
INDUSTRY OVERVIEW

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OVERVIEW OF THE GLOBAL AND CHINA’S NATURAL MEDICINE MARKET

Overview of Natural Medicines

Nature can be viewed as a vast reservoir of molecular diversity, with natural products serving as a rich and indispensable foundation for innovative drug discovery. In China, the NMPA defines Natural Medicines as medicinal substances and their preparations derived from natural sources, including plants, animals, and minerals, and used under the guidance of Modern Medical Theories. In principle, this definition excludes substances derived from genetically modified organisms, those produced via microbial fermentation, or chemically modified compounds. Plants generate secondary metabolites — such as alkaloids, flavonoids/polyphenols, and terpenoids — through secondary metabolism to defend against pests and pathogens, enhance stress tolerance, repair damage, and delay senescence. These metabolites are predominantly small molecules with structurally complex, highly diverse, and species-specific features, and they exhibit broad pharmacological activities. As a result, they play important roles in the treatment of major diseases, including metabolic disorders, malignancies, inflammatory and immune diseases, cardiovascular and cerebrovascular conditions, and respiratory diseases.

Leveraging advances in modern scientific and technological capabilities, Natural Medicines have seen continuous progress in areas such as extraction and isolation, structural characterization, and pharmacological activity research, gradually forming a modern discipline of natural pharmacology and driving ongoing innovation in disease treatment. In China, over 80% of natural medicinal resources are plant-based. Compared with single-component drug, plant-derived “active component groups (有效组分群)” are better suited to exert multi-target and multi-pathway regulatory effects, offering distinct clinical advantages in the treatment of complex chronic diseases. However, the isolation, enrichment, structural elucidation and quality control of these active component groups present higher technical barriers. Studies on pharmacokinetics (“PK”), pharmacodynamics, and regulatory mechanisms are also more complex. This complexity has directly resulted in only a limited number of multi-component Natural Medicines successfully reaching the market. As of now, a very few number, less than 20, of natural medicines have been approved globally, primarily by European Medicines Agency (“EMA”) and the U.S. Food and Drug Administration (the “FDA”), with even fewer indicated for the treatment of major diseases according to public clinical trial information registered under FDA, EMA and NMPA.

Global Market Size of Natural Medicines

The global Natural Medicines market was approximately US\$2.0 billion in 2020 and has grown steadily since then, reaching US\$2.3 billion by 2024, representing a CAGR of 3.9% during this period. With more Natural Medicines expected to gain regulatory approval in the future, and given their demonstrated advantages in long-term disease management, the market

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is projected to continue expanding, growing at a CAGR of 10.3% to reach US\$5.0 billion by 2032. Based on annual reports and expert interviews, Chinese Natural Medicines market size is approximately US\$0.7 billion in 2024 and is expected to grow at a rate exceeding that of the overall global Natural Medicines market, reaching US\$2.0 billion by 2032.

Development Trends and Growth Drivers of China’s Natural Medicine Market

Development Trends of Multi-Component: Multi-component Natural Medicines containing multiple classes of bioactive constituents (e.g., alkaloids, flavonoids, polysaccharides and saponins), act via multiple pathways, offering advantages in complex conditions such as inflammation, cancer, immune and metabolic disorders. With the rising prevalence of multifactorial diseases, multi-component Natural Medicines have broader clinical demand. Advances in omics and network pharmacology further enable systematic understanding of multi-component mechanisms, enhancing their integration into modern medicine.

Rising Demand Driven by Chronic Diseases and Population Aging: By the end of 2024, China’s population aged 60+ reached 310.31 million (22% of total). According to literature review, the prevalence of chronic diseases such as cardiovascular, cerebrovascular, diabetes, metabolic, and immune disorders is rising, often requiring multi-target, long-term interventions. Natural Medicines, with multi-component and multi-target properties, are well-suited for chronic disease management and long-term health maintenance. Growing public awareness of safe, natural, and long-term therapies further supports sustained demand for the Natural Medicine market.

Technological Advancements Driving Industry Upgrading: Advances in multi-component analysis (e.g., componentomics, metabolomics) allow precise characterization of complex compositions and mechanisms. The integration of intelligent and automated production with component extraction and enrichment technologies has significantly improved the precision of component enrichment and quality control, while further aligning products with international standards, strengthening R&D and global competitiveness.

Entry Barriers to China’s Natural Medicine Market

Technological Barriers: R&D and manufacturing of Natural Medicines involve systematic processes including raw material selection, active constituent extraction and purification, analysis, and formulation development. Key challenges include complex compositions and batch-to-batch variability, requiring advanced technologies, e.g., high-performance liquid chromatography, gas chromatography, liquid chromatography-mass spectrometry, high-resolution mass spectrometry, inductively coupled plasma mass spectrometry, and specialized facilities to ensure quality consistency.

Legal and Regulatory Approval Barriers: In China, Natural Medicines seeking approval as innovative drugs must undergo preclinical studies (such as pharmacological and toxicological) and multi-phase clinical trials which are strongly evidence-based. These processes are time-consuming and capital-intensive, and must meet regulatory requirements on quality, efficacy, and safety. The high standard of Natural Medicines, including clear and uniform components, while ensuring scientific rigor and safety, creates significant institutional and regulatory barriers to market entry.

Barriers in Sustainable Resource Utilization Capabilities: Natural Medicines, due to their natural origins and close link with the ecological environment, have gained growing recognition. At the same time, raw material sourcing must ensure environmental sustainability. Establishing a stable, traceable, and sustainable supply has become a key competitive advantage. New entrants lack such capabilities may struggle to maintain supply and consistent product quality.

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OVERVIEW OF THE GLOBAL AND CHINA METABOLIC DISEASE DRUG MARKET

Overview of Metabolic Diseases

Metabolic diseases are chronic and complex disorders caused by persistent dysregulation across multiple metabolic pathways, including carbohydrates, lipids, proteins, and nucleic acids. They include diabetes, obesity, PCOS, metabolic dysfunction-associated steatohepatitis (“MASH”), and certain cardiovascular conditions. Key clinical features include obesity, hypertension, dyslipidemia, and impaired glucose metabolism. Due to multifactorial pathogenesis and frequent co-occurrence of multiple conditions, single treatment strategies are often insufficient.

Prevalence and Market size of Metabolic Diseases Globally and in China

As documented in the International Diabetes Federation (IDF) and based on literature review, the prevalence of metabolic diseases has been increasing globally, with an estimated overall prevalence of approximately 25%, making them a significant global health concern. In China, the prevalence is estimated at around 35%, reaching as high as 58.1% among individuals aged 60 years and above. In 2024, the total number of individuals affected by metabolic diseases worldwide is projected to be approximately 2.6 billion, of which about 550.0 million are in China. The growth rate of metabolic disease prevalence in China is expected to outpace that of developed countries such as the United States.

Growth Drivers and Future Trends of the Metabolic Disease Treatment Market

The growth of the metabolic disease treatment market is primarily driven by the following key factors:

- **Increasing demand from patients with metabolic chronic diseases:** The global prevalence of metabolic chronic diseases continues to rise, with a noticeable trend toward younger populations. The incidence of conditions such as obesity, diabetes, and MASH has been increasing annually, closely associated with lifestyle changes, dietary patterns, and sedentary behavior, representing a key driver of market growth.
- **Trend of multimorbidity:** Conditions such as diabetes, obesity, hyperlipidaemia and hyperuricaemia often coexist in the same patient, with intertwined pathophysiological mechanisms, making single-target interventions insufficient to address clinical needs. As the understanding of metabolic syndrome and its associated complications deepens, clinical practice and research are increasingly focusing on comprehensive therapeutic approaches capable of simultaneously managing glucose, body weight, lipid levels and inflammation.
- **Innovative drug development toward multi-target therapy:** To address the complexity and comorbidity of metabolic diseases, the drug development paradigm is evolving from single-target approaches to multi-target strategies. Whether in the form of multi-target single-molecule drugs based on modern biotechnology, or multi-component drugs derived from natural sources, these therapies can act on multiple targets, providing distinctive advantages in managing complex metabolic conditions.

Overview of the Type 2 Diabetes Drug Market Globally and in China

Overview of Type 2 Diabetes

Diabetes is a chronic metabolic disease characterized by elevated blood glucose. Prolonged hyperglycaemia can cause vascular and nerve damage, leading to cardiovascular and cerebrovascular complications, renal failure, retinopathy, diabetic foot, and neuropathy,

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increasing the risk of disability and premature death. Diabetes is mainly classified into type 1 diabetes and type 2 diabetes. Type 1 diabetes is an autoimmune disease causing absolute insulin deficiency and lifelong insulin dependency, while type 2 diabetes, caused by insulin resistance or insufficient secretion, is the predominant form in China and even globally, accounting for approximately 96% of cases. According to IDF, in the diabetic population, over 70% of patients reported the presence of at least one complication.

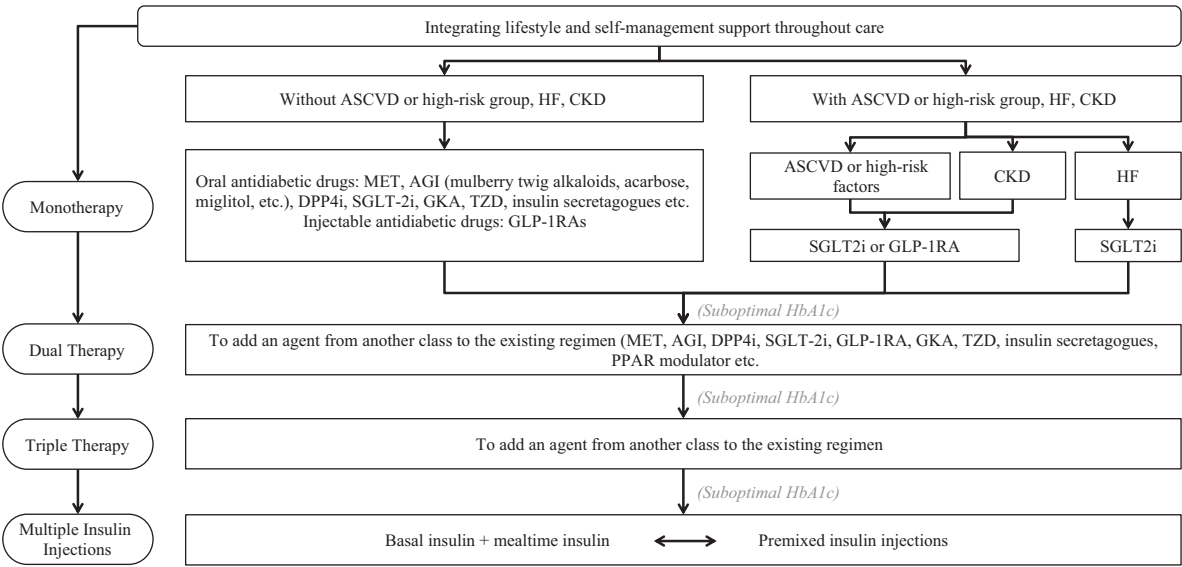
Prevalence of Type 2 Diabetes Globally and in China

According to the International Diabetes Federation (“IDF”), in 2024, the prevalence of diabetes among adults aged 20–79 worldwide was approximately 11%, with type 2 diabetes accounting for over 90% of cases. In China, the prevalence of diabetes among adults was approximately 9.5%. In 2020, the number of individuals with type 2 diabetes was 506.1 million worldwide and 118.9 million in China, both growing at a CAGR of 1.8% to reach 542.9 million and 127.6 million, respectively, by 2024. The global type 2 diabetes population is projected to increase to 609.6 million by 2032, at a CAGR of 1.5%.

Treatment Options for Type 2 Diabetes in China

The table below presents the treatment regimens for type 2 diabetes in China.

Glycemic Management for Type 2 Diabetes



Note: ASCVD, Atherosclerotic Cardiovascular Disease; HF, Heart Failure. CKD, Chronic Kidney Disease. GLP-1RA, Glucagon-Like Peptide-1 Receptor Agonist. SGLT2i, Sodium-Glucose Cotransporter-2 Inhibitor. HbA1c, Glycated Hemoglobin. DPP-4i, Dipeptidyl Peptidase-4 Inhibitor. TZD, Thiazolidinedione. GKA, Glucokinase Activator.

Source: Chinese Guidelines for the Prevention and Treatment of Type 2 Diabetes (2024), National guidelines for the prevention and control of diabetes in primary care (2025), CIC

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Major Type 2 Diabetes drug categories in China

Drug class	MOA	Blood glucose control ¹	Hypoglycemia		Body weight	Risk of muscle loss	Common adverse reaction	Advantage	Limitation
			risk						
GLP-1RA	• Activate GLP-1 receptor, increase insulin secretion, decrease glucagon secretion • Sometimes combined with agonists targeting GCGR and/or GIPR	• High to very high (~1.2%-1.8%)	• x		• Reduction	• High	• GI effects	• Effective blood glucose control and weight loss, cardiovascular benefits	• GI effects, high costs
Metformin	• Decrease in hepatic glucose production; increase in muscle insulin sensitivity by activating AMPK	• High (~1.0%-1.5%)	• x		• Stability	• Neutral	• GI effects	• Low hypoglycemia risk and affordable	• Limited blood glucose control
TZDs	• Bind PPAR-γ, decrease insulin resistance and increase glucose utilization	• High (~0.8%-1.5%)	• x		• Increase	/	• Edema	• Increase HDL cholesterol and reduce triglycerides	• Increased risk of heart failure, dose-dependent AEs, and weight gain
Sulfonylureas	• Stimulates beta cell insulin secretion	• High (~1.0%-1.5%)	• ∇		• Increase	/	• Hypoglycemia	• Affordable	• Hypoglycemia risk and weight gain
DPP-4i	• Prevent degradation of GLP-1	• Intermediate (~0.5%-0.8%)	• x		• Stability	• Neutral	• N/A	• Very low hypoglycemia risk	• Moderate blood glucose control
SGLT2i	• Prevent glucose reabsorption and facilitate its excretion in urine by inhibiting SGLT-2	• Intermediate to high (~0.6%-1.0%)	• x		• Stability	• Neutral	• urinary tract infection	• Cardiorenal protection	• Urinary tract infection
Insulin	• Stimulate glycogen synthesis, increase glycolysis and glucose transport, inhibit glycogenolysis, gluconeogenesis, and glucagon secretion	• High to very high (~1.5%-2.5%)	• ∇		• Increase	/	• Hypoglycemia	• Effective blood glucose control	• Self-management need, hypoglycemia
GKA	• Acts as a glucose sensor, triggering counter regulatory responses following a change in glucose levels to aid restoration of normoglycemia.	• High (~0.7%-1.0%)	• x		• Stability	• Neutral	• N/A	• Oral administration, good blood glucose control	• Limited clinical evidence on cardiovascular effects
Mulberry Twig Alkaloids Tablets (Natural Medicine)	• Inhibit α-glucosidase in the intestine, delay carbohydrate decomposition and glucose absorption, and lower postprandial blood sugar	• High to very high (~1.0%-2.1%)	• x		• Reduction	• Low	• Mild gastrointestinal reactions, which usually subside with prolonged use	• Clear MOA, effective blood glucose control, low hypoglycemia risk, mild gastrointestinal reactions, potential cardiovascular and renal benefits	• More clinical evidence

Note: The values for glycemic control represent the reduction in HbA1c at 24 weeks. Efficacy ratings from “High” to “Very High” denote a strong blood glucose-lowering effect.

Source: Guidelines for the Prevention and Treatment of Type 2 Diabetes in China (2024 Edition), CIC

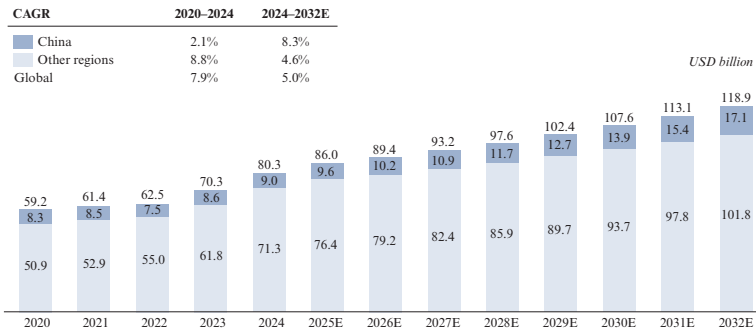
Market Size of Type 2 Diabetes Drugs Globally and in China

In recent years, with the approval of innovative therapies such as Glucagon-Like Peptide-1 Receptor Agonists (“GLP-1RA”) and Mulberry Twig Alkaloid Tablets, the Chinese type 2

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diabetes drug market has attracted increasing attention. The table below presents the historical and projected market size of type 2 diabetes drugs globally and in China from 2020 to 2032.

Global and China’s Type 2 Diabetes drug market size, 2020–2032E



Source: NMPA, FDA, IDF, periodic reports published by listed companies, interviews with industry experts, CIC.

Trends of Clinical Demand for Type 2 Diabetes Drugs Globally and in China

With the global population of type 2 diabetes patients continuing to expand and the onset of the disease occurring increasingly at younger ages, diabetes management is shifting from single glycaemic control toward comprehensive, multi-benefit strategies that address cardiovascular, renal, and metabolic comorbidities. At the same time, growing emphasis on long-term safety and tolerability, particularly for younger patients, and increasing demand for convenient, preferably oral, therapies are reshaping drug development priorities.

Competitive Landscape of Natural Medicine Market for Type 2 Diabetes in China

As of the Latest Practicable Date, only one Natural Medicine for the treatment of type 2 diabetes has been approved in China, namely *Sangbo'en*, which were launched by our Company in 2020. In addition, there is no other Natural Medicine currently in clinical trials in China for the treatment of type 2 diabetes.

Market-Approved Natural Medicines for Type 2 Diabetes in China

Drug name	Drug class	Company	Indication(s)	First approval date	Route of Administration	NRDL year
<i>Sangbo'en</i>	TCM category 1.2	Our Company	Type 2 Diabetes	03/17/2020	Oral	2020

Source: NMPA, CIC

Overview of the PCOS Drug Market Globally and in China

Overview of PCOS

PCOS is a complex reproductive endocrine and metabolic disorder affecting women throughout their lifespan. PCOS is the most common cause of menstrual irregularities and anovulatory infertility, and it also represents a high-risk factor for early miscarriage, gestational diabetes, and endometrial cancer.

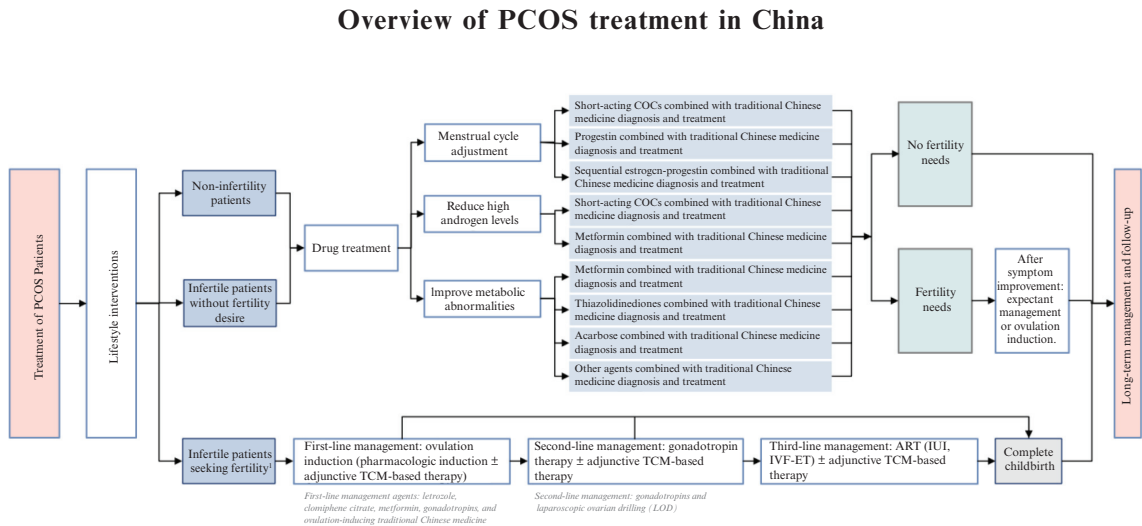
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The pathogenesis of PCOS is complex, involving both external and internal factors. External factors include epigenetics, environmental toxins, physical and emotional stress, and dietary influences, while internal factors include hyperandrogenemia, insulin resistance, and obesity. Dysregulation of the HPO axis and the resulting hyperandrogenemia are currently recognized as one of the core pathological mechanisms, with insulin resistance potentially affecting PCOS directly or indirectly via the HPO axis.

Prevalence of PCOS Globally and in China

According to the WHO, PCOS affects approximately 6%-13% of women of reproductive age worldwide. In population-based estimate, the prevalent rate is 7.8% in China, 10.5% in the US, 11.7% in Europe, and as high as 15.1% in the Middle East regions. Key risk factors include endocrine-disrupting chemicals in industrialized environments, obesity and increased visceral fat, as well as a diet high in calories and fat combined with a sedentary lifestyle. Globally, there were an estimated 200.9 million women living with PCOS in 2024, of whom approximately 34.4 million were in China. The total number of affected individuals is expected to increase further in the coming years.

Treatment Options for PCOS in China



Note: 1. For PCOS patients with infertility solely due to anovulation.

Source: Expert consensus on the pathway of diagnosis and management of polycystic ovary syndrome (2023), PCOS Integrated TCM & Western Medicine Guidelines (2024), CIC

Given the complex etiology of PCOS, which involves multiple pathogenic mechanisms, current medical treatments primarily focus on symptomatic management and may have limitations in addressing the full spectrum of its underlying pathophysiology. In contrast, multi-component Natural Medicines may exert synergistic effects through multiple targets and pathways, thereby enabling a more comprehensive modulation of key pathological processes in PCOS, such as endocrine dysregulation and insulin resistance. As a result, Natural Medicines may offer potential advantages in improving PCOS-related symptoms and associated metabolic abnormalities.

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Analysis of Unmet Clinical Needs in PCOS Drug Therapy Globally and in China

There are no globally approved therapies targeting PCOS. Current management relies on off-label symptomatic treatments — including oral contraceptives, insulin sensitizers, anti-androgens, and ovulation-inducing agents — that may not address its underlying pathophysiology and may not meet the patient needs for natural fertility.

Market Size of PCOS Drugs Globally and in China

According to CIC, the global PCOS drug market is expected to grow from approximately US\$4.3 billion in 2020 to around US\$7.3 billion by 2032E, representing a CAGR of 4.3% in the historical period and 4.6% in the forecast. Among this, the CAGR in China is significantly higher than the global average, 5.9% for the historical and 6.8% for the forecast.

Competitive Landscape of Natural Medicines for PCOS in China

As of the Latest Practicable Date, no drugs have been approved for the direct treatment of PCOS. Only WH007 is planned to initiate a Phase II clinical development in 2026.

Clinical pipelines of Natural Medicines under development for the treatment of PCOS in China, as of the Latest Practicable Date

<u>Drug name</u>	<u>Drug class</u>	<u>Company</u>	<u>Indication(s)</u>	<u>Phase</u>	<u>Route of administration</u>	<u>First posted date</u>
WH007	TCM category 2.3	Our Company	PCOS	Phase II to be initiated	Oral	/

Source: CDE, CIC

Overview of the Obesity Drug Market Globally and in China

Overview of Obesity

The WHO defines obesity as abnormal or excessive fat accumulation that presents a risk to health. Obesity is a chronic disease and a major contributing factor to various other chronic conditions. In recent years, the prevalence of overweight and obesity in China has continued to rise, making obesity a significant public health issue and the sixth leading risk factor for death and disability in the country.

Obesity can independently or in combination with other diseases contribute to or exacerbate various health complications. It increases the risk of cardiovascular diseases, particularly heart failure, coronary heart disease, and arthritis. Overweight and obesity are also major risk factors for prediabetes and type 2 diabetes, with higher degrees of obesity correlating with greater risk. According to World Obesity Federation and based on established literature, among individuals with obesity, the prevalence of prediabetes and type 2 diabetes is 43.1% and 23.0%, respectively. Driven by strong market demand and demonstrated efficacy, GLP-1RA-based therapies have acquired much significance globally. However, certain limitations remain in their clinical use. Current drug development trends are primarily focused on multi-target therapies and their oral formulations. The mechanistic characteristics of multi-component natural medicines are better positioned to meet the needs of obesity drug development.

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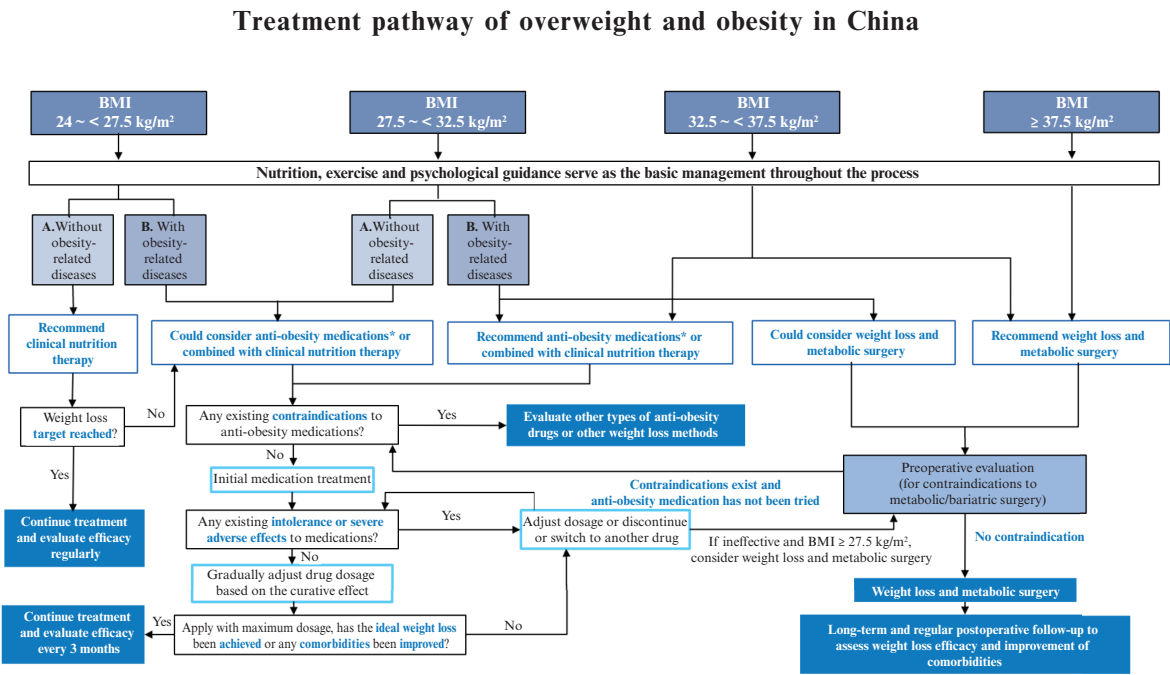
Prevalence of Obesity Globally and in China

Based on World Obesity Federation, obesity has also become an increasingly severe global public health issue, with China having the largest population of individuals affected. According to Chinese standards, the prevalence of overweight and obesity among Chinese adults is 34.3% and 16.4%, respectively. Among children and adolescents aged 6–17 years, the prevalence of overweight and obesity is 11.1% and 7.9%, respectively. And among children under 6 years old, the prevalence of overweight and obesity is 6.8% and 3.6%, respectively. Significant regional variations in overweight and obesity prevalence exist within the Chinese population.

According to WHO, in 2024, the global population with obesity is estimated at 1,002.7 million, projected to grow at a CAGR of 2.9% to reach 1,261.0 million by 2032. In China, the number of individuals with obesity is estimated at 277.4 million in 2024, rising to 330.3 million by 2032.

Treatment Options for Obesity in China

The figure below illustrates the obesity and overweight treatment framework recommended by Chinese national guidelines:



Note: anti-obesity medications e.g., Orlistat, GLP-1 RAs

Source: Chinese Guidelines for the Clinical Management of Obesity (2024 Edition), CIC

Analysis of Unmet Clinical Needs in Obesity Drug Therapy Globally and in China

The current unmet clinical needs in obesity therapy, both globally and in China, include three key aspects. Firstly, existing therapies cannot reduce fat mass without muscle loss. Optimal therapies should therefore enable scientifically guided weight management, reducing fat while preserving muscle to optimize overall health. Secondly, durable long-term efficacy is

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essential, as most current treatments lose effectiveness over time, highlighting the need for interventions that support stable weight maintenance for instance, by multi-target or multi-component therapies. And finally, as adverse effects such as gastrointestinal discomfort, hypoglycemia, pancreatitis, and rare serious risks reduce patient compliance, the safety and tolerability are become major issues. Therefore, there is a strong demand for therapies that are effective, safe, and sustainable for long-term obesity management.

Market Size of Obesity Drug Therapy Globally and in China

In 2024, the global market size of obesity drug is estimated at US\$18.6 billion, projected to grow at a CAGR of 15.6% to reach US\$59.1 billion by 2032. In China, the market size of obesity drug is estimated at US\$0.3 billion in 2024. With the approval of innovative drugs such as GLP-1R, the market will rapidly increase to US\$7.4 billion by 2032 according to annual reports.

Competitive Landscape of Natural Medicine Market for Obesity in China

As of the Latest Practicable Date, no Natural Medicines have been approved for the treatment of obesity in China. At the same time, only one natural product is currently in clinical development, undergoing a Phase II clinical trial.

Clinical pipelines of Natural Medicines under development for the treatment of obesity in China, as of the Latest Practicable Date

<u>Drug Name</u>	<u>Drug Class</u>	<u>Company</u>	<u>Indication(s)</u>	<u>Phase</u>	<u>Route of administration</u>	<u>First Posted Date</u>
WH006	TCM Category 2.3	Our Company	Obesity or overweight in adults	Phase II	Oral	08/21/2025

Source: CDE, CIC

OVERVIEW OF GLOBAL AND CHINA’S ANTI-TUMOR CHEMOTHERAPY MARKET

Incidence of Cancer Globally and in China

In 2024, approximately 20.8 million new cases of malignant tumors are expected worldwide, with around 5.1 million new cases in China. Breast cancer is the most commonly diagnosed malignancy among women globally, accounting for approximately 24.0% of all new female cancer cases, and ranks among the top three high-incidence cancers in Chinese women. With population aging, environmental factors, and lifestyle changes, the overall cancer incidence in China and globally continues to rise, with certain cancer types trending younger, thereby increasing the demand for early screening, accurate diagnosis, and effective treatment.

Market Size of Anti-tumor Drug Globally and in China

Anti-tumor drugs can be broadly categorized into chemotherapy, immunotherapy, and targeted therapy. According to CIC, the global anti-tumor drug market reached US\$262.1 billion in 2024. The China anti-tumor drug market grew from US\$25.8 billion in 2020 to US\$37.2 billion in 2024, representing a CAGR of 9.6%. The market is expected to continue growing at a CAGR of 15.5%, reaching US\$113.4 billion by 2032. Chemotherapy, as a critical

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modality in cancer treatment, has been applied for several decades and remains one of the widely adopted systemic treatment approaches. In 2024, chemotherapy drugs accounted for over 40% of the total anti-tumor drug market in China.

Natural Medicines have consistently played a significant role in anti-tumor treatment, particularly active monomers derived from natural plants. Approximately 50% of previously approved anti-tumor small-molecule drugs are either directly or indirectly sourced from natural products, including plants, marine organisms, and microorganisms. Plant-derived monomers, such as paclitaxel, camptothecin, podophyllotoxin, and their semi-synthetic derivatives, have formed the core foundation of modern chemotherapy drug systems. Natural monomers are characterized by structural diversity, unique targets of action, and high-efficiency intervention in key cellular pathways, providing irreplaceable templates for new drug development.

Overview of Breast Cancer Drug Market Globally and in China

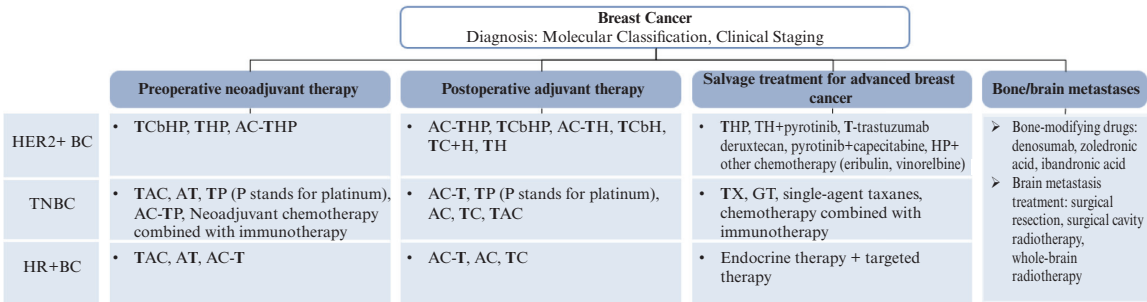
Overview of Breast Cancer and Its Epidemiology

As the most common malignant tumor among newly diagnosed women worldwide, according to WHO Global Cancer Observatory, in 2024, the number of new breast cancer cases globally and in China is estimated to be approximately 2,397.0 thousand and 374.7 thousand, respectively, and it is projected that the global incidence will exceed 2,700 thousand new cases by 2032. As reported in the peer-reviewed literature, among all breast cancer cases, approximately 80% are HER2-negative. Within this HER2-negative population, about 80% are classified as HR-positive Luminal subtype breast cancer and 20% are classified as triple-negative breast cancer. Approximately 30% of patients with HR + /HER2– breast cancer are diagnosed at an advanced stage. The five-year survival rate for advanced and metastatic HR + /HER2– breast cancer in China is estimated to be around 20%, underscoring the urgent need for more effective treatment strategies.

Treatment Pathways for Breast Cancer in China

Breast cancer treatment is typically individualized based on tumor molecular subtype, disease stage, and the overall condition of the patient, encompassing surgery, radiotherapy, endocrine therapy, targeted therapy, immunotherapy, and chemotherapy. For early-stage and locally advanced breast cancer, surgery remains the cornerstone of curative treatment. Within this comprehensive treatment framework, chemotherapy — including paclitaxel — continues to play an indispensable role, maintaining a pivotal position across all stages of the disease.

BC treatment pathway in China



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Note: **T.** Taxanes, including docetaxel, nab-paclitaxel, and paclitaxel; **A.** Anthracyclines, including epirubicin, pirarubicin, and doxorubicin; **C.** Cyclophosphamide; **Cb.** Carboplatin; **H, P.** Trastuzumab, pertuzumab, and their subcutaneous formulations approved in China; **X.** Capecitabine; **G.** Gemcitabine.

Source: CSCO, CIC

According to the *Expert consensus on the clinical practice of taxanes for the treatment of breast cancer*, paclitaxel-based therapies have established a well-recognized role in breast cancer chemotherapy following more than 20 years of clinical research and application. Paclitaxel demonstrates high efficacy as monotherapy and are frequently used in combination with other chemotherapeutic or targeted agents.

In recent years, the use of neoadjuvant therapy has become increasingly prevalent in breast cancer treatment strategies. For certain patients, administering paclitaxel-based chemotherapy prior to surgery can significantly reduce tumor size and downstage the disease, thereby creating more favorable conditions for subsequent surgical intervention and enabling surgery for patients who were initially considered inoperable. Neoadjuvant therapy also plays an important role in improving prognosis, increasing the likelihood of breast-conserving surgery, and providing valuable information for evaluating drug efficacy and guiding subsequent individualized treatment.

Market Size of Luminal Subtype Breast Cancer Drug Therapy Globally and in China

According to CIC analysis, the global market size for Luminal subtype breast cancer drug therapy is expected to demonstrate steady growth over the period from 2020 to 2032E. The market expanded from approximately US\$20.6 billion in 2020 to about US\$26.5 billion in 2024, and is projected to further increase to around US\$40.0 billion by 2032. During the same period, China’s market grew from roughly US\$2.1 billion in 2020 to approximately US\$2.6 billion in 2024, and is expected to reach about US\$4.4 billion by 2032.

Unmet Clinical Needs of Paclitaxel-Based Therapies in Neoadjuvant Treatment of Breast Cancer

Paclitaxel-based combination neoadjuvant chemotherapy regimens constitute the current standard of care for breast cancer treatment. However, according to Global Breast Cancer Conference, the total pathological complete response (“**tpCR**”) rate among Luminal subtype breast cancer patients was reported to be only 9.3%, indicating suboptimal response to conventional paclitaxel therapy, limited tumor shrinkage, and difficulty in achieving ideal surgical downstaging or breast-conserving opportunities. These observations highlight the urgent need to optimize administration methods to further unlock the antitumor potential of paclitaxel.

Clinical Pipelines of Paclitaxel-Based Neoadjuvant Therapy for Luminal Subtype Breast Cancer in China

Currently, according to public clinical trial information registered under NMPA, there is only one clinical product under research in China for the neoadjuvant treatment of breast cancer using paclitaxel-based drugs.

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Market Drivers for Neoadjuvant Breast Cancer Therapies in China

In recent years, China’s neoadjuvant breast cancer drug market has expanded rapidly, driven by growing clinical demand. With the release of updated neoadjuvant treatment guidelines and the advancement of standardized clinical practice, the role of neoadjuvant therapy in preoperative tumor downstaging and improving postoperative outcomes has become increasingly prominent. Multicenter data indicate that during the past decade, the utilization rate of neoadjuvant therapy increased from approximately 15.9% to over 30%, and is expected to further rise, reflecting its expanding clinical adoption nationwide. Beyond improving pathological complete response rates, neoadjuvant therapy enhances opportunities for surgical downstaging, thereby supporting sustained growth in the associated pharmaceutical market.

Overview of Raw Material Price

Mulberry twig. Mulberry twig are the key raw materials of Mulberry Twig Alkaloids. The reference price for bulk procurement of mulberry twig for production purposes is approximately RMB600 per metric ton, subject to variations based on specifications and origin, and has remained relatively stable in recent years.

Source of information

In connection with the [REDACTED], we have engaged CIC to conduct an in-depth analysis of our identified principal markets and to prepare an industry report. CIC is an independent global market research and consulting firm that provides market research services across various industries, including biotechnology. We have agreed to pay CIC total fees of RMB580.0 thousand for the preparation of the CIC Report, and we believe such fees are consistent with market rates. Payment of such fees is not contingent upon whether we successfully [REDACTED] or the outcome of the CIC Report. Other than the CIC Report, we have not commissioned any other industry report in connection with the [REDACTED].

The market forecasts contained in the CIC Report are based on the following key assumptions: (i) China’s overall social, economic and political environment is expected to remain stable during the forecast period; (ii) over the next ten years, China’s economic and industry development is likely to maintain a steady growth trend; (iii) relevant key industry drivers are expected to continue to propel market growth during the forecast period; and (iv) there will be no extreme force majeure events or industry regulatory changes that could materially or fundamentally affect the market. The accuracy of the above key assumptions may affect the reliability of the CIC Report.