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Regulatory Trends

State Council Issued “Regulation on the Administration of Clinical Research and Clinical Transformation and Application of New Biomedical Technologies”

Recently, Li Qiang, Premier of the State Council, signed a Decree of the State Council to promulgate the “*Regulation on the Administration of Clinical Research and Clinical Transformation and Application of New Biomedical Technologies*” (hereinafter referred to as the “*Regulation*”), which shall come into force on May 1, 2026.

The “*Regulation*” aims to regulate the clinical research and clinical transformation and application of new biomedical technologies, promote the progress and innovation of medical science and technology, ensure the quality and safety of medical care, and safeguard human dignity and health. Consisting of 7 Chapters and 58 Articles, the “*Regulation*” mainly stipulates the following contents:

1. Clarify general requirements. It stipulates that carrying out clinical research and clinical transformation and application of new biomedical technologies shall adhere to taking people’s health as the central task, persist in innovation-driven development, attach equal importance to development and safety, encourage and support clinical research and clinical translation applications, and strengthen the whole-process safety management.

2. Standardize clinical research. It stipulates that new biomedical technologies can be used for clinical research only after being proven safe and effective through non-clinical research and passing academic review and ethical review. Clinical research shall be filed with the National Health Commission of the State Council, which will assess the filed clinical research and promptly correct or even terminate it if risks are identified. The management of clinical research implementation is strengthened and measures are taken to prevent, control and handle risks. The protection of subjects’ rights and interests is enhanced, emphasizing that clinical research must respect the will of the subjects, no fees shall be charged to the subjects, and timely treatment shall be provided if subjects suffer any health damage.

Support transformation and application. It stipulates that new biomedical technologies that have been proven safe, effective through clinical research and conform to ethical principles can be transformed and applied in clinical practice upon approval by the National Health Commission of the State Council, with clear approval procedures and time limits specified. When approving the clinical transformation and application of the new biomedical technologies, the National Health Commission of the State Council shall concurrently announce the conditions that medical institutions and professional and technical personnel applying the technology shall meet, as well as the clinical application operation specifications, to ensure the quality and safety of clinical application. It also stipulates that the National Health Commission of the State Council shall re-evaluate the new biomedical technologies for clinical transformation and application in light of the development of scientific research, and prohibit clinical application if the evaluation shows that safety and effectiveness cannot be guaranteed.

In addition, the Regulation stipulates strict legal liabilities for illegal acts in the clinical research and clinical transformation and application of new biomedical technologies.

Source: Xinhua News Agency

2025 Edition of “*Pharmacopoeia of the People’s Republic of China*” Enforced on October 1

The 2025 Edition of the “*Pharmacopoeia of the People’s Republic of China*” has been enforced since October 1 this year, serving as the statutory technical standard to be followed by all relevant entities involved in drug research and development, production (importation), operation, use, and supervision and administration.

This edition of the “*Pharmacopoeia*” includes a total of 6,385 varieties, with 159 newly added, 1,101 revised, and 32 no longer included. Specifically:

Volume I (Traditional Chinese Medicines): 3,069 varieties, including 28 new additions, 420 revisions, and 19 no longer included.

- Volume II (Chemical Drugs): 2,776 varieties, including 66 new additions, 483 revisions, and 2 pharmaceutical excipient varieties no longer included here and transferred to Volume IV for inclusion.

- Volume III (Biological Products): 153 varieties, including 13 new additions, 62 revisions, and 13 no longer included.

Volume IV (Pharmaceutical Excipients): 387 varieties, including 52 new additions and 136 revisions.

The edition also includes 410 general technical requirements (69 new additions, 133 revisions) and 72 guiding principles (33 new additions, 17 revisions, 3 no longer included).

Source: <https://www.cnpharm.com/>

China Planned to Accelerate Post-Marketing Research and Evaluation of Traditional Chinese Medicine Injections

The National Medical Products Administration recently issued the “*Announcement of the National Medical Products Administration, the National Health Commission, and the National Administration of Traditional Chinese Medicine on Further Promoting Drug Marketing Authorization Holders to Accelerate Post-Marketing Research and Evaluation of Traditional Chinese Medicine Injections (Draft for Comment)*” to solicit public opinions. The draft clarifies that it will promote drug marketing authorization holders to accelerate post-marketing research and evaluation of traditional Chinese medicine injections through a combination of voluntary and mandatory measures, ultimately achieving the goal of “voluntarily evaluating some, mandatorily evaluating some, and eliminating some in accordance with the law”.

The draft specifies that drug marketing authorization holders are the primary responsible persons for the quality and safety of traditional Chinese medicine injections. They shall voluntarily conduct post-marketing research and evaluation, conduct in-depth research on the material basis and the mechanism of action related to clinical efficacy, verify product safety and effectiveness, and improve quality controllability. Before initiating research and evaluation, the holders shall first assess the clinical safety and efficacy of the varieties; for those failing to meet expectations, it is possible to voluntarily apply for the cancellation of their approval numbers; and for those meeting expectations, research may be promoted in accordance with technical requirements, and all data must be true, accurate and traceable.

Source: Xinhua News Agency

National Medical Products Administration Issued “*Guidelines for On-Site Inspection of Quality Management Specifications for Online Sales of Medical Devices*”

Recently, the National Medical Products Administration issued a notice to promulgate the “*Guidelines for On-Site Inspection of Quality Management Specifications for Online Sales of Medical Devices*”. The “*Guidelines*” apply to the supervision and inspection conducted by drug regulatory departments in accordance with the law on online sellers of medical devices and operators of e-commerce platforms for medical devices.

[Source: National Medical Products Administration](#)

China Biotech Conference Opened in Wuhan

On September 4, the 17th China Biotech Conference was held at the China Optics Valley Science and Technology Convention and Exhibition Center in Wuhan. Through five sections including policy interpretation, technical seminars, resource coordination, international cooperation, and achievement transformation, as well as professional exhibitions, the conference allowed participants to “one-stop” experience the strength and innovative achievements of China’s biotech industry.

The conference was co-hosted by 17 national societies (associations) including the Chinese Society of Biotechnology, and the China Science Daily. In addition to the opening ceremony, i.e. the summit forum on biomanufacturing, the conference also featured over 10 specialized sub-forums focusing on specific fields. These covered a range of cutting-edge areas, including synthetic biology, biomedicine, high-end medical equipment, brain science, AI + biotech, and stem cell therapy.

At the conference site, the “*China Bioeconomy Development Report 2025*” was released, the launching ceremony of the national innovative drug “Insight” system was held, awards were presented to winners of the 2025 Biomanufacturing Innovation and Entrepreneurship Competition, and an innovation list was announced.

[Source: China News Network](#)

SASAC: Accelerate the Development of the Biomedical Industry and Build a National Team in the Biomedical Field

From August 27 to 30, the State-owned Assets Supervision and Administration Commission of the State Council (SASAC) and the Chinese Academy of Sciences co-hosted the Advanced Seminar on Biotech Industry for Central Enterprises. Tan Zuojun, Vice Chairman of SASAC, attended the opening and closing ceremonies and delivered speeches. He emphasized that centering on serving the construction of Healthy China, we should accelerate the development of the biomedical industry of central enterprises, adhere to innovation-driven development, long-term development, and differentiated development. Through in-depth learning, ideological collision, and brainstorming, we should more clearly judge the development trend of the biomedical industry, more accurately grasp the key development directions and implementation paths of central enterprises, and more actively promote industry-university-research application collaborative innovation with institutes of the Chinese Academy of Sciences, so as to accelerate the building of a national team in the biomedical field and promote the high-quality development of China’s biomedical industry.

[Source: Economic Observer Online](#)

China's First Provincial-Level Compliance Guidelines for Biomedical Enterprises to Be Released

The 2025 “National Drug Safety Public Awareness Week” was held from September 1 to 7. Relying on the national platform, the Beijing Municipal Drug Administration will launch a series of thematic publicity activities through the linkage of municipal and district drug regulatory departments to form a setup of co-governance and shared drug safety governance. During the event, Beijing will release China’s first provincial-level compliance guidelines for biomedical enterprises.

Source: [Beijing Municipal People's Government](#)

27th International Analytical Ultracentrifugation Symposium Held at Tsinghua University

From August 24 to 30, the 27th International Analytical Ultracentrifugation Symposium (AUC 2025) was held at Tsinghua University. Nearly 130 experts and scholars from around the world gathered at Tsinghua Campus to conduct in-depth exchanges on the cutting-edge applications of analytical ultracentrifugation technology in fields such as life sciences, biomedicine, and materials science. This is also the first time this international academic conference has been held in China.

Source: [Tsinghua University](#)

Three Ministries and Commissions Jointly Issued Updated Catalogs Related to Narcotic and Psychotropic Drugs

Recently, the National Medical Products Administration (NMPA), the Ministry of Public Security, and the National Health Commission jointly issued an announcement on releasing catalogs of medicinal narcotic drugs and psychotropic drugs, including the 2025 Edition of the Catalog of Medicinal Narcotic Drugs and the 2025 Edition of the Catalog of Medicinal Psychotropic Drugs. In addition, the three ministries and commissions also jointly released the Catalog of Non-Medicinal Narcotic Drugs and Psychotropic Drugs. The above catalogs have all come into force on the date of release.

The Catalog of Medicinal Narcotic Drugs includes 32 varieties such as alfentanil, alphaprodine, and anileridine. The Catalog of Medicinal Psychotropic Drugs includes 18 varieties of Class I psychotropic drugs and 78 varieties of Class II psychotropic drugs. Suvorexant, which was regulated in the 2023 version, has been removed from the Catalog of Medicinal Psychotropic Drugs, while cebranopadol, zuranolone, serdexmethylphenidate, and valiloxylate have been newly added. In addition, etizolam, which was previously regulated as a non-medicinal narcotic and psychotropic drug, has been adjusted to the Catalog of Medicinal Psychotropic Drugs.

The Catalog of Non-Medicinal Narcotic Drugs and Psychotropic Drugs includes not only 231 varieties from the Supplementary Catalog of Previously Regulated Non-Medicinal Narcotic and Psychotropic Drugs, 3 categories (fentanyl-related substances, synthetic cannabinoids, and nitazenes), but also 91 varieties split from the 2013 Edition of the Catalog of Narcotic Drugs and 74 varieties split from the 2013 Edition of the Catalog of Psychotropic Drugs (no longer distinguishing between Class I and Class II psychotropic drugs), totaling 396 varieties and 3 categories.

Source: [National Medical Products Administration](#)

Two guidelines for the R&D of drugs for rare diseases released

Recently, the Center for Drug Evaluation (CDE) of the NMPA released the “*Technical Guiding Principle for*

Clinical Pharmacology Research of Drugs for Rare Diseases” and the “*Technical Guiding Principle for Model-Guided Drug Development for Rare Diseases*”, which apply to the R&D of drugs for rare diseases, including chemical drugs and biological products.

The “*Technical Guiding Principle for Clinical Pharmacology Research of Drugs for Rare Diseases*” covers general considerations, basic considerations for study design, research considerations for different molecular types of drugs, and communication and exchange. Regarding research considerations for different molecular types of drugs, it introduces gene therapy drugs, cell therapy drugs, small molecule drugs, and other types of drugs, respectively, emphasizing that while referring to the “*Technical Guiding Principle for Clinical Pharmacology Research of Innovative Drugs*”, more attention should be paid to “specific drugs for specific diseases, and specific analysis for specific issues”.

The “*Technical Guiding Principle for Model-Guided Drug Development for Rare Diseases*” includes overall considerations, application scenarios, modeling and simulation methods, research considerations for different molecular types of drugs, and communication and exchange. The section on modeling and simulation methods states that it is necessary to fully tap and utilize all available data in the R&D of drugs for rare diseases, including, but not limited to, non-clinical research data, real-world data, literature data, and pre-marketing clinical trial data. The non-clinical research data includes, but not limited to, genetic, molecular, cellular, organoid, organ-on-a-chip, and animal research data.

Source: <https://www.cnpharm.com/>

Signing Ceremony of Joint Fund for Innovative Development of Private Enterprises under the National Natural Science Foundation of China Held in Beijing

On June 30, the signing ceremony of Joint Fund for Innovative Development of Private Enterprises under the National Natural Science Foundation of China was held in Beijing. Four private enterprises, namely Jiangsu Hengrui Pharmaceuticals Co., Ltd. (hereinafter referred to as Hengrui Pharma), Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (hereinafter referred to as Mindray), Hang Zhou Singclean Medical Products Co., Ltd. (hereinafter referred to as Singclean Medical), and Qilu Pharmaceutical Co., Ltd. (hereinafter referred to as Qilu Pharmaceutical), officially joined the Joint Fund for Innovative Development of Private Enterprises under the National Natural Science Foundation of China (hereinafter referred to as the Private Enterprise Joint Fund), marking a key step for Chinese private enterprises to deeply participate in national basic research.

Source: National Natural Science Foundation of China

Guiding Principle for Locally Acting Chemical Generic Drugs Released

Recently, the Center for Drug Evaluation (CDE) of the NMPA released the “*Technical Guiding Principle for In Vitro Release (IVRT) and In Vitro Permeation (IVPT) Studies of Locally Acting Chemical Generic Drugs (Trial)*”.

The “*Guiding Principle*” mainly elaborates on general considerations and recommendations for the method development, method validation, and implementation of IVRT and IVPT studies of chemical generic drugs, mainly including method development, method validation, sample analysis method validation, formal determination and research, data statistical analysis, and equivalence determination etc.

In Vitro Release Test (IVRT) can be used to evaluate the drug release rate of preparations, and *In Vitro* Permeation Test (IVPT) can be used to evaluate the transdermal penetration behavior of drugs and simulate the transdermal process of drugs under physiological conditions. The “*Guiding Principle*” is mainly applicable to semi-solid generic chemical drugs (ointments, creams, gels) for topical skin use or transdermal administration with

local effects. When conducting IVRT/IVPT comparative studies between generic drugs and reference preparation with reference to relevant guiding principles and drug-specific guidelines, this *Guiding Principle* can be referred to.

Source: [Center for Drug Evaluation, National Medical Products Administration](#)

NMPA Issued “*Catalog of In Vitro Diagnostic Reagents Exempted from Clinical Trials (2025)*”

Recently, the National Medical Products Administration (NMPA) issued the “*Catalog of In Vitro Diagnostic Reagents Exempted from Clinical Trials (2025)*”, which was revised by the NMPA in accordance with the “*Measures for the Administration of Registration and Filing of In Vitro Diagnostic Reagents*”.

Source: [National Medical Products Administration](#)

CDE of NMPA Released “*Annual Report on the Progress of New Drug Registration Clinical Trials in China (2024)*”

On June 19, 2025, to show the current status of new drug registration clinical trials in China, further improve the transparency of clinical trials, and provide scientific reference for new drug R&D, review and approval, the Center for Drug Evaluation (CDE) of NMPA systematically sorted out the clinical trials for new drug registration in China in 2024 based on clinical trial data from the Drug Clinical Trial Registration and Information Disclosure Platform. It summarized and analyzed from aspects such as the overall overview of clinical trial registration, basic characteristics of clinical trials of various drug types, implementation status, and quality control, and compiled the “*Annual Report on the Progress of New Drug Registration Clinical Trials in China (2024)*”.

Source: [Center for Drug Evaluation, National Medical Products Administration](#)

CSRC: Launch “1+6” Policy Measures to Further Deepen the Reform of the Science and Technology Innovation Board

On June 18, 2025, Wu Qing, Chairman of the China Securities Regulatory Commission (CSRC), stated at the 2025 Lujiazui Forum that he will continue to give full play to the demonstration effect of the Science and Technology Innovation Board (STAR Market) and vigorously launch the “1+6” policy measures to further deepen the reform.

He introduced that “1” means setting up a science and technology innovation growth layer on the STAR Market and restarting the listing of unprofitable enterprises under the fifth set of standards of the STAR Market, so as to more accurately serve high-quality technology enterprises with major technological breakthroughs, broad commercial prospects, and continuous R&D investment. At the same time, special arrangements will be made to strengthen information disclosure and risk disclosure, and improve investor suitability management.

“6” refers to 6 innovative reform measures launched on the STAR Market, including: piloting the introduction of a qualified institutional investor system for enterprises applying the fifth set of standards of the STAR Market; piloting the pre-review mechanism for IPOs for high-quality technology enterprises; expanding the scope of application of the fifth set of standards to support more cutting-edge technology fields such as artificial intelligence, commercial aerospace, and low-altitude economy; supporting unprofitable technology enterprises under review to carry out capital increase and share expansion for existing shareholders; improving the refinancing system and strategic investor identification standards for STAR Market companies; and increasing investment products and risk management tools on the STAR Market.

Wu Qing also revealed that the third set of standards will be officially activated on the ChiNext to support the listing of high-quality unprofitable innovative enterprises.

When introducing the advantages of further strengthening the linkage between equity and debt to serve technological innovation, Wu Qing said that efforts will be made to develop science and technology innovation bonds, optimize the issuance and trading system arrangements, promote the improvement of supporting mechanisms such as interest subsidies and guarantees, accelerate the launch of science and technology innovation bond ETFs, and actively develop equity-debt hybrid products such as exchangeable bonds and convertible bonds.

Source: Xinhua News Agency

National Health Commission Issued “*Guidelines for the Construction and Management of Geriatrics Departments (2025 Edition)*”

On May 8, the National Health Commission issued the “*Guidelines for the Construction and Management of Geriatrics Departments (2025 Edition)*”, which clearly requires that qualified secondary and above general hospitals should set up geriatrics departments and refine standards for department settings, staffing, service models, etc.

Revised on the basis of the 2019 pilot version, the new Guidelines emphasize that geriatrics departments should be centered on elderly patients, strengthen the early screening, early diagnosis and early treatment of key diseases in the elderly population, standardize the conduct of comprehensive geriatric assessment while providing diagnosis and treatment of various diseases, strengthen the management of geriatric syndromes and the treatment of comorbidities, enhance the guidance on safe medication, pay attention to the mental health of the elderly, and maximize the maintenance or improvement of the functional status of the elderly and improve their ability to live independently and quality of life.

Source: National Health Commission

NMPA Issued “*Quality Management Specifications for Online Sales of Medical Devices*”

On April 28, the NMPA issued the “*Quality Management Specifications for Online Sales of Medical Devices*” (hereinafter referred to as the “*Specifications*”). As the basic requirement for the quality management of online sales of medical devices, the “*Specifications*” provide guidance for operators engaged in online sales of medical devices and e-commerce platform operators providing online trading services for medical devices, and shall come into force on October 1, 2025.

Consisting of 4 chapters and 50 articles, the “*Specifications*” mainly provide guidance for the management of online sellers of medical devices and e-commerce platform operators. Firstly, basic principles are clarified. Engaging in online sales of medical devices and providing e-commerce platform services for online trading of medical devices shall adhere to honesty, trustworthiness, and risk governance, ensure that the information on medical devices sold online is true, accurate, complete and traceable, and take effective measures to prevent and control the quality and safety risks of medical devices sold online. Secondly, online sales behaviors are standardized. It stipulates that medical device enterprises engaged in online sales should display business entity information and product information, and strengthen the construction of quality management systems, including key contents such as the establishment of quality management institutions, personnel training, software and hardware equipment, system documents, online sales records, and transportation. Thirdly, the management of e-commerce platforms is strengthened. e-commerce platform operators shall be guided to take effective quality control

measures throughout the whole process of providing online trading services for medical devices, including system establishment, institutional responsibilities, organizational personnel, document and data management, management of online operators, quality and safety risk management, system review and continuous improvement, so as to fully ensure the quality, safety and traceability of medical devices sold online.

Source: National Medical Products Administration

CDE Released “Simplified Application Materials and Technical Requirements for the Registration and Approval of Traditional Oral Chinese Patent Medicines Already Marketed in Hong Kong and Macao in the Mainland”

On April 18, the CDE of the NMPA released the “*Simplified Application Materials and Technical Requirements for the Registration and Approval of Traditional Oral Chinese Patent Medicines Already Marketed in Hong Kong and Macao in the Mainland*”, elaborating on the simplified requirements for the registration, post-marketing changes and re-registration of traditional oral Chinese patent medicines already marketed in Hong Kong and Macao in the Mainland.

The technical requirements clarify that the application materials to be submitted for registration include three parts: administrative documents, pharmaceutical materials, and marketing support materials, instructions, and packaging labels.

The administrative documents include 10 aspects such as an explanatory letter, application form, and application materials for the approval of the generic name of the drug.

The pharmaceutical materials require detailed explanations and clarify the key points around the evaluation of prescription flavors and medicinal material resources, processing of decoction pieces, preparation process, research on preparation quality and quality standards, packaging, storage and validity period. For example, the quality standard of the medicinal materials used for the decoction pieces shall be provided, specifying the origin, medicinal parts, producing area, harvesting period of the medicinal materials, whether the medicinal materials are cultivated or bred or derived from the wild, etc. For medicinal materials with multiple origins, the origin shall be fixed. For rare and endangered wild medicinal materials, documents and relevant materials proving legal sources shall be provided.

In the marketing support materials, generally, no new pharmacological and toxicological research data is required. However, in the following cases, it is necessary to fully evaluate the support of the existing toxicological research data for the marketing application, and add relevant research if necessary: major safety concerning indicated by the prescription composition and human use history; the prescription containing toxic flavors listed in the “*Measures for the Administration of Toxic Medical Products*” or slices proven to be toxic and prone to serious adverse reactions by modern toxicology; and drug use in special populations such as pregnant women and children.

Source: China Pharmaceutical News

Nine Departments Including the Beijing Municipal Medical Security Bureau Issued “Several Measures for Supporting the High-Quality Development of Innovative Pharmaceuticals in Beijing (2025)”

On April 7, nine departments including the Beijing Municipal Medical Security Bureau issued the “*Several Measures for Supporting the High-Quality Development of Innovative Pharmaceuticals in*

Beijing (2025)” (hereinafter referred to as the “*2025 Edition of Several Measures*”). Based on the “*Several Measures for Supporting the High-Quality Development of Innovative Pharmaceuticals in Beijing (2024)*”, the “*2025 Edition of Several Measures*” was formulated to further accelerate the innovation of Beijing’s medical and health industry and meet the requirements of relevant national departments on supporting innovative pharmaceuticals.

The main contents of the “*2025 Edition of Several Measures*” include: first, the improvement of original policies. For example, in terms of improving the efficiency of clinical trials, the overall time for starting clinical trial projects will be further shortened from 28 weeks in 2024 to within 20 weeks. Second, the addition of new policy measures. A number of new tasks are added, for example, incentives will be given to medical institutions and research teams that take the lead in completing international multi-center clinical trials; and support will be provided for the development of more accurate, rapid and low-cost diagnostic screening reagents and drugs for Alzheimer’s disease.

Source: [Beijing Municipal Medical Security Bureau](#)

Seven Departments Including the Ministry of Industry and Information Technology Issued “*Implementation Plan for the Digital and Intelligent Transformation of the Pharmaceutical Industry (2025-2030)*”

On April 3, seven departments including the Ministry of Industry and Information Technology jointly issued the “*Implementation Plan for the Digital and Intelligent Transformation of the Pharmaceutical Industry (2025-2030)*”.

The “*Implementation Plan*” proposes to take the coordinated development of the entire industrial chain as the thread, take digital and intelligent transformation as the main target, take scenario application as the traction, adhere to planning guidance, problem orientation, classified policies and systematic promotion, comprehensively improve the level of digital and intelligent development and intelligent supervision of the pharmaceutical industry, and promote the high-end, intelligent, green and integrated development of the pharmaceutical industry in a scenario-based and map-based manner.

The “*Implementation Plan*” sets forward development goals in two phases: by 2027, significant progress will be made in the digital and intelligent transformation of the pharmaceutical industry, the competitiveness of the entire pharmaceutical industry chain driven by digital and intelligent technologies and the quality management level of the entire life cycle will be significantly improved. Focusing on three dimensions: the construction of the foundation for digital and intelligent development, the promotion of digital and intelligent transformation, and the construction of a supporting service system, ten specific goals to be achieved in the next three years are determined, including standard formulation, equipment R&D, scenario creation, enterprise cultivation, park construction, platform construction, and service provider cultivation. By 2030, basically all above-scale pharmaceutical industrial enterprises will have completed digital and intelligent transformation, the ability of integrated innovation of digital and intelligent technologies will be greatly improved, the data system of the entire pharmaceutical industry chain will be further improved, and the ecological system for the digital and intelligent transformation of the pharmaceutical industry will be further improved.

Centering on the main goals, the “*Implementation Plan*” systematically proposes 14 specific tasks in four aspects: the digital and intelligent technology empowerment action, the digital and intelligent transformation promotion action, the digital and intelligent service system construction action, and the digital and intelligent supervision improvement action. It also puts forward guarantee measures from aspects such as improving the working mechanism, strengthening policy support, promoting exchanges and cooperation, deepening evaluation and publicity, and strengthening talent cultivation.

Source: [Ministry of Industry and Information Technology of the People's Republic of China](#)

Industry Trends

Hengrui Pharma and Braveheart Bio Enter Exclusive License Agreement

On September 5, Hengrui Pharma announced that it has entered into an exclusive license agreement with Braveheart Bio for HRS-1893, a small-molecule inhibitor of cardiac myosin independently developed by Hengrui Pharma.

Under the terms of the agreement, Hengrui Pharma has granted Braveheart exclusive rights to develop, manufacture and commercialize HRS-1893 worldwide, excluding Mainland China, the Hong Kong SAR, the Macao SAR, and Taiwan Region. Braveheart will make an upfront payment of \$65 million (consisting of \$32.5 million in cash and \$32.5 million in Braveheart shares) and a near-term payment of up to \$10 million upon technology transfer completion, totaling \$75 million. In addition, Hengrui Pharma is eligible to receive potential development and commercial milestone payments of up to \$1.013 billion, and related royalties based on the net sales.

Source: [Hengrui Pharma](#)

Biocytogen Signs Agreement with Merck

On September 4, Biocytogen Pharmaceuticals (Beijing) Co., Ltd and Merck have entered into an evaluation agreement for antibody option to advance the development of antibody-conjugated lipid-based delivery solutions for nucleic acid payloads, such as antibody-conjugated lipid nanoparticle (LNP).

Under the terms of the agreement, Biocytogen will provide proprietary, fully human antibodies derived from its RenMice® platform for evaluation in Merck's antibody-conjugated LNP services. Merck has been granted an exclusive option to acquire rights to selected antibody assets in return for fees and royalties on sales and sublicenses.

Source: [Biocytogen](#)

World's First Innovative Drug for Delaying Diabetes Approved for Marketing in Beijing

On September 3, teplizumab injection (trade name: Tziel) of Sanofi (Beijing) Pharmaceutical Co., Ltd. was approved by the NMPA. As the world's first and only innovative drug for delaying type 1 diabetes, it is indicated for patients aged 8 years and above with stage 2 type 1 diabetes, and can delay the progression of the disease by 3 years.

The product was approved for marketing in the United States in November 2022 and the first prescriptions are issued in Asia at the Hainan Boao Lecheng pilot zone in June this year. Teplizumab is a CD3-targeted monoclonal antibody that can achieve protection of pancreatic islet β cells from the etiological perspective. According to public data from Sanofi, if a type 1 diabetes patient receives, for example, at least 4 insulin injections per day,

the total number of injections over 3 years is as high as 4,380. Teplizumab delays the onset of the disease by nearly 3 years, which can delay the entry into the long-term insulin treatment stage.

Source: [Beijing Municipal Bureau of Economy and Information Technology](#)

70 Biomedical Enterprises Jointly Launched the “Laifu Initiative”: Actively Layout the Global Market

At the recently held 2025 Supply Chain Ecology Conference, Sinovac Group, together with 70 enterprises in the biomedical and other fields including Cytiva, Thermo Fisher Scientific, WeiGao, Cobetter, and Truking, jointly launched the “Laifu Initiative”.

The initiative states that global partners are welcome to participate in the development of China’s health industry and share market opportunities and development dividends; it advocates that Chinese enterprises should take the initiative to expand their international perspective, actively layout the global market, and promote high-quality products and services to the world.

Source: [China News Network](#)

Macao’s First New Drug Clinical Trial Officially Launched

On August 29, Boehringer Ingelheim signed a strategic cooperation agreement with the Macau University of Science and Technology Clinical Trial Center (MUST-CTC), and on the same day, Macao’s first international standard new drug clinical trial was officially launched. It is reported that the approved FIBRONEER™-SARD trial is a global multi-center phase IIIb clinical trial, sponsored by Boehringer Ingelheim and conducted by the Macau University of Science and Technology Clinical Trial Center (MUST-CTC), with the University Hospital as the clinical trial site, and supported by the University of Hong Kong Clinical Trial Center (HKU-CTC) as a strategic collaborator.

FIBRONEER™-SARD is a double-blind, randomized, placebo-controlled trial evaluating the efficacy and safety of nerandomilast in patients with systemic autoimmune rheumatic disease-related interstitial lung disease (SARD-ILD), which is planned to be carried out simultaneously in about 15 countries and regions around the world.

Source: <http://www.china.com.cn/>

Sino Biopharmaceutical’s Oral Targeted Drug Zongertinib for HER2-Mutated Advanced Non-Small Cell Lung Cancer Approved

On August 29, Boehringer Ingelheim and Sino Biopharmaceutical jointly announced that [zongertinib](#), which they co-promote in Chinese mainland, has been officially approved by the NMPA for the treatment of adult patients with unresectable locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring activating HER2 (ERBB2) mutations who have received at least one prior systemic therapy.

Zongertinib is an oral HER2 tyrosine kinase inhibitor. Its conditional approval in China is based on the positive results of the Beamion-LUNG 1 study, which evaluated the efficacy and safety of zongertinib in patients with HER2 (ERBB2)-mutated advanced NSCLC. Data showed that for the treated [cohort 1](#) patients (N=75), the objective response rate (ORR) reached 71% (95% CI: 60-80), including 7% complete response, and the disease control rate (DCR) was as high as 96%. The median duration of response (DoR) was 14.1 months, and the medi-

an progression-free survival (PFS) was 12.4 months. These data were presented at the 2025 American Association for Cancer Research (AACR) Annual Meeting and simultaneously published in the New England Journal of Medicine.

Source: Xinhua News Agency

XtalPi Signed Cooperation with South Korea's Dong-A Pharm

On August 20, XtalPi announced that it has signed a Memorandum of Understanding (MOU) with South Korea's Dong-A Pharm. Based on AI & Automation platform of XtalPi, the two parties will combine their respective advantages to jointly develop innovative therapies for immune and inflammatory diseases. Through this partnership, Dong-A ST aims to strengthen its pipeline in the immunology and inflammation space and expand its R&D scope beyond small molecule therapeutics into areas such as targeted protein degradation (TPD), biologics, antibody-drug conjugates (ADC), and gene therapies.

Source: XtalPi Holdings Limited

Jingxin Pharmaceutical Signed “Patent License Agreement” with Gedeon Richter Plc.

On August 7, Jingxin Pharmaceutical signed a “Patent License Agreement” with Gedeon Richter. According to the agreement, Gedeon Richter will grant Jingxin Pharmaceutical an exclusive patent license, allowing Jingxin Pharmaceutical to use the patent to develop, manufacture and commercialize cariprazine hydrochloride preparations and active pharmaceutical ingredients (API) in the licensed territory (Chinese Mainland).

After the agreement comes into effect, Jingxin Pharmaceutical will use the patent to develop and independently produce cariprazine hydrochloride and commercialize it under its own brand. During the development and marketing stages of cariprazine hydrochloride, if the set milestone conditions are met (including favorable rulings on patent validity, and regulatory approval), Jingxin Pharmaceutical will pay Gedeon Richter a total of up to 530,000 euros in milestone payments. In addition, after cariprazine hydrochloride is approved for marketing and sale in the licensed territory (Chinese Mainland), Jingxin Pharmaceutical will pay Gedeon Richter corresponding sales shares based on the net sales of the product in the licensed territory under different applicable conditions in accordance with the agreement.

Source: Jingxin Pharmaceutical

China Completed Phase I Clinical Trial of the First Replication-Competent Tiantan Vaccinia Vector AIDS Vaccine

Recently, teams including the National Center for AIDS/STD Control and Prevention of China CDC completed the phase I clinical trial of China's first replication-competent Tiantan vaccinia vector AIDS vaccine. This study innovatively adopted the “Tiantan strain” vaccinia virus, which was once used to eradicate smallpox, as the vector. The trial verified the safety of the scheme and its ability to induce an effective immune response, marking an important progress in China's AIDS vaccine R&D field.

Source: Observer Network

China Resources Sanjiu Signed Cooperative R&D Agreement with BrightGene Bio-Medical on BGM0504 Injection Project

On August 1, China Resources Sanjiu and BrightGene Bio-Medical (688166.SH) held a signing ceremony for the cooperative R&D agreement on the BGM0504 injection project in Suzhou, officially announcing the conclusion of the cooperative R&D agreement.

BGM0504 injection is a dual agonist of GLP-1 (glucagon-like peptide 1) and GIP (glucose-dependent insulino-tropic polypeptide) receptors, belonging to an innovative peptide drug (Class 1 chemical drug), intended for the treatment of T2DM and obesity. Its unique mechanism is expected to overcome some shortcomings of existing drugs and provide patients with a more effective, safe and convenient treatment plan. Currently, BGM0504 injection has progressed to the critical stage of phase III clinical trials.

[Source: China Resources Sanjiu](#)

CSPC Pharmaceutical Group Signed Exclusive License Agreement with MADRIGAL for SYH2086

On July 30, CSPC Pharmaceutical Group (1093.HK) announced that the Group has entered into an exclusive license agreement with Madrigal Pharmaceuticals, Inc. (Madrigal) for the global development, manufacturing and commercialization of the Group's oral small molecule glucagon-like peptide-1 (GLP-1) receptor agonist, SYH2086.

Under the terms of the Agreement, the Group agreed to grant Madrigal an exclusive license to develop, manufacture and commercialize SYH2086 worldwide, while retaining the Group's right to develop and commercialize other orally administered small-molecule GLP-1 receptor agonist products in China. The Group is eligible to receive a total consideration of up to US\$2.075 billion, including an upfront payment of US\$120 million plus potential development, regulatory, and commercial milestone payments of up to US\$1.955 billion, and up to double-digit royalties based on the annual net sales of SYH2086.

[Source: CSPC Pharmaceutical Group](#)

2025 Fortune China 500 List Released, 17 Pharmaceutical Enterprises Included

On July 22, the 2025 Fortune China 500 list was released, with a total of 17 pharmaceutical enterprises included. They are: China National Pharmaceutical Group Corporation (34), Shanghai Pharmaceuticals Holding Co., Ltd. (98), Guangzhou Pharmaceutical Group Co., Ltd (115), Jointown Pharmaceutical Group Co., Ltd. (165), Nanjing Pharmaceutical Co., Ltd. (307), Huadong Medicine Co., Ltd. (348), Yunnan Baiyao Group Co., Ltd. (357), WuXi AppTec Co., Ltd. (362), Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (382), Zhejiang Int'l Group Co., Ltd. (408), Shenzhen Neptunus Bioengineering Co., Ltd. (434), CSPC Pharmaceutical Group Limited (448), Sino Biopharmaceutical Limited (451), Jiangsu Hengrui Pharmaceuticals Co., Ltd. (467), BeOne Medicines Ltd. (478), Dashenlin Pharmaceutical Group Co., Ltd. (494), and Chongqing Zhifei Biological Products Co., Ltd. (499).

[Source: Sina Finance](#)

World's First Cell Therapy Product for Chronic Hepatitis B SCG101V Approved for Clinical Trial

On July 4, the Center for Drug Evaluation (CDE) of the NMPA approved the Investigational New Drug (IND) application for phase 1/2 clinical trial of new drug SCG101V, a hepatitis B virus (HBV)-specific T cell receptor (TCR)-engineered T cell therapy developed by SCG Cell Therapy Pte. Ltd., for the treatment of chronic hepatitis

B.

Source: [SCG Cell Therapy](#)

[Brii Biosciences Announced License Agreement with Joincare Pharmaceutical Group for BRII-693 in the Greater China region](#)

On July 4, Brii Bio announced that it has entered into a license and technology transfer agreement with Joincare Pharmaceutical Group Industry Co., Ltd (“Joincare Group”). Joincare Group will obtain an exclusive license from Brii Bio for the research, development, and commercialization of BRII-693 in the Greater China region.

Under the terms of the agreement, Joincare Group will assume full responsibility for the development, regulatory approval and commercialization of BRII-693 in Greater China. In return, Brii Bio has received an upfront payment and will receive additional development and commercial milestone payments upon certain future milestone events plus tiered royalties on net product sales.

Source: [Brii Biosciences](#)

[XtalPi Signed Multi-Billion Dollar Pipeline License Intent with DoveTree, a New Drug Company Founded by Harvard Professor Gregory Verdine](#)

On June 23, 2025, XtalPi announced that it has signed a letter of intent for cooperation with DoveTree LLC, a company founded by Harvard University Professor Gregory Verdine, and will sign a final agreement in the near future based on this letter of intent. According to the letter of intent, XtalPi will use its end-to-end AI-driven drug discovery platform based on AI & Automation to discover and develop small molecule and antibody-based drug candidates for multiple targets selected by DoveTree in the fields of oncology, autoimmune diseases and neurological diseases.

Based on the letter of intent, XtalPi will receive upfront payments of \$51 million and \$49 million within 10 days and 180 days after the signing of the final agreement, respectively, and will be eligible to receive potential development milestone and sales milestone payments of up to several billion US dollars, as well as potential single-digit percentage royalties based on the annual net sales of the products (subject to the amount determined in the final agreement). DoveTree will obtain the exclusive global rights to develop and commercialize the above products.

Source: [XtalPi](#)

[Harbour BioMed Enters Global Strategic Collaboration with Otsuka](#)

On June 23, 2025, Harbour BioMed announced a global strategic collaboration with Otsuka Pharmaceutical Co., Ltd. (“Otsuka”) to advance BCMAxCD3 bispecific T-cell engagers for the treatment of autoimmune diseases.

Under the terms of the agreement, Otsuka is granted an exclusive license to develop, manufacture, and commercialize HBM7020, a BCMAxCD3 bispecific T-cell engager globally, excluding Greater China (Mainland China, Hong Kong, Macau and Taiwan). In return, Harbour BioMed will receive a total of \$47 million in upfront and near-term payments. The company is also eligible for additional payments of up to \$623 million upon the achievement of specified development and commercial milestones, as well as tiered royalties on future net sales. This strategic collaboration establishes a foundation for potential future partnerships between the two companies in the T-cell engager area.

[Source: Harbour BioMed](#)

Novo Nordisk Entered Strategic Cooperation with Alibaba Health

On June 16, 2025, Novo Nordisk and Alibaba Health announced the conclusion of a strategic cooperation. Against the backdrop of the country's continuous promotion of the "Weight Management Year" campaign, relying on Novo Nordisk's over 100 years of professional experience and innovative treatment solutions in the field of chronic diseases, as well as Alibaba Health's innovative business model in the field of internet medical care, the two parties will jointly build a one-stop weight management knowledge and service zone to help the public understand healthy weight standards, master weight management methods, manage weight scientifically, and assist in the digital transformation and upgrading of one-stop diabetes diagnosis and treatment and chronic disease management.

[Source: Xinhua News Agency](#)

CSPC Pharmaceutical Group Entered into Strategic R&D Cooperation Agreement with ASTRAZENECA

On June 13, 2025, CSPC Pharmaceutical Group announced that the Group has entered into a strategic research collaboration agreement (the "Agreement") with the global biopharmaceutical leader AstraZeneca for the discovery and development of novel oral small molecule candidates utilizing the Group's AI-driven, dual-engine efficient drug discovery platform. This platform uses AI technology to analyze the binding patterns of target proteins with existing compound molecules and conduct targeted optimization, with the aim of selecting highly effective small molecules with excellent developability.

Under the terms of the Agreement, the Group agreed to discover pre-clinical candidates (PCC) for multiple targets as selected by AstraZeneca with potential to treat diseases across indications, including a pre-clinical small molecule oral therapy for immunological diseases.

For each PCC program, AstraZeneca shall have rights to exercise the option for an exclusive license for development, manufacturing and commercialization worldwide. The Group will receive an upfront payment of US\$110 million, and is also eligible to receive up to US\$1,620 million in potential development milestone payments and up to US\$3,600 million in potential sales milestone payments, plus potential single digit royalties based on annual net sales of the products.

[Source: CSPC Pharmaceutical Group](#)

IBM Collaborates with Roche Group to Create AI-Driven Blood Glucose Detection Tool

Recently, IBM and Roche Group officially launched their co-created AI-driven solution, Roche's Accu-Chek® SmartGuide Predict application, aimed at optimizing the daily management of diabetes. The solution emphasizes the importance of cross-industry cooperation and teamwork in supporting the daily lives of diabetes patients and providing healthcare services. Launched in Switzerland a few months ago, the solution was showcased as a key case of digital innovation and cross-industry cooperation during the Swiss Economic Forum held in Interlaken, Switzerland, on June 5-6.

[Source: IBM](#)

China's First Domestic Nine-Valent HPV Vaccine Approved for Marketing

Recently, the nine-valent human papillomavirus vaccine (Escherichia coli) jointly developed by the team of Xia Ningshao from Xiamen University and Xiang An Biomedicine Laboratory, and Wantai Bio, was approved for marketing by the NMPA. This is China's first domestic nine-valent HPV vaccine, marking that China has officially become the second country in the world after the United States with the independent capability to supply high-valent HPV vaccines.

Source: People's Network

First Clinical Proof-of-Concept Result of AI-Driven Drug R&D in the Industry Published in *Nature Medicine*

On June 3, 2025, the first clinical proof-of-concept result of AI-driven drug R&D in the industry was published in "*Nature Medicine*". Insilico Medicine and its co-authors jointly released the safety and efficacy data of the phase IIa clinical trial of the TNIK inhibitor Rentosertib (ISM001-055). Rentosertib is a potential first-in-class small molecule drug for the treatment of idiopathic pulmonary fibrosis (IPF) discovered and designed with the empowerment of Insilico Medicine's generative AI platform Pharma.AI. In addition, the exploratory biomarker analysis in the study further verified the biological mechanism of the novel target TNIK discovered through artificial intelligence methods, and the research results support that Rentosertib has potential anti-fibrotic and anti-inflammatory effects.

Source: Global Network

3SBio Entered into License Agreement with Pfizer for PD-1/VEGF Bispecific Antibody SSGJ-707

On May 20, 2025, 3SBio announced that the company and its subsidiaries Shenyang Sunshine and Sunshine Guojian have entered into an agreement with Pfizer to exclusively grant Pfizer the global rights (excluding Chinese Mainland) to develop, produce and commercialize the company's independently developed breakthrough PD-1/VEGF bispecific antibody SSGJ-707. The company and Shenyang Sunshine will retain the rights to develop, produce and commercialize SSGJ-707 in Chinese Mainland, and grant Pfizer the option to commercialize SSGJ-707 in Mainland China based on mutually agreed financial terms.

Under the agreement, 3SBio will receive an irrevocable and non-refundable upfront payment of US\$1.25 billion, as well as up to US\$4.8 billion in development, regulatory approval and sales milestone payments. The company will also receive tiered sales royalties in the double-digit percentage range based on the product sales in the licensed territories. In addition, Pfizer will subscribe for US\$100 million worth of common shares of 3SBio on the effective date of the agreement.

Source: 3SBio

Roche Invested Over 2 Billion RMB to Build New Production Base in Shanghai

On May 8, the groundbreaking ceremony of Roche Pharmaceuticals China's new biopharmaceutical production base investment project was held at the Shanghai Zhangjiang Science Hall. With an investment of 2.04 billion RMB, the first-phase products will be mainly used for the localized production of drugs for the treatment of ocular fundus diseases, accelerating the meeting of Chinese patients' demand for high-quality drugs.

Source: Pudong Release

Henlius Entered into License Cooperation with Sandoz for Proposed Ipilimumab Biosimilar

On April 29, Henlius announced a licensing agreement with Sandoz, granting exclusive commercialization rights for its self-developed ipilimumab biosimilar HLX13 in the United States, 42 European countries and regions, Japan, Canada, and Australia.

Under the agreement, Henlius will be responsible for development, manufacturing and commercial supply of HLX13, and is eligible to receive up to a total of \$301 million, including a \$31 million upfront.

Source: Henlius

Shanghai Pharmaceutical and Ipsen China Entered into strategic cooperation

On April 28, Ipsen China and Shanghai Pharmaceutical Co., Ltd. jointly announced the conclusion of a strategic cooperation agreement to cooperate around Decapeptyl® and further promote the in-depth coverage of Triptorelin® products in the Chinese market.

Source: Shanghai Pharmaceutical Co., Ltd.

Novo Nordisk Entered into Strategic Cooperation with JD Health

On April 21, Novo Nordisk and JD Health officially entered into a strategic cooperation agreement in Beijing, marking a new stage of cooperation between the two parties in the fields of diabetes and weight management. Relying on Novo Nordisk's professional experience and innovative treatment solutions, and with the help of JD Health's full-scenario medical service capabilities, the two parties will jointly build a public science popularization zone for obesity, helping with one-stop diabetes diagnosis and treatment.

The two parties will also jointly build a multi-party dialogue platform to improve the accessibility and convenience of high-quality medical and health services; at the same time, with the help of medical big data analysis and AI-assisted diagnosis and treatment systems, actively build an intelligent medical solution covering the entire cycle of "prevention-diagnosis and treatment-management", realizing the full-process digital service from online consultation to drug delivery.

Source: China Association of Enterprises with Foreign Investment R&D-based Pharmaceutical Association Committee (RDPAC)

China's First Gene Therapy Drug for Hemophilia B Xinjiuning® (Dalnacogene Ponparvovec Injection) Officially Approved

On April 10, Belief BioMed Inc and Takeda China jointly announced that Xinjiuning® (BBM-H901 injection, generic name: dalnacogene ponparvovec injection) has been officially approved by the NMPA for the treatment of adult patients with moderate to severe hemophilia B (congenital factor IX deficiency). As China's first approved gene therapy drug for hemophilia B, Xinjiuning® is developed and produced by Belief BioMed, and Takeda China is responsible for the commercialization process of the product in Chinese Mainland, Hong Kong and Macao of China.

Source: Belief BioMed Inc

World's First Gene-Edited Pig Liver Transplantation into Human Body

On March 26 London time, a Chinese research team published a paper online in the British journal *Nature*, reporting the successful case of the world's first transplantation of a gene-edited pig's liver into a brain-dead human body. The transplanted liver showed good performance in various physiological functions, which will help solve the problem of organ shortage for transplantation.

Led by Academician Dou Kefeng of the Chinese Academy of Sciences, the research team from Xijing Hospital and other institutions used a pig that had undergone 6 gene edits as the donor, transplanted the pig's liver into a brain-dead human whose basic bodily functions were still maintained, and retained the human recipient's own liver to simulate the alternative support treatment process for patients with clinical liver failure.

Source: CCTV.com

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