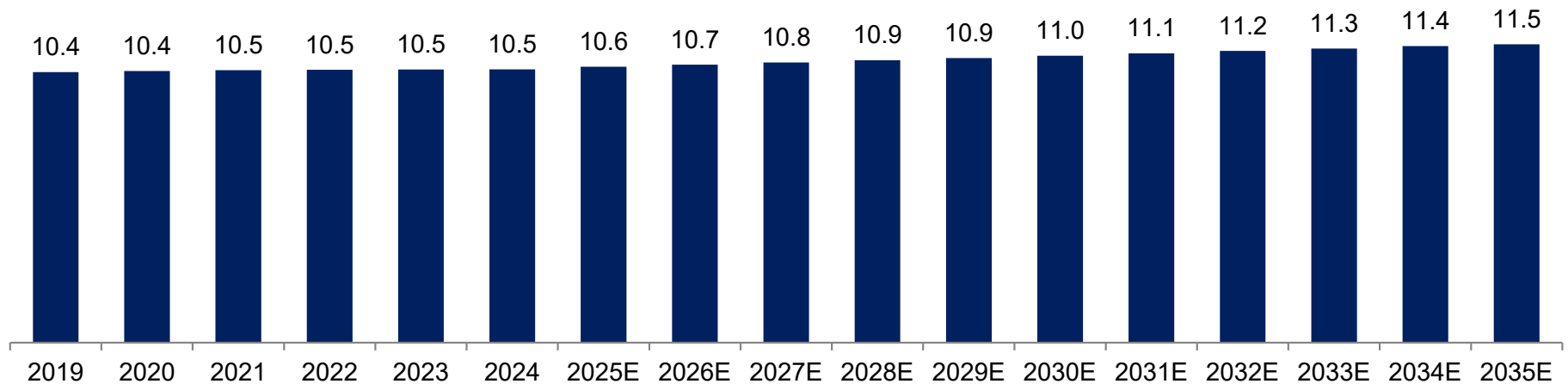
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Unit: Million

Period	CAGR
2019-2024	0.2%
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Source: Literature Review, Frost & Sullivan Analysis

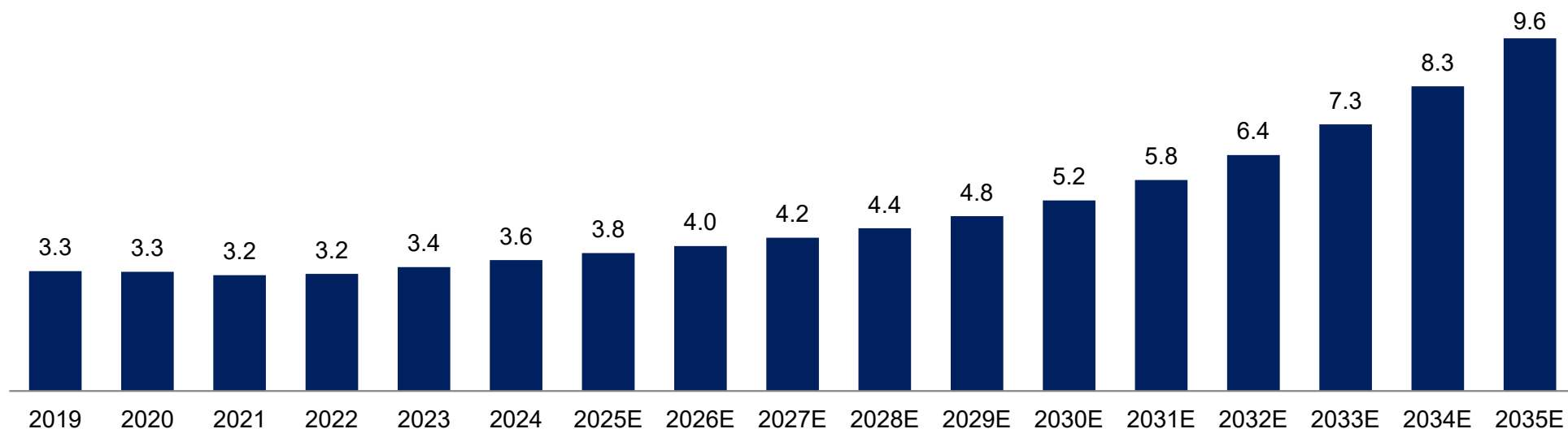
# China Diabetic Foot Infection Drugs Market Size

- In 2019, the market size was RMB3.3 billion. From 2019 to 2024, it grew at a CAGR of 1.8%. In 2024, the market size reached RMB 3.6 billion. The market size is expected to reach RMB4.8 billion in 2029, with a CAGR of 6.0% from 2024 to 2029. The market will further grow to RMB9.6 billion in 2035, with a CAGR of 12.4% from 2029 to 2035.

**China Diabetic Foot Infection Drugs Market Size, 2019-2035E**

Unit: Billion RMB  
At wholesales price level

Period	CAGR
2019-2024	1.8%
2024-2029E	6.0%
2029E-2035E	12.4%



Source: Frost & Sullivan analysis

# Drug Cost Comparison for Indications

Indication	Treatment / Drug	Route of Administration	Typical Regimen	Treatment course cost (CN, post-NRDL / reimbursed basis)	Treatment course cost (US)
<b>H. pylori infection</b>	Bismuth-based Quadruple Therapy (BQT)	Oral	10–14 days	RMB 750–1,000 / course; generally reimbursed	US\$ 700–1000 / course; brand-dependent
ABSSSI	Dalbavancin	Intravenous	1–2 doses	Not approved in China	US\$ 3,000–5,000 / course
	NUZYRA® (omadacycline)	Oral / Intravenous	7–14 days	~RMB 4,800–7,200 / course	US\$ 4,300–8,000 / course
	Contezolid	Oral	10–14 days	~RMB 2,700–5,400 / course	N/A — no standard U.S. commercial price identified
<b>Prosthetic Joint Infection (PJI)</b>	Vancomycin	Intravenous	4–6 weeks	RMB 6,000–25,000 per 4–6 weeks	US\$ 1,000–2,000 / course
	Linezolid	Oral / Intravenous	4–6 weeks	RMB 1,800–2,600 per month	300–1,500 USD per month
	Daptomycin	Intravenous	4–6 weeks	RMB 4,000–6,000 / course; reimbursement varies by indication	US\$ 13,400–20,100 / course

Note: Examples provided are for illustrative purposes only, showcasing MRCT or real-world study data.

# Drug Cost Comparison for Indications

Drug / Regimen	Primary Target(s)	Mechanism of Action	Resistance Avoidance Potential
TNP-2198 (Rifasutenizol)	RNA polymerase + nitroreductase-activated DNA damage	Dual-target synergistic effect (RNA inhibition + DNA damage)	High (requires multiple mutations for resistance)
TNP-2092 / Rifaquizinone (oral)	RNA polymerase + DNA gyrase + Topoisomerase IV	Triple-target synergistic inhibition	Very high (multi-target cumulative suppression)
Bismuth Quadruple Therapy (BQT)	Multiple antibiotics cumulative effect	Combination therapy	Limited (susceptible to resistance development)
MRX-4 / Conteozolid	Peptidyl transferase (protein synthesis)	Single-target inhibition	Moderate
Traditional antibiotics (e.g., Clarithromycin)	Single bacterial target	Single-target inhibition	Low

Note: F&S analysis

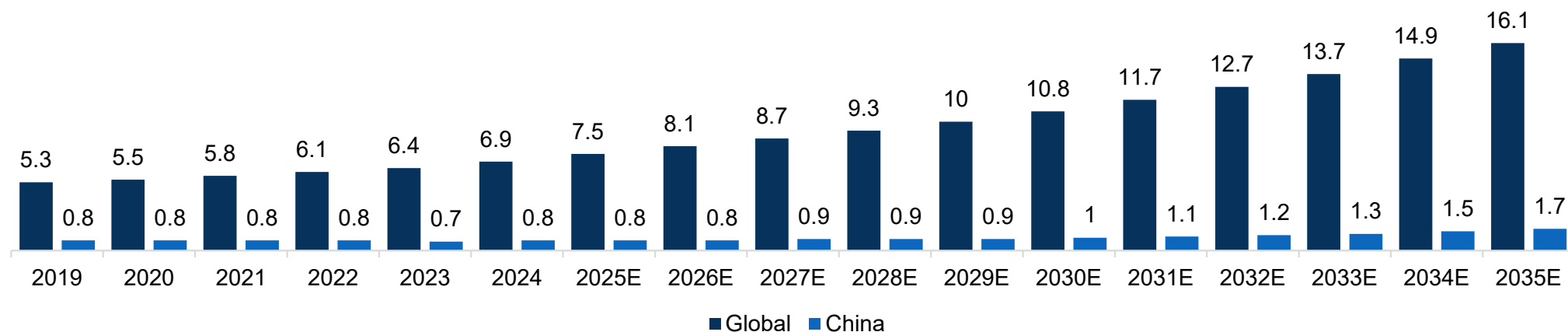
# Global Helicobacter Pylori Infection Drugs Market Size

- In 2019, the market size was USD5.3 billion. From 2019 to 2024, it grew at a CAGR of 6.0%. In 2024, the market size reached USD6.9 billion. The market size is expected to reach USD10.0 billion in 2029, with a CAGR of 7.6% from 2024 to 2029. The market will further grow to USD16.1 billion in 2035, with a CAGR of 9.6% from 2029 to 2035.
- In 2019, the market size was USD0.8 billion in China. From 2019 to 2024, it grew at a CAGR of 0.0%. In 2024, the market size reached USD0.8 billion. The market size is expected to reach USD0.9 billion in 2029, with a CAGR of 2.4% from 2024 to 2029. The market will further grow to USD1.7 billion in 2035, with a CAGR of 11.2% from 2029 to 2035.

## Global Helicobacter Pylori Infection Drugs Market Size, 2019-2035E

Unit: Billion USD  
At wholesales price level

Period	CAGR	
	Global	China
2019-2024	6.0%	0.0%
2024-2029E	7.6%	2.4%
2029E-2035E	9.6%	11.2%



Source: Frost & Sullivan analysis

# Appendix

- Approximately 44.2% of the patient population is treatment-naïve, multidrug-resistant population
- Between 2019 and 2024, the global incidence of ABSSSI increased modestly from 43.1 million to
- Among *S. aureus* isolates, one of the most common causative pathogens in ABSSSI, Approximately 28.4% are MRSA, and 26.9% of these MRSA strains are resistant to levofloxacin
- Oxazolidinones are approved for the treatment of ABSSSI but have not been incorporated into clinical guidelines
- In 2024, Contezolid recorded sales of RMB130.3 million in China, Representing approximately 5.0% of the ABSSSI drug market
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Source: Frost & Sullivan analysis