The information and statistics set out in this section and other sections of this document were extracted from different official government publications, available sources from public, market research and other sources from independent suppliers, and from the independent industry report prepared by China Insights Consultancy. We engaged China Insights Consultancy to prepare the CIC Report, an independent industry report, in connection with the [**REDACTED**]. *The information from official government sources has not been independently verified by us, the Sole Sponsor, the* [**REDACTED**]*, the* [**REDACTED**]*, the* [**REDACTED**]*, the* [**REDACTED**]*, the* [**REDACTED**]*, the* [**REDACTED**]*, any of their respective directors and advisors, or any other person or parties involved in the* [**REDACTED**]*, and no representation is given as to its accuracy. Accordingly, the information from official government sources contained herein may not be accurate and should not be unduly relied upon.*

SOURCE OF INFORMATION

In connection with the [**REDACTED**], we have commissioned China Insights Consultancy, or CIC, an independent market research and consulting company, to conduct an analysis of, and prepare an industry report on, the global and Chinese vaccine market, or the CIC Report. The fee for the preparation of the CIC Report is RMB0.7 million. We believe this fee is in line with market rates for reports of this nature. The payment of such amount was not contingent upon our successful [**REDACTED**] or on the findings of the CIC Report.

CIC conducted both primary research, which involved interviewing key industry experts and leading industry participants, and secondary research, which involved analyzing data from various publicly available sources, such as the National Bureau of Statistics, National Medical Products Administration, Food and Drug Association, National Health Commission of the People's Republic of China, the International Monetary Fund, World Health Organization, and others.

The market projections in the commissioned report are based on the following key assumptions: (i) the overall social, economic and political environment in China is expected to remain stable during the forecast period; (ii) China's economic and industrial development is likely to maintain a steady growth trend over the next decade; (iii) related key industry drivers are likely to continue driving the growth of the market during the forecast period, such as the increasing cancer incidences mainly owing to aging population, strengthened public awareness of cancer care, enhanced patient affordability, enriched drugs and therapies, etc.; and (iv) there is no extreme force majeure or industry regulation in which the market may be affected dramatically or fundamentally.

Our Directors confirm, to the best of their knowledge, and after making reasonable inquiries, that there have been no adverse changes in the industry since the date of the CIC Report and up to the Latest Practicable Date which may qualify, contradict or have an impact on the information set out in this section.

OVERVIEW OF VACCINES

A vaccine is a biological agent that enables the body to generate acquired antibodies and allows the immune system to memorize the pathogen. A vaccine usually contains one or more substances like the pathogenic microbe, and is typically made from artificially attenuated or inactivated pathogens, or the toxins and surface proteins of the microbe. When a vaccinated person is exposed to the same microbe again, the immune system will quickly identify the pathogen through its antigens and resist the infection through antibodies.

Based on technical design, vaccines can be broadly classified into live-attenuated, inactivated, toxoid, subunit/recombinant/polysaccharide/conjugate, recombinant vector, and mRNA/DNA vaccines. Live-attenuated vaccines use weakened pathogens to induce strong, long-lasting immunity; inactivated vaccines use killed pathogens and often require multiple doses; toxoid vaccines use detoxified bacterial toxins; subunit and related vaccines use selected antigenic components with improved safety and stability; recombinant vector vaccines deliver antigen genes through another microbe; and mRNA/DNA vaccines introduce genetic instructions that enable host cells to produce antigens and trigger immune responses.

OVERVIEW OF THE GLOBAL VACCINE MARKET

Global Vaccine Market

The global vaccine market plays a crucial role in public health by preventing infectious diseases and reducing healthcare burdens. The value of vaccines extends beyond individual protection to community-wide benefits and economic productivity. The size of the global vaccine market in terms of sales revenue, excluding COVID-19 vaccines, increased from US$52.9 billion in 2019 to US$73.3 billion in 2025, at a CAGR of 5.6%. Driven by the emergence of innovative vaccines, increasing vaccination awareness, and market growth in developing countries, the global vaccine market is expected to reach US$139.8 billion in 2035, representing a CAGR of 6.7% from 2025 to 2035.

China is one of the largest and fastest-growing vaccine markets globally, supported by favorable government policies, technological innovation, and rising public health awareness. The size of the vaccine market in China in terms of sales revenue, excluding COVID-19 vaccines, grew from RMB42.5 billion in 2019 to RMB101.5 billion in 2025, representing a CAGR of 15.6%, and is expected to further grow to RMB354.7 billion in 2035, representing a CAGR of 13.3% from 2025 to 2035.

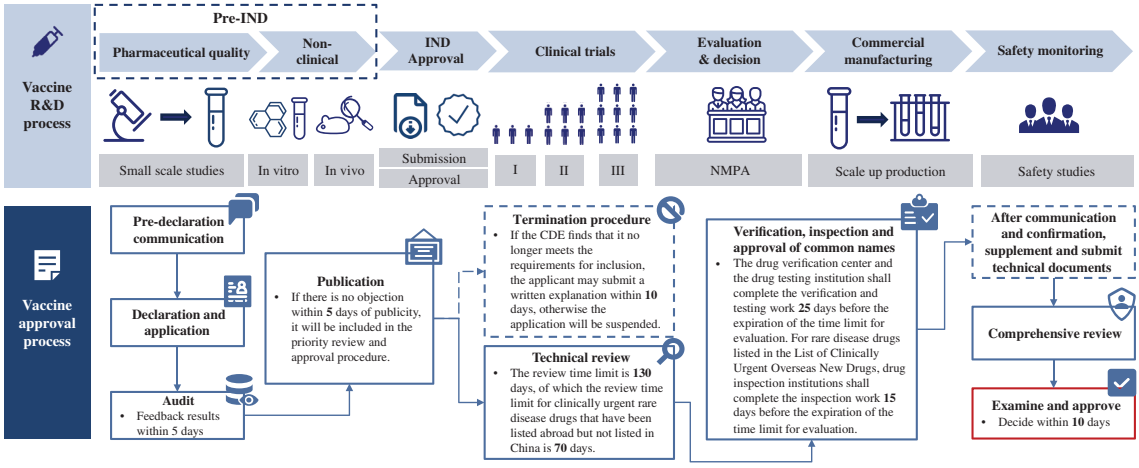
Vaccine Industry Chain and Regulatory Framework in China

Vaccine Industry Chain

The vaccine industry chain in China comprises (i) upstream raw material suppliers, which provide raw materials and laboratory equipment used for R&D and industrial production; (ii) midstream vaccine manufacturers, which are responsible for R&D, conducting clinical trials, often with contract research organizations, or CROs, and the industrialized production of vaccines; and (iii) downstream distribution and vaccination providers, which distribute vaccines from manufacturers to various levels of CDCs and ultimately to vaccination points, such as community health service centers, where vaccines are administered to the public.

Vaccine R&D and Regulatory Approval Process

The development and approval of a vaccine in China is a lengthy and highly regulated process overseen by the NMPA. The following chart set forth the vaccine R&D process and regulatory process for vaccine approval in China.



Source: NMPA, CIC

As China enacted comprehensive regulations governing the vaccine industry, covering the entire value chain from research and development to inoculation, only a limited number of vaccines were approved by the NMPA each year in the past few years.

Price of Main Vaccine Raw Materials in China

The price trends of the main vaccine raw materials in China are as follows (i) glycine, the current price of glycine (industrial/food grade, ≥99%) in China is around RMB9,800–15,000 per metric ton on an ex-works basis. Price levels have generally stabilized within a lower band. Key price drivers include upstream monochloroacetic acid (MCAA) and ammonia costs, energy and utilities, and environmental compliance expenses. Pricing for glycine is typically stable. Price fluctuations, when they occur, are primarily attributable to factors such as inventory levels, feedstock and energy costs, and typically involve moderate quarter-to-quarter changes rather than significant volatility. The availability of glycine is generally stable, as China has substantial and expanding production capacity and is a major global exporter of the material; (ii) recombinant human serum albumin (rHSA), publicly listed retail prices of rHSA (small-pack, RUO) currently span roughly US$60–550 per gram, depending on supplier and grade. Overall pricing is driven by production platform (yeast/rice/insect), purity and endotoxin specifications, RUO vs. GMP/DMF documentation, formulation, pack size and distribution margins. Pricing for rHSA is typically stable. The availability of rHSA is also generally stable; for materials requiring higher levels of regulatory compliance, pricing factors are more closely related to supplier qualification processes and associated lead times, rather than significant spot-price fluctuations; and (iii) 2-Phenoxyethanol, bulk spot prices of 2-Phenoxyethanol in Asia are typically around US$2–3.5/kg, while retail/offer quotes from Chinese suppliers commonly show US$2–5/kg on an EXW/FOB basis. The pricing of 2-Phenoxyethanol has eased and stabilized in recent years, with no indication of extreme volatility. 2-Phenoxyethanol is generally readily available, supported by a broad supplier base and standardized grades produced by major manufacturers.

Market Drivers and Future Trends of Vaccine Market in China

The primary drivers and future trends of the vaccine market in China include:

- ***Innovative vaccine technologies.*** Vaccine technology is shifting from traditional live-attenuated and inactivated vaccines toward subunit, conjugate, multivalent and combination vaccines, driving product upgrades and broader disease coverage. At

present, multivalent conjugate vaccines and combination vaccines are the main technological development trends. Chinese vaccine makers are developing core R&D strategies to introduce new vaccine technologies and update traditional vaccines.

- ***A growing number of breakthrough innovative vaccines.*** Several new breakthrough innovative products have been approved by the NMPA, including EV71 vaccines, HPV vaccines, and 13-valent pneumococcal conjugate vaccines. In addition, a series of promising new vaccines, including AC-Hib triple vaccine and DTcP-IPV-Hib five-combination vaccine, are in advanced clinical stages and are expected to enter the market soon. These products contribute to the growth of relevant companies and the development of the vaccine industry in China.

- ***Expanding awareness and adult vaccine market.*** While vaccine market in China is mainly occupied by pediatric vaccines, the adult vaccine market is a promising segment. In the United States and Western Europe, the adult vaccine segment plays a significant role. With the increasing public awareness of vaccination and the introduction of new vaccines, the adult vaccine market is expected to be a promising segment in China for the next 10-20 years.

- ***More supporting policy environment.*** In recent years, China has issued many policies to promote the development of the vaccine industry, such as the 14th Five-Year National Health Plan. These policies educate the public on the importance of vaccines and show the country's determination to develop the vaccine industry. Domestic substitution of imports is an imperative trend, and more supporting policies are likely to be released in favor of domestic vaccine manufacturers.

Entry Barriers of Vaccine Market in China

The vaccine market in China is characterized by significant entry barriers, which include: (i) production and quality barriers, as vaccine production is complex, lengthy and highly sensitive to manufacturing parameters. Chinese vaccine companies are generally required to produce their own vaccines, while rigorous quality control, product safety standards and comprehensive quality management systems create significant barriers for new entrants; (ii) R&D and talent barriers, as vaccine development requires strong scientific expertise, experienced technical teams and long-term R&D investment. The process from preclinical research to NDA approval can take more than a decade, with high uncertainty and demanding requirements in clinical development and registration; (iii) regulatory barriers, as the Chinese government has formulated a series of stringent laws and regulations governing the vaccine industry. The Vaccine Administration Law imposes clear and stringent requirements, making it more difficult for small and medium-sized companies with limited production capacity to obtain approvals; and (iv) capital barriers, as companies need to make substantial investments in the development of new vaccines. The construction of R&D and production facilities requires large capital expenditures. In addition, vaccine development requires extensive testing and clinical trials, which involve significant funding.

TETANUS VACCINES

Overview of Tetanus and Tetanus Vaccines

Tetanus is an infection caused by the bacterium Clostridium tetani, which is commonly found in soil, saliva, dust, and manure. The bacteria generally enter the body through a break in the skin, such as a cut or puncture wound from a contaminated object. Once inside the body in an oxygen-free environment, the bacteria replicate and produce a neurotoxin called tetanospasmin, which interferes with muscle contractions. There is no cure for tetanus. Treatment focuses on managing complications until the effects of the tetanus toxin resolve. Prevention through vaccination is the most effective measure against the disease. The Centers for Disease Control and Prevention in the U.S. recommends that adults receive a booster vaccine every ten years. The management of tetanus

involves both the treatment of active infections and prevention through diligent wound care and immunization. For individuals presenting with an active tetanus infection, immediate treatment requires cleaning the wound to thoroughly remove dirt, debris, or foreign matter that may harbor the bacteria. Medical intervention also relies heavily on drugs, including antitoxin therapy to target toxins that have not yet attacked nerve tissue, sedatives to control muscle spasms, antibiotics to fight the tetanus bacteria, and other medications to regulate involuntary muscle activity. In terms of prevention, accordance with WHO requirements dictates that the efficacy of a tetanus vaccine for children shall not be less than 40 IU per dose, with the standard dose of a TT-containing vaccine ("TTCV") being 0.5ml administered via intramuscular injection. Although adequate vaccination provides robust protection, a booster dose of TTCV is often administered in the event of serious injuries or if a patient's immunization history is unreliable.

Market Size of Tetanus Vaccines in China

The tetanus vaccine market in China has experienced rapid growth in recent years. The market size increased from RMB0.2 billion in 2019 to RMB1.0 billion in 2025, representing a CAGR of 35.9%. Driven by an aging population and expanding applications, the market is expected to further increase to RMB3.1 billion in 2035, representing a CAGR of 12.5% from 2025 to 2035.

Competitive Landscape of Tetanus Vaccines in China

As of the Latest Practicable Date, there were seven approved tetanus vaccines in China. We are a major player in the tetanus vaccine market in China. The following table sets forth details of the marketed tetanus vaccines in China as of the Latest Practicable Date:

Product	Company	First approval date	2025 Price (RMB)	Lot release in 2025 (Mn doses)	Market share in 2025 (Lot release)	Market share in 2025 (Revenue)
Tetanus Vaccine, Adsorbed	**Chengdu Olymvax Biopharmaceuticals**	**2016-10-25**	**~178-190**	**4.8**	**86.5%**	**98.8%**
	Wuhan Institute of Biological Products	1982	~142-166	0.4	8.1%	0.6%
	Sinovac Life Sciences	2025-08-19	~957	0.3	5.4%	0.7%
	Hualan Biological Bacterin	2023-02-21	~188	0	NA	NA
	Lanzhou Institute of Biological Products	1982	/	0	NA	NA
	Beijing Institute of Biological Products	1982	/	0	NA	NA
	Chengdu Institute of Biological Products	1982	/	0	NA	NA

Sources: NMPA, CIC

Market Drivers of Tetanus Vaccine

The growth of the tetanus vaccine market in China is driven by the following factors:

- ***Aging Population.*** With China's population aging rapidly, the number of elderly individuals is steadily increasing. According to National Bureau of Statistics of China, the population aged 60 and above in China reached 323.4 million, accounting for 23.0% of the total population in 2025. By 2030, this population is expected to reach 369.2 million, accounting for 26.4% of the total population. As immune function declines with age, the elderly are at a significantly higher risk of tetanus infection following injuries. As a result, targeted tetanus prevention measures for this demographic are becoming increasingly important, and the expanding elderly population is expected to be a key driver of future demand for tetanus vaccines.

- ***Expanding Application.*** Tetanus vaccines are no longer limited to traditional childhood immunization programs. Their use in trauma care, surgical procedures, obstetric care, and disaster response is gaining increasing attention. There is growing awareness among medical professionals in emergency departments and primary care settings of the importance of tetanus immunization in preventing secondary infections. To prevent

tetanus, the Chinese Preventive Medicine Association's 2024 Expert Consensus on the Use of Active Immunization Agents for High-Risk Populations for Tetanus Prevention recommends tetanus vaccination as catch-up or booster doses for the following groups: adults at high risk of trauma, older adults, immunocompromised individuals, and pregnant women. It also states that individuals without documented immunization history should complete a three-dose tetanus vaccination series, while those with uncertain immunization history are recommended to receive one dose of tetanus vaccine, with subsequent booster doses to be considered once every 10 years depending on individual risk. Furthermore, as public awareness of preventive care improves, more adults are proactively seeking tetanus vaccination, broadening the sources of demand across multiple age groups and healthcare settings.

- ***Rapid Growth of Rural Markets.*** Under national policies aimed at strengthening grassroots healthcare, the medical infrastructure in county-level and rural areas has significantly improved. Compared to saturated markets in major cities, these regions offer substantial untapped potential. Rural China remains a massive addressable market, with 451.09 million rural residents as of the end of 2025, accounting for 32% of the total population, according to the National Bureau of Statistics of China. Compared with the more saturated markets in major cities, these regions offer substantial untapped potential. According to National Institutes of Health and CIC, the reported burden of tetanus is also disproportionately rural, among cases with recorded residence, more than 80% were from rural areas. By enhancing training for local healthcare workers and improving vaccine supply chain logistics, the penetration of tetanus vaccines in rural markets is expected to rise, positioning these markets as critical growth engines for the industry.

HAEMOPHILUS INFLUENZAE TYPE B (HIB) VACCINE

Overview of Haemophilus Influenzae Type b (Hib) and Hib vaccines

Haemophilus influenzae type b (Hib) is a bacterium that can cause different kinds of infections. These infections usually affect children under five years of age but can also affect adults with certain medical conditions. Hib bacteria can cause mild illness, such as ear infections or bronchitis, or they can cause severe illness, such as infections of the blood. Severe Hib infection, also called "invasive Hib disease," requires treatment in a hospital and can sometimes result in death. Before the introduction of the Hib vaccine, Hib disease was the leading cause of bacterial meningitis among children under five years old in the United States. Symptoms of Hib infection depend on the part of the body affected and may include high temperature, difficulty breathing, unusual sleepiness, changes in skin color, a non-blanching rash that looks like small bruises or bleeding under the skin, headache, sore throat, and swollen or painful joints.

The Hib vaccine is categorized as a polysaccharide conjugate vaccine, which is a type of inactivated bacterial vaccine. Hib vaccines are available as monovalent vaccines or as part of combination vaccines, such as DTaP-Hib, MCV2-Hib, DTaP-IPV-Hib, and others.

Hib vaccination primarily targets infants and young children, as invasive Hib disease is a major cause of severe illness in this group (e.g., pneumonia, meningitis, and other invasive infections). In China, Hib vaccines are approved mainly for children aged 2 months to 5 years, and the commonly used schedule comprises three primary doses starting at 2-3 months, followed by a booster dose at 18 months, with age-based catch-up schedules: two doses if initiated at 6-12 months, or one dose if initiated at 1-5 years. In special circumstances, Hib vaccination may also be considered for certain high-risk populations depending on age and prior vaccination status, such as individuals receiving chemotherapy, hematopoietic stem cell transplant recipients, those with anatomic asplenia or undergoing elective splenectomy, and persons living with HIV infection. Hib vaccination in China is currently administered through the non-NIP channel.

Competitive Landscape of Hib Vaccines in China

As of the Latest Practicable Date, there were six approved Hib conjugate vaccines in China. The market is relatively concentrated among a few key domestic players. The following table sets forth details of the marketed Hib vaccines in China with the highest market share based on lot release volume in 2025:

Product	Company	First approval date	2025 Price (RMB)	Lot release in 2025 (Mn doses)	Market share in 2025 (Lot release)	Market share in 2025 (Revenue)
Haemophilus Influenzae Type b Conjugate Vaccine (Hib)	Beijing Minhai Biotechnology	2012-03-23	~115	0.7	34.9%	49.6%
	Beijing Zhifei Lvzhu Biopharmaceutical	2011-12-31	~102	0.6	30.1%	3.7%
	Walvax Biotechnology	2007-04-02	~105	0.3	15.5%	22.0%
	Chengdu Olymvax Biopharmaceuticals	**2017-05-18**	**~100**	**0.2**	**11.3%**	**12.2%**
	Lanzhou Institute of Biological Products	2004-01-19	~43	0.2	8.2%	12.5%
	Chengdu Institute of Biological Products	2013-06-03	/	0	NA	NA

Sources: NMPA, CIC

Market Size of Hib Vaccines in China

The market size of Hib vaccines in China recorded negative growth from 2019 to 2025, primarily due to the decline in the annual total lot release volume of Hib vaccines, particularly those produced by Beijing Zhifei Lvzhun Biopharmaceutical Co., Ltd., Walvax Biotechnology Co., Ltd., and Beijing Minhai Biotechnology Co., Ltd. However, the total lot release volume of the Hib vaccine market is expected to increase from 2025 to 2030, driven by the growing research and development of pediatric Hib-containing combination vaccines and the rising willingness of consumers to pay. The market also demonstrated a positive growth trend from 2022 to 2024. With relatively stable pricing, the market size of Hib vaccines in China is expected to maintain positive growth from 2025 to 2030. The Hib vaccine market in China is expected to increase from RMB0.2 billion in 2025 to RMB2.3 billion in 2035, at a CAGR of 26.2% from 2025 to 2035.

Drivers and Future Trends of Hib Vaccine Market

The primary drivers and future trends of the Hib vaccine market in China include:

- ***Persistent Hib disease burden***. Although the Hib monovalent vaccine was introduced in China in 1996, coverage rates remain low, recorded at 42.6% for the one-dose scheme and 25.0% for the three-dose scheme in 2023. As of 2023, China is the only WHO member country that has not included the Hib conjugate vaccine in its National Immunization Program (NIP). Consequently, China accounts for approximately 11% of global Hib deaths. As the Hib vaccine is not included in China's NIP, coverage remains materially below universal levels, leaving a large susceptible population. This unmet need for prevention continues to translate into self-paid demand for Hib vaccination, including for Hib-containing combination vaccines. Moreover, the sizable preventable disease burden suggests that an expansion of public financing or the inclusion of the vaccine in the NIP would be expected to structurally increase vaccination coverage and market volumes. It is estimated that incorporating the Hib vaccine into China's NIP could prevent approximately 235,700 Hib cases and 2,700 Hib deaths in children under five years old annually.

- ***Low current coverage of non-NIP vaccines and rising willingness-to-pay***. While coverage for NIP vaccines in China generally exceeds 95%, the uptake of non-NIP vaccines, such as Hib, remains suboptimal. However, there is a rapidly growing segment of urban, middle-income families willing to pay for optional vaccines. As income levels rise and public awareness regarding bacterial meningitis and severe pneumonia

improves, coupled with the emergence of private pediatric clinics and digital vaccination platforms, manufacturers have a significant opportunity to capture market upside by narrowing the gap between non-NIP and NIP coverage levels.

- ***Healthcare-sector initiatives and R&D in pediatric combination vaccines***. Domestic manufacturers and public health agencies are actively promoting Hib-containing combination vaccines, such as DTaP-IPV-Hib and hexavalent formulations. These combination vaccines can reduce overall vaccination costs by saving indirect and non-medical expenses while maintaining or improving coverage rates. Surveys indicate high acceptance for Hib combination vaccines, particularly among urban families. This shift from stand-alone Hib vaccines to higher-value combination products is expected to drive market growth through product upgrades and schedule simplification.

MENINGOCOCCAL VACCINES

Overview of Meningococcal Meningitis and Meningococcal vaccines

Meningococcal meningitis is an acute inflammation of the protective membranes covering the brain and spinal cord (the meninges), typically caused by an infection with microorganisms. It can be life-threatening due to the inflammation's proximity to the brain and spinal cord. Even for those who recover, permanent disabilities such as brain damage, hearing loss, and learning disabilities can result. In older children, adults and people over 50 years old, the disease is most commonly caused by Neisseria meningitidis. Neisseria meningitidis has 13 clinically significant serogroups. Six serogroups, A, B, C, Y, W-135, and X, are responsible for all cases of the disease in humans. About 10% of adults are carriers of the bacteria in their nasopharynx. As an exclusively human pathogen, it causes developmental impairment and death in about 10% of cases. It causes the only form of bacterial meningitis known to occur epidemically, mainly in Africa and Asia. It occurs worldwide in both epidemic and endemic form.

Treatment for bacterial meningitis primarily involves antibiotics, with ceftriaxone or cefotaxime often being the first choice for empirical treatment. In some cases, corticosteroid hormones like dexamethasone are used alongside antibiotics to reduce the inflammatory reaction and lower the incidence of complications such as deafness. Prevention is mainly achieved through vaccination, with various types of meningococcal vaccines available, including (i) Monovalent Meningococcal Group A vaccine (MenA); (ii) Bivalent Meningococcal Polysaccharide Vaccine (Serogroups A & C) (MPSV2); (iii) Bivalent Meningococcal Conjugate Vaccine (Serogroups A & C) (MCV2); (iv) Quadrivalent Meningococcal Polysaccharide Vaccine (Serogroups A, C, Y, W-135) (MPSV4); (v) Quadrivalent Meningococcal Conjugate Vaccine (Serogroups A, C, Y, W-135) (MCV4); and (vi) a combination conjugate vaccine targeting Hib and Serogroups A & C (MCV2-Hib).

Market Size of Meningococcal Vaccine in China

The market for meningococcal vaccines in China has shown steady growth. The market size increased from RMB2.6 billion in 2019 to RMB2.6 billion in 2025, at a CAGR of 0.4%. The market is projected to reach RMB5.8 billion in 2035, growing at a CAGR of 8.2% from 2025 to 2035.

Competitive Landscape of Meningococcal Vaccines in China

As of the Latest Practicable Date, there were multiple meningococcal vaccines approved in China, including polysaccharide and conjugate vaccines of various valencies. Our approved AC Conjugate Vaccine (MCV2 type) held a market share of 38.4% in the MCV2 type vaccine in 2025, in terms of revenue.

Market Drivers and Future Trends of Meningococcal Vaccines

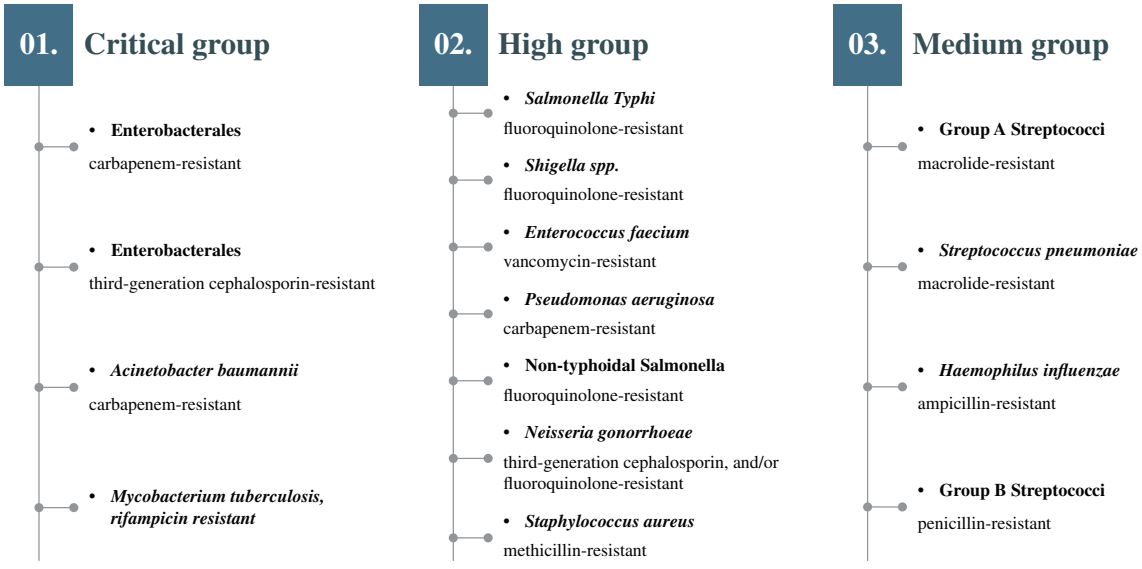
The growth of the meningococcal vaccine market in China is influenced by the following key factors: (i) technological advancements, as traditional polysaccharide meningococcal vaccines remain in use but have limitations, such as poor immunogenicity in infants and inability to induce immune memory. These limitations are addressed by conjugate vaccines, which link polysaccharides to carrier proteins and significantly enhance the immune response. With ongoing technological progress, conjugate vaccines have become the central focus of R&D and commercialization, driving the next phase of market expansion; and (ii) regional market development, as the meningococcal vaccine market in China shows regional disparities, with higher vaccination rates in more developed eastern coastal regions. However, central and western regions are rapidly catching up due to increased government investment in public health and improved healthcare infrastructure. This is unlocking previously untapped market potential and suggests that regional markets will become more balanced, offering new growth opportunities for manufacturers.

OVERVIEW OF SUPERBUGS

Antimicrobial resistance ("AMR") occurs when bacteria, viruses, fungi, and parasites change over time and no longer respond to medicines, making infections harder to treat and increasing the risk of disease spread, severe illness, and death. Microorganisms that develop AMR are sometimes referred to as "superbugs."

AMR poses a significant threat to global health and economic stability. According to WHO, it is estimated that bacterial AMR was directly responsible for 1.27 million global deaths in 2019 and contributed to 4.95 million deaths indirectly worldwide. In addition to death and disability, AMR has significant economic costs. The World Bank estimates that AMR could result in US$1 trillion additional healthcare costs by 2050, and between US$1 trillion and US$3.4 trillion gross domestic product losses per year by 2030.

In 2024, the WHO published its bacterial priority pathogens list to guide research and development for new treatments. The list is categorized into critical, high, and medium priority groups as follows:



Sources: WHO, CIC

Some of our commercialized and pipeline vaccine products target bacterial pathogens identified in the list across different priority levels. our commercialized product, the Hib Conjugate Vaccine, targets Haemophilus influenzae, which is categorized as a medium-priority pathogen. Our pipeline products (i) rFSAV, targets Staphylococcus aureus, a high-priority pathogen; (ii) rFPAV, targets Pseudomonas aeruginosa, a high-priority pathogen; (iii) rABV, targets Acinetobacter baumannii, a critical-priority pathogen; and (iv) GAS Vaccine, targets Group A Streptococcus, identified as a medium-priority pathogen.

The rise of superbugs presents several market pain points for the global healthcare system, including (i) the failure of existing antibiotics against pathogens resistant to multiple treatments, threatening a "post-antibiotic era" where routine infections become untreatable; (ii) increased treatment cost and complexity, as managing these resistant infections requires expensive backup drugs, longer hospitalizations, and intensive isolation protocols that strain healthcare resources; (iii) a lack of innovation incentives, driven by high development costs combined with low sales volumes, since new drugs are strictly reserved for severe cases — and short commercial lifespans due to rapid bacterial mutation; and (iv) a severe threat to public health security, where global travel accelerates the cross-border spread of resistant strains, ultimately undermining the safety of routine surgeries, cancer treatments, and organ transplants.

STAPHYLOCOCCUS AUREUS VACCINES

Overview of Staphylococcus aureus

Staphylococcus aureus is a bacterium commonly found on the skin and in the nose of about 30% of healthy individuals. While often harmless, it can cause infections if it enters the bloodstream or tissues, particularly in healthcare settings. Transmission is typically via direct contact or contaminated objects.

Staphylococcus aureus infections can range from minor skin problems to life-threatening conditions such as sepsis, pneumonia, endocarditis (infection of the heart valves), osteomyelitis (bone infection). Treatment is complicated by the emergence of multidrug-resistant strains, most notably methicillin-resistant Staphylococcus aureus. However, any staph infection, even if not antibiotic-resistant, can be dangerous.

Treatment for Staphylococcus aureus infections depends on the type of infection and the presence of drug resistance. The primary treatment is antibiotics. For MRSA infections, vancomycin is often the top choice, while for methicillin-susceptible Staphylococcus aureus (MSSA) infections, penicillin-type antibiotics and anti-staphylococcal β-lactams are preferred. In addition to antimicrobial therapy, surgical intervention or source control, such as the debridement of infected tissue or removal of infected medical devices, is often required, as antibiotics alone may be insufficient for abscesses or biofilm-related infections.

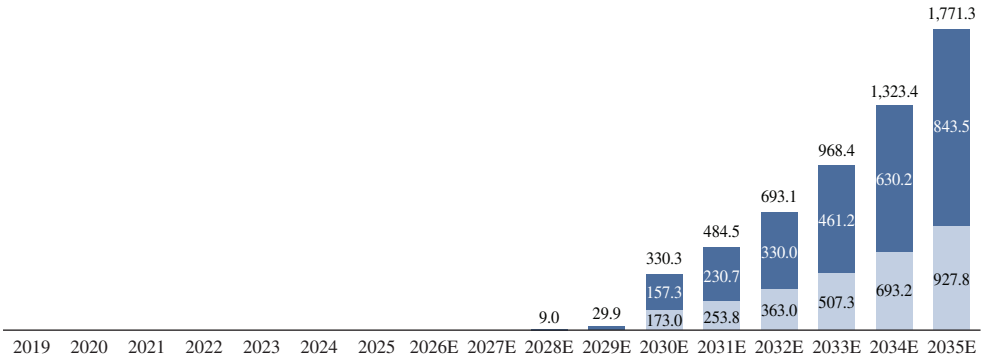
Market Size of Staphylococcus aureus Vaccine in China and Globally

As of the Latest Practicable Date, there are no approved Staphylococcus aureus vaccines globally or in China. The development of an effective vaccine is a major medical need due to the high disease burden and increasing antibiotic resistance.

The number of MRSA infections globally is projected to reach 7.4 million in 2035, representing a CAGR of 1.0% between 2025 and 2035. The number of MRSA infections in China was 2.4 million in 2025 and is projected to gradually increase to 2.6 million by 2035, representing a CAGR of 1.0% between 2025 and 2035.

The market for Staphylococcus aureus vaccine in China and globally is shown below:

CAGR	2028-2035E
China	91.2%
ROW	/
Total	112.6%



Source: HCUP, National Bureau of Statistics, CIC

Competitive Landscape of Staphylococcus aureus Vaccines

The development of a Staphylococcus aureus vaccine has been a long-standing challenge in the global pharmaceutical industry, with many previous candidates failing in late-stage clinical trials. Our recombinant Staphylococcus aureus vaccine candidate is one of the few candidates that has advanced to Phase III clinical trials globally.

The following table sets forth details of the Staphylococcus aureus vaccine candidates in the global pipeline that have entered clinical stages as of the Latest Practicable Date:

Product	Antigen Components	Company/Sponsor	Indication	Age Coverage	Phase	First Posted Date	Register Number	Location
LTB-SA7	Toxoid based vaccine consisting of five components including seven toxoids formulated with Alhydrogel	LimmaTech Biologics AG	Preventing Staphylococcus (S.) Aureus Infection	18 to 50 years old	I	2024-12-05	NCT06719219	U.S.
rFSAV	**mHla/IsdB/SpA/ mSEB/MntC**	**Chengdu Olymvax Biopharmaceuticals**	**Preventing S. Aureus infection after orthopedic surgery**	**18 to 70 years old**	**III**	**2022-05-31**	**CTR20221329**	**China**
			Preventing S. Aureus Infection	**18 to 70 years old**	**Ib**	**2019-06-03 2019-05-29**	**CTR20190552 NCT03966040**	**China**
NDV-3	Candida Als3	NovaDigm Therapeutics	Preventing S. Aureus Colonization	17 to 35 years old	II	2018-03-06	NCT03455309	U.S.

Source: ClinicalTrials, CDE, CIC

Drivers and Future Trends of Staphylococcus aureus Vaccine Market

The development and potential launch of a Staphylococcus aureus vaccine are driven by the following factors: (i) high clinical demand, stemming from a substantial unmet need, high morbidity and mortality, and significant hospital costs, alongside the rise of AMR (particularly MRSA) which undermines antibiotic effectiveness and increases treatment failures; (ii) competitive landscape and first-mover advantage, as there are currently no approved human Staphylococcus aureus vaccines and regulatory barriers to entry remain high, allowing the first company to successfully obtain approval to secure a major market advantage; and (iii) significant overseas market potential, because the vaccine addresses a global public health priority, allowing its indications to expand from high-risk inpatient settings (e.g., surgery, dialysis) to broader outpatient prevention and creating a clear pathway for globalization through out-licensing, partnerships, and multi-regional clinical trials.

HELICOBACTER PYLORI VACCINES

Overview of Helicobacter pylori

Helicobacter pylori is a spiral-shaped bacterium found in the gastric mucous layer or attached to the epithelial lining of the stomach. It is a common pathogen, affecting up to 50% of the global population, with a higher prevalence in developing countries. The infection is usually acquired in early childhood and can persist for life if left untreated. Transmission is commonly person-to-person through saliva or via fecal contamination of food or water. Helicobacter pylori is a primary cause of chronic gastritis and is responsible for more than 90% of duodenal ulcers and up to 80% of gastric ulcers. Other complications linked to Helicobacter pylori include iron deficiency or vitamin B12 deficiency anemia, diabetes mellitus, and certain cardiovascular and neurological disorders.

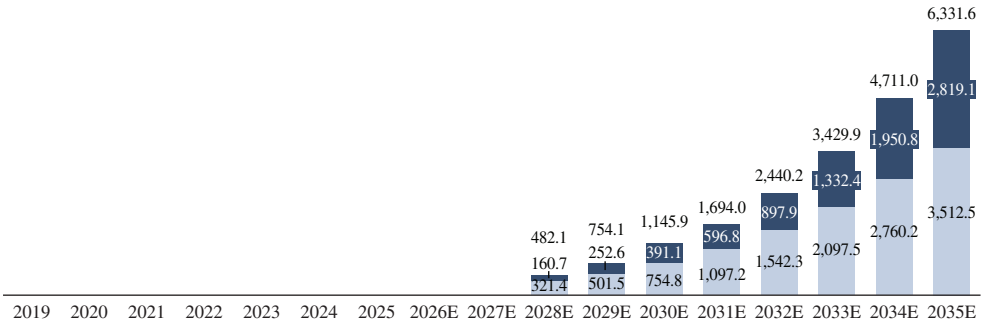
Current treatment for Helicobacter pylori infection involves a 10- to 14-day course of therapy with one or two effective antibiotics combined with a proton pump inhibitor ("PPI"). A common first-line regimen is a triple therapy consisting of a PPI, amoxicillin, and clarithromycin. However, the effectiveness of this therapy is threatened by rising antibiotic resistance. In China, resistance rates to clarithromycin and levofloxacin are approximately 20-40%, and resistance to metronidazole is as high as 60-90%. When resistance is present or unknown, a bismuth-based quadruple therapy is often used. Successful eradication of the bacteria reduces inflammation, heals ulcers, and lowers the future risk of gastric cancer.

Market Size of Helicobacter pylori Vaccine in China and Globally

The number of Helicobacter pylori infections around the globe was 3,539.6 million in 2025 and is projected to gradually increase to 3,820.6 million by 2035. The number of individuals infected with Helicobacter pylori in China is substantial, estimated at 612.0 million in 2025. This number is projected to remain stable, reaching 612.9 million by 2035.

As of the Latest Practicable Date, there are no approved Helicobacter pylori vaccines in China or globally. The market for Helicobacter pylori vaccine in China and globally is shown below:

CAGR	2028-2035E
China	50.6%
ROW	40.7%
Total	44.5%



Source: HCUP, National Bureau of Statistics, CIC

Competitive Landscape of Helicobacter pylori Vaccines

While there were no approved Helicobacter pylori vaccines globally, there are a few candidates in clinical development, including a candidate being developed by us. The following table sets forth details of the Helicobacter pylori vaccine candidates in the global pipeline that have entered clinical stages as of the Latest Practicable Date:

Product	Company/Sponsor	Age coverage	Phase	First posted date	Register number	Location
IMX101 vaccine	ImevaX	18 to 50 years	Ia/Ib	2017-09-01	NCT03270800	Germany
Oral Recombinant Helicobacter Pylori Vaccine	Wuhu Kangwei Biotechnology	6 to 15 years	III	2014-11-26	NCT02302170	China
H. Pylori Vaccine	Novartis	18 to 40 years	I/II	2008-08-15	NCT00736476	Germany
Oral Recombinant Helicobacter Pylori Vaccine	**Chengdu Olymvax Biopharmaceuticals**	**/**	**I**	**/**	**CT-2024-CTN-01799-1**	**Australia**

Source: Clinical Trials, CIC

Market Drivers and Future Trends of Helicobacter pylori Vaccine

The development of a Helicobacter pylori vaccine is driven by several key factors: (i) a large addressable population with a high disease burden, as the bacterium infects up to 50% of the global population and is strongly linked to gastritis, peptic ulcers, and a two- to six-fold increase in gastric cancer risk; (ii) a current prevention gap and high public health payoff, given that no specific preventive measures exist beyond basic hygiene, meaning an effective vaccine would deliver massive long-term health and economic value by preventing disease before it occurs; and (iii) the eroding efficacy of the standard of care due to antibiotic resistance, which has significantly reduced the success rates of traditional eradication therapies — particularly in regions like China — making drug-only population control increasingly difficult and creating an urgent unmet need for a vaccine.

ACINETOBACTER BAUMANNII VACCINES

Overview of Acinetobacter baumannii

Acinetobacter baumannii is a type of bacteria commonly found in the environment, such as in soil and water. It is one of the "ESCAPE" pathogens, a group of clinically important organisms known for their potential to develop significant antimicrobial resistance. Infections caused by Acinetobacter baumannii occur predominantly in healthcare settings but can be severe. Acinetobacter baumannii can cause a range of infections, including hospital-acquired pneumonia, community-acquired pneumonia, bloodstream infections, meningitis, skin, soft tissue, and bone infections, urinary tract infections, etc.

Acinetobacter baumannii infections are generally treated with antibiotics. However, many Acinetobacter baumannii strains are resistant to multiple antibiotics, making them difficult to treat. Healthcare providers must rely on laboratory testing to determine which antibiotics, if any, remain effective against a specific infection.

Market Size of Acinetobacter baumannii Vaccine in China and Globally

The number of Acinetobacter baumannii infections around the globe was 8.9 million in 2025 and is projected to gradually increase to 9.8 million by 2035. The number of Acinetobacter baumannii infections in China was 3.1 million in 2025 and is projected to increase to 3.4 million by 2035. As of the Latest Practicable Date, there are no Acinetobacter baumannii vaccines in clinical trials worldwide. The market for a vaccine is projected to emerge in the future. The market size of acinetobacter baumannii vaccine around the globe is projected to reach US$116.9 million in 2032 and US$784.1 million in 2035, growing at a CAGR of 88.6% from 2032 to 2035. The market size of acinetobacter baumannii vaccine in China is projected to reach US$116.9 million in 2032 and US$451.1 million in 2035, growing at a CAGR of 56.9% from 2032 to 2035.

Market Drivers and Future Trends of Acinetobacter baumannii Vaccine

The future market for an Acinetobacter baumannii vaccine is supported by the following drivers: (i) significant unmet clinical need, as the bacterium frequently exhibits multidrug or pan-drug resistance that renders traditional antibiotics ineffective, making vaccine prevention a far more cost-effective and sustainable strategy than treatment; (ii) increased public health awareness, highlighted by the WHO listing carbapenem-resistant Acinetobacter baumannii as a critical priority pathogen and its status as a major cause of high-mortality ICU infections, where a vaccine could drastically reduce complications and deaths in critically ill patients; and (iii) advances in vaccine technology, where breakthroughs in platforms such as mRNA, outer membrane vesicle-based, and multicomponent subunit vaccines provide new, highly adaptable pathways for targeting complex bacteria.

PSEUDOMONAS AERUGINOSA VACCINES

Overview of Pseudomonas aeruginosa

Pseudomonas aeruginosa is a Gram-negative bacterium commonly found in the environment, particularly in freshwater and hospital settings (e.g., taps, sinks, and respiratory equipment). It is an opportunistic pathogen that combines virulence with a high capacity for antibiotic resistance, allowing it to cause complex and difficult-to-treat infections, especially in vulnerable and immunocompromised patients. Infections can affect various parts of the body, including the respiratory tract, bloodstream, heart, central nervous system, bones, joints, and skin. Antimicrobials are the primary therapy for Pseudomonas aeruginosa infections. Due to high rates of resistance, selecting an effective antibiotic regimen is critical. Combination therapy is often used for severe infections, and an interprofessional team approach involving infectious disease specialists is recommended to improve patient outcomes.

Market Size of Pseudomonas aeruginosa Vaccine in China and Globally

The number of Pseudomonas aeruginosa infections around the globe was 11.0 million in 2025 and is projected to gradually increase to 12.2 million by 2035. The number of Pseudomonas aeruginosa infections in China was 3.8 million in 2025, with a projected increase to 4.2 million by 2035. As of the Latest Practicable Date, there are no approved Pseudomonas aeruginosa vaccines. The market size of pseudomonas aeruginosa vaccine around the globe is projected to reach US$324.0 million in 2031 and US$1,655.2 million in 2035, growing at a CAGR of 50.3% from 2031 to 2035. The market size of pseudomonas aeruginosa vaccine in China is projected to reach US$115.7 million in 2031 and US$657.0 million in 2035, growing at a CAGR of 54.4% from 2031 to 2035.

Competitive Landscape of Pseudomonas aeruginosa Vaccines

As of the Latest Practicable Date, there were no Pseudomonas aeruginosa vaccines globally or in China. The pipeline is limited, with one candidate having reached late-stage clinical trials. The following table sets forth details of the Pseudomonas aeruginosa vaccine candidate in the global pipeline that have entered clinical stages as of the Latest Practicable Date:

Product	Company/Sponsor	Age coverage	Phase	First posted date	Register number	Location
IC43 Recombinant Pseudomonas Vaccine	Valneva	18 to 80 years	II/III	2012-03-26	NCT01563263	Austria, Belgium, Czechia, Germany, Hungary, Spain

Source: ClinicalTrials, CIC

Market Drivers and Future Trends of Pseudomonas aeruginosa Vaccine

The development of a Pseudomonas aeruginosa vaccine is driven by the following factors (i) significant unmet clinical need, as this common opportunistic pathogen causes severe infections in high-risk settings like ICUs and burn units, where its tendency to develop MDR renders traditional antibiotics increasingly ineffective and results in prolonged hospital stays, high costs, and elevated mortality; (ii) advances in technology, which have made targeting complex Gram-negative bacteria increasingly feasible through advanced platforms that offer faster antigen design, enhanced immunogenicity, and broad-spectrum protection against diverse bacterial strains; and (iii) market expansion potential, as these vaccines can be developed as multivalent or combined preventive solutions targeting other common hospital-acquired pathogens (such as Acinetobacter baumannii), further enhancing their commercial value.

GROUP A STREPTOCOCCAL VACCINES

Overview of Group A Streptococcus

GAS is a bacterium that can cause a wide range of infections, from mild skin and respiratory illnesses to severe, life-threatening invasive diseases. GAS can trigger epidemic waves, often driven by the emergence of new genotypes. GAS infections include minor infections like Strep throat, scarlet fever, and impetigo, invasive infections like cellulitis, necrotizing fasciitis and streptococcal toxic shock syndrome, inflammatory diseases like post-streptococcal glomerulonephritis and rheumatic fever, which can lead to rheumatic heart disease.

The primary treatment for GAS infections is antibiotics, with penicillin or amoxicillin being the drugs of choice for common infections like strep throat.

Market Size of Group A Streptococcal Vaccine in China and Globally

The number of invasive Group A streptococcal infections around the globe was 675.0 thousand in 2025 and is projected to gradually increase to 728.6 thousand by 2035. The number of invasive Group A streptococcal infections in China was estimated at 117.6 thousand in 2025 and is projected to grow to 118.0 thousand by 2035. As of the Latest Practicable Date, there are no approved GAS Vaccines. The global market size of the GAS vaccine is projected to reach US$354.5 million in 2030 and US$2,206.7 million in 2035, growing at a CAGR of 44.2% from 2030 to 2035. The market size of the GAS vaccine in China is projected to reach US$152.2 million in 2030 and US$1,084.0 million in 2035, growing at a CAGR of 48.1% from 2030 to 2035.

Competitive Landscape of Group A Streptococcal Vaccines

As of the Latest Practicable Date, there were no approved GAS Vaccines globally or in China. There are a few candidates in early-stage clinical development, including a candidate with which we are involved. The following table sets forth details of the Group A streptococcal vaccine candidates in the global pipeline that have entered clinical stages as of the Latest Practicable Date:

Product	Company/Sponsor	Age coverage	Phase	First posted date	Register number	Location
GAS Vaccine	University of Alberta, Griffith University	18 to 45 years	I/II	2021-05-12	NCT04882514	Canada
StreptInCor	University of Sao Paulo General Hospital	18 to 45 years	I/IIa	2025-07-22	NCT07078357	Brazil
GSK 4-component Vaccine	GSK	18 to 25 years	I	2025-07-25	NCT07085702	Australia

Source: ClinicalTrials, CIC

INFLUENZA VACCINE

Overview of Influenza

Influenza is a contagious respiratory illness caused by influenza viruses of the Orthomyxoviridae family. The viruses infect the nose, throat, and sometimes the lungs, and can cause mild to severe illness, and at times can lead to death.

Influenza spreads mainly through droplets from coughs and sneezes of infected people, or through contact with contaminated surfaces. Symptoms can range from mild (fever, cough, sore throat, muscle aches) to severe (viral pneumonia and shock). The incidence of influenza globally increased from 924.2 million cases in 2019 to 1,003.1 million cases in 2025, representing a CAGR of 1.4%. The number of cases is projected to reach 1,293.4 million in 2035, representing a CAGR of 2.6% between 2025 and 2035. The incidence of influenza in China increased from 20.4 million cases in 2019 to 27.8 million cases in 2025, representing a CAGR of 5.3%. The number of cases is projected to reach 51.2 million in 2035, representing a CAGR of 6.3% between 2025 and 2035.

Overview of Influenza Vaccine

Vaccination is the primary method for preventing influenza. Influenza vaccines can be categorized based on their production technology including inactivated influenza vaccine (IIV), live attenuated influenza vaccine (LAIV) and recombinant influenza vaccine (RIV).

Influenza vaccines are also produced using different manufacturing platforms, namely (i) egg-based influenza vaccines, which represent one of the most common production methods where the vaccine seed strain is propagated in embryonated chicken eggs. However, this method has limitations, including long production cycles, dependence on egg supply, and the risk of antigenic mutations due to egg adaptation, which can reduce vaccine effectiveness, particularly against the influenza A/H3N2 strain; and (ii) MDCK-based (cell-based) influenza vaccines, which utilize MDCK cells for vaccine production. This technology offers many advantages over egg-based methods, including rapid and large-scale production, avoidance of egg-related antigenic mutations, and suitability for individuals with egg allergies, and cell-based production is emerging as a key direction for the next generation of influenza vaccines.

Market size of Influenza Vaccine in China

The influenza vaccine market in China has grown significantly. The market size increased from RMB1.5 billion in 2019 to RMB8.6 billion in 2025, representing a CAGR of 33.5%. The market is composed of quadrivalent (IIV4) and trivalent (IIV3) inactivated influenza vaccines. The IIV4 market grew from RMB0.8 billion in 2019 to RMB6.9 billion in 2025, representing a CAGR of 42.5%, while the IIV3 market grew from RMB0.7 billion in 2019 to RMB1.7 billion in 2025, at a CAGR of 16.0%. The total influenza vaccine market in China is estimated to further increase to RMB39.7 billion in 2035, representing a CAGR of 16.5% from 2025 to 2035.

Competitive Landscape of Influenza Vaccines in China

The influenza vaccine market in China is competitive, with numerous domestic and international manufacturers offering a range of products, including trivalent and quadrivalent inactivated split virion vaccines, subunit vaccines, and live attenuated nasal spray vaccines.

As of the Latest Practicable Date, there were a number of influenza vaccine candidates under clinical development in China, including those utilizing advanced MDCK cell-based technology. We are involved in the development of both trivalent and quadrivalent MDCK cell-based influenza vaccine candidates. The following table sets forth details of selected influenza vaccine candidates using MDCK cell technology in China:

Product	Company	Age coverage	Phase	First posted date
Influenza Vaccine (Split Virion, MDCK cell), Inactivated, Quadrivalent	Chengdu Xinnuoming Biotechnology/Chengdu Olymvax Biopharmaceuticals/Lanzhou Bailing Biotechnology	3 years old and above	III	2025-10-29
	Wuhan Institute of Biological Products/Lanzhou Bailing Biotechnology		III	2023-10-09
	Shenzhen Kangtai Biological Products/Lanzhou Bailing Biotechnology		I	2026-04-16
	Changchun Institute of Biological Products		I	2024-04-08
	Shanghai Institute of Biological Products	6 months old and above	I	2024-03-27
	Zhejiang Tianyuan Bio-pharmaceutical/Lanzhou Bailing Biotechnology		I	2024-03-05
Influenza Vaccine (Split Virion, MDCK cell), Inactivated, Trivalent	Lanzhou Bailing Biotechnology/Shenzhen Kangtai Biological Products	3 years old and above	I	2026-04-17
	Shanxi Kunqin Biotechnology	3 months old and above	I	2026-03-12
	Chengdu Xinnuoming Biotechnology/Chengdu Olymvax Biopharmaceuticals/Lanzhou Bailing Biotechnology	6 months old and above	I	2025-01-23

Sources: CDE, CIC

Market Drivers and Future Trends of Influenza Vaccine

The primary drivers and future trends of the influenza vaccine market in China include: (i) significant market potential, as the influenza vaccination rate in China has remained low, at only around 3% of the total population annually. This is significantly lower than the 50%–60% coverage observed in developed countries, highlighting substantial unmet need and significant growth potential in the Chinese market; (ii) product iteration, as quadrivalent influenza vaccines have increasingly become the mainstream products, gradually replacing trivalent vaccines. By covering two influenza B virus lineages, quadrivalent influenza vaccines enhance the overall protective effect. As public demand for broader immunization coverage increases, quadrivalent influenza vaccines are rapidly gaining market penetration; and (iii) technological advancements, as traditional egg-based production remains the mainstream method, while cell culture technologies, particularly those based on MDCK cells, are emerging as a key direction for the next generation of influenza vaccines due to their multiple advantages, including shorter production timelines and better antigenic match with circulating virus strains.

PROPHYLACTIC MONOCLONAL ANTIBODY

Prophylactic monoclonal antibodies are pre-prepared monoclonal antibodies produced using genetic technology. They function by providing immediate, passive protection through the direct injection of the pre-prepared antibody into the body. The primary goal is to prevent the onset of specific diseases or reduce their severity. The use of these antibodies can significantly reduce the risk of hospitalization and the incidence of severe illness due to infection. A key distinction is that unlike vaccines, which stimulate the body to produce antibodies, monoclonal antibodies provide ready-made antibodies. Prophylactic monoclonal antibodies provide passive, immediate and targeted protection by delivering antibodies directly into the body, rather than relying on the body to produce antibodies after vaccination. They can offer rapid protection against specific pathogens and are useful in high-risk populations, such as infants or patients undergoing major surgery. Their key applications include RSV prevention in infants, tetanus post-exposure prophylaxis, and prevention or reduction of severe infections and complications caused by Staphylococcus aureus and Pseudomonas aeruginosa.

STAPHYLOCOCCUS AUREUS MONOCLONAL ANTIBODY

Staphylococcal monoclonal antibodies are antibodies against Staphylococcus aureus. They are primarily used to treat and prevent Staphylococcus aureus infections, specifically methicillin-resistant Staphylococcus aureus infections that are resistant to multiple antibiotics. These antibodies are engineered to bind specific Staphylococcus aureus virulence factors or surface antigens — such as α-toxin or protein A — to neutralize toxins, prevent tissue injury, and enhance opsonophagocytic clearance, independent of classical antibiotic resistance mechanisms. Monoclonal antibodies against Staphylococcus aureus may target different bacterial components, including protein A, toxins, surface structures and Cas9. These antibodies may be used to treat active infections, including drug-resistant strains, often together with antibiotics; support diagnostic testing; and enhance immune clearance by helping the body recognize and destroy the bacteria.

ANTI-PSEUDOMONAS AERUGINOSA MONOCLONAL ANTIBODY

Anti- Pseudomonas aeruginosa monoclonal antibodies are recombinant human/humanized antibodies directed against key virulence factors or surface antigens of Pseudomonas aeruginosa. They work by neutralizing toxins, blocking secretion systems, and/or enhancing opsonophagocytic clearance. Therefore, they do not rely on the bacterium's antibiotic susceptibility profile. Monoclonal antibodies against Pseudomonas aeruginosa remain under development, with no approved product to date. Clinical-stage candidates have targeted mechanisms such as toxin injection systems, dual or bispecific targets, and bacterial surface polysaccharides to reduce tissue damage and support bacterial clearance. This is a high-value but technically challenging area, particularly because Pseudomonas aeruginosa is a WHO critical-priority pathogen. These antibodies may complement antibiotics and vaccines by providing rapid, short-term protection for high-risk patients, while sharing antigen discovery, biologics manufacturing and quality-control capabilities with vaccine programs.

ANTI-TETANUS MONOCLONAL ANTIBODY

The Anti-tetanus monoclonal antibody is a recombinant human/humanized monoclonal antibody targeting tetanus toxin (TeNT). It serves as an upgraded alternative to traditional human tetanus immunoglobulin (HTIG) for passive immunization after high-risk tetanus wounds. Its mechanism involves binding to key epitopes of TeNT with high affinity to neutralize toxin activity and block toxin entry into the nervous system. It provides protection in a short time without relying on the body's own immune response. This antibody primarily targets individuals with insufficient pre-existing immunization, unclear vaccination history, or impaired immune function. It is used in combination with tetanus vaccines in scenarios such as emergency trauma and industrial injuries, and disasterrelief. While the monoclonal antibody provides immediate post-exposure protection, the vaccine provides long-term active immunization; the combination allows for integrated management of passive and active immunization within a single treatment process.