

REGULATORY OVERVIEW

OVERVIEW OF LAWS AND REGULATIONS IN THE PRC

This section summarizes the principal PRC laws, rules and regulations that are relevant to our business:

Regulatory Authorities

The regulatory authorities of the drug industry in the PRC include: the National Medical Products Administration (國家藥品監督管理局) (the “NMPA”), the National Health Commission of the PRC (中華人民共和國國家衛生健康委員會) (the “NHC”) and the National Healthcare Security Administration (國家醫療保障局) (the “NHSA”).

Laws and Regulations in Relation to Drug Manufacturer

Drug Manufacturing Permit

Pursuant to the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the “Drug Administration Law”) promulgated by the Standing Committee of the National People’s Congress (the “SCNPC”) in September 1984 and lastly amended in August 2019 and came into effect in December 2019, the state adopts an industry entry permit system for drug manufacturers. The conduct of drug manufacturing activities shall be approved and granted with a Drug Manufacturing License (《藥品生產許可證》) by the drug regulatory authority of the people’s government at provincial, autonomous regional or municipal level. The Drug Manufacturing License shall indicate the validity period and the scope of production, and shall be reviewed for renewing upon expiration.

Good Manufacturing Practices

Pursuant to the Announcement on the Relevant Issues Concerning the Implementation of the Drug Administration Law of the PRC (《關於貫徹實施〈中華人民共和國藥品管理法〉有關事項的公告》), promulgated by the NMPA on November 29, 2019, and the Drug Administration Law, the GMP and Good Supply Practice (GSP) certifications have been cancelled, applications for GMP and GSP certifications are no longer accepted, and GMP and GSP certificates are no longer issued. When engaging in drug manufacturing activities, a manufacturer shall comply with the GMP and establish a sound GMP management system, to ensure that the entire process of drug manufacturing maintain to meet the statutory requirements, and meet the GMP requirements enacted by the drug regulatory authority under the State Council in accordance with the law. The legal representative of and principal person in charge of a drug manufacturer are fully responsible for the drug manufacturing activities of the enterprise.

Laws and Regulations in Relation to New Drugs

Application for New Drug Registration

Drug registration refers to an approval process where the NMPA conducts review of the safety, efficacy and quality controllability of the drugs intended for marketing according to the application for drug registration made by an applicant, and decides whether to approve the application. Pursuant to the provisions of the Measures for the Administration of Drug Registration (2020) (《藥品註冊管理辦法》(2020)), promulgated by the SAMR on January 22, 2020 and came into effect on July 1, 2020, the Measures for the Administration of Drug Registration (2020) shall apply to the development, registration, supervision and management activities carried out in the territory of the PRC for marketing of drugs.

Non-clinical Research and Animal Testing

The non-clinical safety assessment of drugs for marketing approval shall be conducted in accordance with the Good Laboratory Practices for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範》) promulgated by the State Food and Drug Administration (the “SFDA”) in August 2003 and latest amended by the China Food and Drug Administration (the “CFDA”) in July

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2017 and came into effect on September 1, 2017. The SFDA promulgated the Administrative Measures for the Certification of Good Laboratory Practices for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範認證管理辦法》) in April 2007, which specifies the requirements for institutions applying for Good Laboratory Practices (GLP) certification of non-clinical laboratory studies. On January 19, 2023, the NMPA amended the Administrative Measures for the Certification of Good Laboratory Practices for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範認證管理辦法》), which came into effect on July 1, 2023.

According to the Regulations for the Administration of Affairs Concerning Experimental Animals (《實驗動物管理條例》) promulgated by the State Science and Technology Commission in November 1988 and lastly amended in March 2017 by the State Council, the Administration Measures on Good Practice of Experimental Animals (《實驗動物質量管理辦法》) jointly promulgated by the State Science and Technology Commission and the State Bureau of Quality and Technical Supervision in December 1997, and the Administrative Measures on the Certificate for Experimental Animals (Trial) (《實驗動物許可證管理辦法(試行)》) promulgated by the Ministry of Science and Technology and other regulatory authorities in December 2001 and came into effect in January 2002, using experimental animals and related products requires a Certificate for Utilization of Laboratory Animals. A Certificate for Utilization of Laboratory Animals shall be valid for five years, and the holder shall apply for renewal six months prior to the expiry of the validity period. A Certificate for Utilization of Laboratory Animals shall be inspected annually by the local Science and Technology Bureau.

Application for Clinical Trial

After completing the preclinical studies, the applicant must obtain approval for clinical trials of drugs from the NMPA before the conduction of new clinical drug trials. Pursuant to the Drug Administration Law, the dossier on a new drug research and development, including the manufacturing method, quality specifications, results of pharmacological and toxicological tests and the relevant data, files and samples, shall, in accordance with the regulations of the drug regulatory authority under the State Council be truthfully submitted to the said department for approval before clinical drug trial is conducted.

Before conducting the clinical trial, the applicant shall file a series of detailed documents with the NMPA. According to the Announcement on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》), which came into effect in September 2013, and the Standard for the Management of Drug Clinical Trial Registration and Information Disclosure (Trial) (《藥物臨床試驗登記與信息公示管理規範(試行)》), which came into effect in July 2020, all clinical trials approved by the CFDA and conducted in the PRC shall complete the clinical trial registration and information disclosure on the Drug Clinical Trial Information Platform.

After obtaining clinical trial approval, the applicant shall choose institutions qualified for clinical trials of the drug to conduct clinical trials. Pursuant to the Administrative Regulations for Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》), which came into effect in December 2019, if engaging in drug development activities and conducting clinical trials of drugs (including bioequivalence test conducted after filing) approved by the NMPA within the territory of the PRC, they shall be conducted in the Drug Clinical Trial Institutions.

Clinical Trial

In compliance with the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》), clinical trials are divided into Phase I, Phase II, Phase III, Phase IV and bioequivalence trial:

A clinical drug trial to be carried out shall be examined and approved by the ethics committee. The management of drugs used in a clinical drug trial shall satisfy the relevant requirements of the GCP. A sponsor approved to carry out clinical drug trial shall, before carrying out subsequent clinical drug trial by stages, develop corresponding plan for clinical drug trial, carry out clinical drug trial upon examination and with consent of the ethics committee, and submit corresponding plan for clinical drug trial and supporting materials on the website of the CDE.

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Clinical trials shall be conducted for the application of new drug registration and shall be implemented in accordance with the Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》), promulgated by the NMPA and NHC, lastly amended on May 21, 2026 and will come into effect on September 1, 2026.

According to the Announcement of the National Medical Products Administration on Adjusting the Review and Approval Procedures for Drug Clinical Trials (《國家藥品監督管理局關於調整藥物臨床試驗審評審批程序的公告》), if a new drug clinical trial has been approved to be carried out, after the completion of Phase I and Phase II clinical trials and before the implementation of Phase III clinical trials, the applicant shall submit an application for a communication meeting to the CDE to discuss with the CDE on key technical issues including the design of the Phase III clinical trial design. The applicant can also apply for communication on key technical issues at different stages of clinical research and development.

New Drug Application

Pursuant to the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》), after completing the pharmaceutical research, pharmacological and toxicological research, clinical drug trial, and other researches supporting the marketing registration of a drug, determining the quality standards, completing the verification of commercial large-scale production process, and making sound preparation for the acceptance of drug registration inspection and examination, an applicant shall file an application for drug marketing authorization, and submit relevant research materials in accordance with the requirements of the application materials. After the formal examination of the application materials, an application that satisfies the requirements shall be accepted. Where a generic drug, *in vitro* diagnostic reagent managed as a drug, or any other eligible circumstance assessed by an applicant to be unnecessary or impossible for conducting clinical drug trial and meeting the conditions for exempting clinical drug trial, the applicant may directly file an application for drug marketing authorization. The technical guiding principles and relevant specific requirements for exempting clinical drug trial shall be developed and announced by the CDE.

Reform of Evaluation and Approval System for Drugs

In August 2015, the State Council promulgated the Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices and Equipment (《關於改革藥品醫療器械審評審批制度的意見》) (the “Reform Opinions”), which provides a framework for reforming the evaluation and approval system for drugs and indicates enhancing the standard of approval for drug registration and accelerating the evaluation and approval process for innovative drugs.

In November 2015, the CFDA promulgated the Announcement on Certain Policies for Drug Registration, Evaluation and Approval (《關於藥品註冊審評審批若干政策的公告》) (the “Certain Policies Announcement”), which further clarifies the measures and policies on simplifying and accelerating the approval process on the basis of the Reform Opinions.

Pursuant to the Decision on Adjusting the Approval Procedures of Certain Administrative Approval Items for Drugs (《關於調整部分藥品行政審批事項審批程序的決定》) promulgated by the CFDA in March 2017 and came into effect in May 2017, the clinical trial approval decisions on drugs (including domestic and imported) can be directly made by the CDE in the name of the CFDA; decisions on approval of drug supplementary applications (including domestic and imported); decisions on approval of re-registration of imported drugs.

The Evaluation and Approval Procedures for Breakthrough Therapeutic Drugs (Trial) (《突破性治療藥物審評工作程序(試行)》), the Evaluation and Approval Procedures for Conditionally Approved Drugs (Trial) (《藥品附條件批准上市申請審評審批工作程序(試行)》) and The Preferential Evaluation and Approval Procedures for Drug Marketing Authorization (Trial) (《藥品上市許可優先審評審批工作程序(試行)》) promulgated by the NMPA in July 2020 and came into effect in July 2020, replace the Opinions on Implementing Priority Review and Approval to Encourage Drug Innovation (《關於鼓勵藥品創新實行優先審評審批的意見》) promulgated by the CFDA in December 2017 and came into effect in December 2017, which further clarified the Accelerating Registration Procedures for Drugs.

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Regulations on International Multi-Center Clinical Trials and Acceptance of Overseas Clinical Trial Data

According to the Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Trial) (《關於發佈國際多中心藥物臨床試驗指南(試行)的通告》), (“the Multi-Center Clinical Trial Guidelines”), promulgated by the NMPA on January 30, 2015 and came into effect from March 1, 2015, international multi-center clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol.

According to the Opinions on Deepening the Reform of the Evaluation and Approval System and Inspiring Innovation of Drugs and Medical Devices, clinical trial data obtained in an international multi-center that conforms to China’s requirements for registration of drugs and medical devices can be used for the application for registration in China.

According to the Technical Guiding Principles for the Acceptance of Overseas Clinical Trial Data of Drugs (《接受藥品境外臨床試驗數據的技術指導原則》) promulgated by the NMPA on July 6, 2018, the basic principles for accepting overseas clinical trial data include: (i) applicants shall ensure the authenticity, integrity, accuracy and trace-ability of overseas clinical trial data; (ii) the process of generating overseas clinical trial data shall comply with the relevant requirements of the ICH-GCP; (iii) applicants shall ensure the scientific design of overseas clinical trials, the compliance of clinical trial quality management system with the requirements, and the accuracy and integrity of statistical analysis of data; and (iv) to ensure that the clinical trial design and statistical analysis of the data are scientific and reasonable, for the drugs with simultaneous R&D at home and abroad and forthcoming clinical trials in China, the applicants may, prior to implementing registrational clinical trials, contact the CDE to ensure the compliance of registrational clinical trial’s design with the essential technical requirements for drug registration in China.

Marketing Authorization Holder System

Pursuant to the Drug Administration Law and the Administrative Measures for Drug Registration, the state implements the drug marketing authorization holder system for drug management. After obtaining a drug registration certificate, an applicant shall be the drug marketing authorization holder. The marketing authorization holder shall apply for re-registration six months prior to the expiry of the validity period of the drug registration certificate. Marketing authorization holder is separated from manufacturing license. The entity named in the Drug Registration Certificate serves as the Marketing Authorization Holder, who may opt for self-manufacturing or entrust manufacturing to third parties.

Transfer of Drug Marketing Authorization

Pursuant to the Drug Administration Law (《中華人民共和國藥品管理法》), upon approval by the drug administrative department of the State Council, a drug marketing authorization holder may transfer its drug marketing authorization. The transferee shall possess the quality management, risk control and liability compensation competence to ensure drug safety, effectiveness and quality controllability, and perform the obligations of the drug marketing permit holder.

According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》), transfer of drug marketing authorization by the holder shall declare by way of supplementary application, and implement upon approval.

Pursuant to the Administrative Measures for Drug Post-marketing Changes (for Trial Implementation) (《藥品上市後變更管理辦法(試行)》), drug post-marketing changes shall not have any adverse impact on the safety, effectiveness and quality controllability of drugs.

The CDE shall make a decision on whether to approve the change within the prescribed time limit. If the change is approved, the CDE shall issue a supplementary drug application notice with the drug approval number and the valid period of the certificate remains unchanged. The CDE shall also send a copy thereof to the provincial drug regulatory authority at the place where the transferor, the transferee and the manufacturer are located.

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NRDL

The NRDL for Basic Medical Insurance, Work Injury Insurance and Maternity Insurance (《國家基本醫療保險、工傷保險和生育保險藥品目錄》) sets out the standards for payment of medicines by the basic medical insurance, work injury insurance and maternity insurance funds. The National Healthcare Security Administration of the PRC and other governmental organizations have the authority to determine the drugs to be included in the NRDL.

On November 27, 2024, the NHSA and the Ministry of Human Resources and Social Security of the PRC released the latest NRDL (effective from January 1, 2025), which has been expanded to cover a total of 3,159 drugs. Inclusion in the NRDL will generally result in increased sales volume and lower drug prices (which are determined on a case-by-case basis and negotiated based on factors such as the initial drug price).

On July 30, 2020, the NHSA issued the Provisional Measures for the Administration of Medicines for Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》) (“Measures for the Administration of the NRDL”), which came into effect on September 1, 2020. The Measures for the Administration of the NRDL provides guidance on the inclusion and adjustment of the NRDL and the payment, management and supervision of basic medical insurance.

NEDL

On August 18, 2009, the MOH and eight other ministries and commissions in the PRC issued the Provisional Measures on the Administration of the NEDL (《國家基本藥物目錄管理辦法(暫行)》), which was revised on January 27, 2026 by the Notice on Issuing the Measures on the Administration of the NEDL (《關於印發國家基本藥物目錄管理辦法的通知》), and the Guidelines on the Implementation of the NEDL System (《關於建立國家基本藥物制度的實施意見》), which aims to promote essential medicines sold to consumers at fair prices in the PRC and ensure that the general public in the PRC has equal access to the drugs contained in the NEDL. On September 13, 2018, the General Office of the State Council issued the Opinions of the General Office of the State Council on Improving the National Essential Drug System (《國務院辦公廳關於完善國家基本藥物制度的意見》). The NHC, the National Administration of Traditional Chinese Medicine and the National Disease Control and Prevention Administration promulgated the NEDL (2026 version) (《國家基本藥物目錄(2026年版)》) on May 21, 2026, which came into effect on September 1, 2026, replacing the NEDL (2018 version) (《國家基本藥物目錄(2018年版)》) which was promulgated on September 30, 2018.

The Drug Centralized Procurement in Nationwide

According to the Implementing Opinions on Expanding the Pilot Program for Conducting Centralised Procurement and Use of Drugs by the State to Wider Areas (《關於國家組織藥品集中採購和使用試點擴大區域範圍的實施意見》) promulgated and came into effect on September 25, 2019, together with the Documents on National Centralised Drug Procurement (GY-YD2025-1) (《全國藥品集中採購文件(GY-YD2025-1)》) issued by the Joint Procurement Office on September 20, 2025, the centralised procurement program of drugs has been extended to nationwide. The centralised VBP program of drugs will be implemented on a nationwide basis. Eligible participants include all pharmaceutical manufacturers, sole agents of imported drugs and holders of marketing authorisations for drugs, provided that they own the drugs covered by the centralised purchasing program.

The NHSA, the NHC, the NMPA, the MIIT and the Ministry of Logistics and Security of the Central Military Commission jointly issued the Circular on Conducting the Second Batch of Centralised Procurement and Use of Drugs Organised by the State (《關於開展第二批國家組織藥品集中採購和使用工作的通知》) (the “Circular”), which became effective on January 13, 2020, and stipulated a number of principles for the implementation of the centralised procurement of drugs by the State in order to comprehensively deepen the reforms and to establish a standardised and regularized centralised purchasing program of drugs nationwide. The Joint Purchasing Office issued the Documents on National Centralised Drug Procurement (GY-YD2020-1) (《全國藥品集中採購文件(GY-YD2020-1)》) on July 29, 2020 to launch a new batch of centralized procurement of drugs that meet the conditions for centralised procurement.

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On January 22, 2021, the General Office of the State Council issued the Opinions on Promoting the Normalisation and Institutionalisation of the Centralised VBP of Drugs (《關於推動藥品集中帶量採購工作常態化制度化開展的意見》), stating that various measures will be taken to promote the normalisation and institutionalization of the centralised VBP of drugs nationwide. All public medical institutions are required to participate in the centralised drug procurement program.

The Joint Purchasing Office issued the Documents on National Centralised Drug Procurement (GY-YD2021-2) (《全國藥品集中採購文件(GY-YD2021-2)》) on June 2, 2021, the Documents on National Centralised Drug Procurement (Insulin Specific) (GY-YD2021-3) (《全國藥品集中採購文件(胰島素專項)(GY-YD2021-3)》) on November 5, 2021, the Documents on National Centralised Drug Procurement (GY-YD2022-1) (《全國藥品集中採購文件(GY-YD2022-1)》) on June 20, 2022, the Documents on National Centralised Drug Procurement (GY-YD2023-1) (《全國藥品集中採購文件(GY-YD2023-1)》) on March 2, 2023, the Documents on National Centralised Drug Procurement (GY-YD2023-2) (《全國藥品集中採購文件(GY-YD2023-2)》) on October 13, 2023, the Documents on National Centralised Drug Procurement (Insulin Specific Continuation) (GY-YD2024-1) (《全國藥品集中採購文件(胰島素專項接續)(GY-YD2024-1)》) on March 29, 2024, and the documents on National Centralised Drug Procurement (GY-YD2025-1) (《全國藥品集中採購文件(GY-YD2025-1)》) on September 20, 2025, to launch multiple batches of centralised drug procurement.

Drug Distribution and Two-Invoice System

According to the Implementing Opinions on Promoting the “Two-Invoice System” for Drug Procurement By Public Medical Institutions (For Trial Implementation) (《關於在公立醫療機構藥品採購中推行「兩票制」的實施意見(試行)》) which was issued on December 26, 2016, the Two-Invoice System is a system under which invoices are issued by drug manufacturers to drug distributors on a once-off basis while invoices are issued by drug distributors to medical institutions on a once-off basis.

According to the Several Opinions of the General Office of the State Council on Further Reform and Improvement in Policies of Drug Production, Circulation and Use (《國務院辦公廳關於進一步改革完善藥品生產流通使用政策的若干意見》), which was issued on January 24, 2017, on a priority basis, Pharmaceutical companies must comply with the Two-Invoice System in order to engage in procurement processes with public hospitals.

Drug Recall

According to the Measures on Drug Recall (《藥品召回管理辦法》) promulgated on December 10, 2007, latest amended in October 2022 and came into effect on November 1, 2022, a drug manufacturer should establish and improve its recall system by collecting relevant information about drug safety and making an investigation and evaluation with respect to any drugs with potential safety hazards. If there are any potential safety hazards that endanger human health and life safety in respect of any drugs sold in the PRC, such manufacturer must start the drug recall procedures.

Gathering, Collection and Filing of Human Genetic Resources

The Interim Measures for the Management of Human Genetic Resources (《人類遺傳資源管理暫行辦法》) set out rules for the protection and use of human genetic resources in China. Pursuant to the Service Guide for Administrative Licensing of Gathering, Collection, Deal, Export and Exit Approval of Human Genetic Resources of Human genetic resources (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) promulgated by the Ministry of Science and Technology in July 2015 and the Notice on the Implementation of the Administrative License for the Gathering, Collection, Deal, Export and Exit of Human Genetic Resources (《關於實施人類遺傳資源採集、收集、買賣、出口、出境審批行政許可的通知》) promulgated by the Ministry of Science and Technology in August 2015, foreign investment sponsors who gather and

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collect human genetic resources through clinical trials should file a record with the China Human Genetic Resources Management Office through an online system. The Ministry of Science and Technology promulgated the Notice on Updating the Scope and Procedures for Administrative Licensing, Filing, and Prior Reporting of Human Genetic Resource Services Guidelines (《關於更新人類遺傳資源行政許可事項服務指南、備案以及事先報告範圍和程序的通知》) on July 14, 2023 and came into effect since July 1, 2023, which has further refined the approval process for the gathering and collection of human genetic resources for the listing of drugs in the PRC.

Pursuant to the Regulations on the Management of Human Genetic Resources of the People’s Republic of China (《中華人民共和國人類遺傳資源管理條例》) (the “HGR Regulations”) promulgated by the State Council in May 2019, newly amended in March 2024 and came into effect on May 1, 2024, the state supports the rational use of human genetic resources for scientific research, development of the biomedical industry, improvement of diagnosis and treatment technology, improvement of China’s ability to guarantee biosafety and improvement of the level of people’s health. In addition, the gathering, preservation, utilization and external provision of Chinese genetic resources shall (i) conform to ethical principles and conduct ethical review in accordance with relevant regulations; (ii) respect the privacy of the human genetic resource providers, obtain their prior consents, and protect their lawful rights and interests; (iii) comply with technical specification promulgated by the healthcare department of the State Council.

On October 17, 2020, SCNPC promulgated Biosecurity Law of the PRC (《中華人民共和國生物安全法》), and latest amended and came into effect on April 26, 2024. The Biosecurity Law establishes a comprehensive legislative framework for the pre-existing regulations in such areas including security management of human genetic resources and biological resources. The Ministry of Science and Technology promulgated the Implementation Rules for the Administrative Regulation on Human Genetic Resources (《人類遺傳資源管理條例實施細則》) (the “Implementation Rules”) on May 26, 2023 and came into effect on July 1, 2023. The Implementation Rules has further provided detailed implementation regulations for the administration of human genetic resources of the PRC.

Good Clinical Practice Certification and Compliance with the Good Clinical Practice (GCP)

To improve the quality of clinical trials, the NMPA and NHC promulgated the Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》) (the “GCP”) in April 2020, lastly amended on May 21, 2026 and will come into effect on September 1, 2026, which aims to ensure that the clinical trials of drugs are standardized and the results are scientific and reliable, protecting the rights and safety of human subjects. Pursuant to the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation of Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) promulgated by the general offices of the Chinese Communist Party Central Committee and the State Council in October 2017, the qualification of clinical trial institutions shall be subject to record management. Clinical trials should follow GCP and protocols approved by the ethics committee of each research center.

Other Laws and Regulations in Relation to Medical Industry

Basic Medical Insurance Policy

Pursuant to the Opinions of the State Council on the Integration of the Basic Medical Insurance System for Urban and Rural Residents (《國務院關於整合城鄉居民基本醫療保險制度的意見》) promulgated by the State Council on January 3, 2016, a unified basic medical insurance system for urban and rural residents was established, including the existing urban residents’ medical insurance and all the insured personnel of New Rural Cooperative Medical System, covering all urban and rural residents except those who should be covered by the employee’s basic medical insurance.

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Medical Insurance Catalogue

Pursuant to the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee (《城鎮職工基本醫療保險用藥範圍管理暫行辦法》), the scope of medical insurance coverage for pharmaceutical products needs to be managed through the formulation of the Medical Insurance Catalogue. The currently effective one is the National Insurance Drug List for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (2024) (《國家基本醫療保險、工傷保險和生育保險藥品目錄(2024年)》) came into effect since January 1, 2025.

Drug Price

Pursuant to the Drug Administration Law, for drug products with market-regulated prices in accordance with the law, the drug marketing authorization holder, the drug manufacturer, the drug distributor and medical institution shall determine the price pursuant to the principles of fairness, reasonableness, integrity and trustworthiness as well as quality for value in order to supply drug users with reasonably priced drug products; and shall comply with the requirements relating to drug price administration promulgated by the State Council’s pricing authorities, determine and clearly mark the retail prices of drug products. Pursuant to the Notice on Issuing Opinions on Promoting Drug Price Reform (《關於印發<推進藥品價格改革意見>的通知》) jointly promulgated by NDRC, NHC, the Ministry of Human Resources and Social Security, Ministry of Industry and Information Technology, the Ministry of Finance, the MOFCOM and the CFDA on May 4, 2015 and came into effect on June 1, 2015. From June 1, 2015, except for narcotic drugs and first-class psychotropic drugs, the price of drugs set by the government will be cancelled.

Pricing Regulations and Policies relating to Traditional Chinese Medicine

According to the Notice on Issuing Opinions on Current Drug Price Management Work (《關於印發<關於做好當前藥品價格管理工作的意見>的通知》) promulgated by the NHSA on November 26, 2019, the scope of drugs managed by the department of healthcare security includes traditional Chinese medicine, chemical medicines, biochemical drugs, and hospital preparations, among which narcotic drugs and first-class psychotropic drugs implement government-guided prices, while other drugs implement market-adjusted prices. Pursuant to the Opinions on Promoting the Normalization and Institutionalization of the Centralized Volume-based Procurement of Drugs (《關於推動藥品集中帶量採購工作常態化制度化開展的意見》) issued by the General Office of the State Council on January 22, 2021, the highest effective declared price for purchasing drugs and other shortlisting conditions are determined based on the existing market prices. The number of eligible enterprises is determined according to the market competition pattern and supply capacity. In May 2026, the National Joint Purchasing Office of Traditional Chinese Medicine issued the National Joint Purchasing Office of Traditional Chinese Medicine Centralized Procurement Document (ZYYPLM-2026-1) (《全國中藥飲片採購聯盟集中採購文件(ZYYPLM-2026-1)》) to launch the centralized procurement of 41 species of traditional Chinese medicines that meet the conditions for centralized procurement.

Advertising of Pharmaceutical Products

Pursuant to the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food and Formula Food for Special Medical Purposes (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》), which promulgated by SAMR in December 2019 and came into effect on March 1, 2020, advertisements for drugs, medical devices, health food and formula food for special medical purposes shall be true and legitimate, and shall not contain any false or misleading contents.

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Insert Sheet, Labels and Packaging of Pharmaceutical Products

Pursuant to the Measures for the Administration of the Insert Sheets and Labels of Drugs (《藥品說明書和標籤管理規定》), which promulgated by SFDA and came effective on June 1, 2006, the insert sheets and labels of drugs should be reviewed and approved by the SFDA. Pursuant to the Measures for The Administration of Pharmaceutical Packaging (《藥品包裝管理辦法》) which came effective on September 1, 1988, pharmaceutical packaging must comply with the national and professional standards.

Drug Technology Transfer

Drug technology transfer refers to the transfer of drug production technology by the owner to a drug manufacturer as the transferee and the application for drug registration by the drug manufacturer as the transferee pursuant to the laws and regulations in relation to drug technology transfer. The registration process of drug technology transfer, which includes application for, evaluation, review, approval and supervision of drug technology transfer registration, is regulated by the Administrative Measures for Drug Registration and the Administrative Regulation for Technology Transfer Registration of Drugs (《藥品技術轉讓註冊管理規定》) promulgated by the SFDA on August 19, 2009. According to the above regulations, drug technology transfer includes new drug technology transfer and drug production technology transfer. An application for drug technology transfer must be submitted to the provincial drug regulatory authority, and the SFDA will ultimately make an approval decision based on the comprehensive opinions of the drug review center. Eligible applications will receive a letter of approval and a drug approval number for the supplementary application.

Administration of Pathogenic Microorganism Laboratories

According to the Regulations on the Bio-safety Management of Pathogenic Microbe Laboratories (《病原微生物實驗室生物安全管理條例》) promulgated by State Council and latest amended in December 2024, the pathogenic microorganism laboratories are classified into Level 1, Level 2, Level 3 and Level 4 in accordance with its biosafety level for pathogenic microorganisms and the national standards for the bio-safety.

Laws and Regulations in Relation to Intellectual Property

Patent

Patents in the PRC are mainly protected by the Patent Law of the PRC (《中華人民共和國專利法》) (the “Patent Law”), which was promulgated by the SCNPC on March 12, 1984 and latest amended on October 17, 2020 and came into effect on June 1, 2021, and the Implementation Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》) (the “Implementation Rules”), promulgated by the State Council on June 15, 2001 and latest amended on December 11, 2023 and came into effect on January 20, 2024. The Patent Law and the Implementation Rules provide for three types of patents, namely “invention,” “utility model” and “design.” The duration of a patent right for “invention” is twenty (20) years; the duration of a patent right for “utility model” is ten (10) years; and the duration of a patent right for “design” is fifteen (15) years, all of which duration are from the date of application.

Trademarks

Registered trademarks in the PRC are mainly protected by the Trademark Law of the PRC (《中華人民共和國商標法》), which was promulgated by the SCNPC on August 23, 1982 and latest amended on June 26, 2026 and will come into effect on January 1, 2027, and the Implementation Rules of the Trademark Law of the PRC (《中華人民共和國商標法實施條例》), which were

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promulgated by the State Council on August 3, 2002 and latest amended on April 29, 2014 and came into effect on May 1, 2014. The Trademark Office is responsible for the registration and administration of trademarks throughout China and grants a term of ten (10) years to registered trademarks.

Domain Names

Domain names are regulated under the Administrative Measures on the Internet Domain Names (《互聯網域名管理辦法》) issued by the Ministry of Industry and Information Technology (the “MIIT”), on August 24, 2017 and effective from November 1, 2017. The MIIT is the main regulatory authority responsible for the administration of the PRC internet domain names. Domain names registrations are handled through domain name service agencies established under the relevant regulations, and the applicants become domain name holders upon successful registration.

Trade Secret

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》) promulgated by SCNPC, lastly amended on June 27, 2025 and came into effect on October 15, 2025, the term “trade secrets” refers to technical and business information that is unknown to the public, has utility, may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Under the Anti-Unfair Competition Law of the PRC, business persons are prohibited from infringing others’ trade secrets by: (i) acquiring a trade secret from the right holder by theft, bribery, fraud, coercion, electronic intrusion, or any other means; (ii) disclosing, using, or allowing another person to use a trade secret acquired from the right holder by any means as specified in the item (i) above; (iii) disclosing, using, or allowing another person use a trade secret in its possession, in violation of its confidentiality obligation or the requirements of the right holder for keeping the trade secret confidential; (iv) abetting a person, or tempting another person into or in acquiring, disclosing, using, or allowing another person to use the trade secret of the right holder in violation of his or her non-disclosure obligation or the requirements of the right holder for keeping the trade secret confidential. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed to have committed a misappropriation of the others’ trade secrets.

Regulations in Relation to Foreign Direct Investment

Since January 1, 2020, the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the “Foreign Investment Law”) promulgated by the National People’s Congress (the “NPC”) has come into effect. Since then, the Foreign Investment Law has become the basic law regulating foreign-invested enterprises wholly or partially invested by foreign investors. While the organization form, institutional framework and standard of conduct of foreign-invested enterprises shall be subject to the provisions of the Company Law of the PRC and other laws. Negative List refers to a special administrative measure for the entry of foreign investment in specific sectors as imposed by the PRC. The PRC accords national treatment to foreign investment outside of the Negative List. The current Negative List is the Special Management Measures (Negative List) for the Access of Foreign Investment (2024 Revision) (《外商投資准入特別管理措施(負面清單)(2024年版)》) issued by the NDRC and the MOFCOM on September 6, 2024 and came into effect on November 1, 2024, which lists the special management measures for foreign investment access for industries regulated by the Negative List, such as equity requirements and senior management requirements. While strengthening investment promotion and protection, the Foreign Investment Law further regulates foreign investment management and proposes the establishment of a foreign investment information reporting system that replaces the original foreign investment enterprise approval and filing system of the MOFCOM.

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Regulations in Relation to Overseas Direct Investment

Pursuant to the Administrative Measures for Outbound Investment (《境外投資管理辦法》) (Order No. 3 [2014] of the MOFCOM, effective on October 6, 2014) promulgated by the MOFCOM, the MOFCOM and provincial competent commerce departments shall carry out administration either by record-filing or approval, depending on different circumstances of outbound investment by enterprises. Outbound investment by enterprises that involves sensitive countries and regions or sensitive industries shall be subject to administration by approval. Outbound investment by enterprises that falls under any other circumstances shall be subject to administration by record-filing.

Pursuant to the Administrative Measures for Outbound Investment by Enterprises (《企業境外投資管理辦法》) (Order No. 11 of the NDRC, effective on March 1, 2018), a domestic enterprise (the “investor”) making an outbound investment shall obtain approval, conduct record-filing or other procedures applicable to outbound investment projects (the “Projects”), reporting relevant information, and cooperating with the supervision and inspection. Sensitive Projects carried out by Investors directly or through overseas enterprises controlled by them shall be subject to approval; non-sensitive Projects directly carried out by Investors, namely, non-sensitive projects involving investors’ direct contribution of assets or rights and interests or provision of financing or guarantee shall be subject to record-filing. The aforementioned “sensitive project” means a project involving a sensitive country or region or a sensitive industry. The NDRC promulgated the Catalogue of Sensitive Sectors for Outbound Investment (2018 Edition) (《境外投資敏感行業目錄(2018年版)》), effective on March 1, 2018 to list the current sensitive industries in detail. As of the Latest Practicable Date, we do not have any “sensitive Project” involving a sensitive country or region or a sensitive industry.

The Provisions of the State Council on Outbound Investment (《國務院關於對外投資的規定》) were issued by the State Council on May 5, 2026 and effective on July 1, 2026. The Provisions strengthen the regulation of outbound investment, and guide and supervise investors to conduct standardized investment and business activities. The Provisions also prohibit any illegal cross-border transfer of goods, technologies, services and data subject to export prohibitions or restrictions, and specify compliance obligations governing outbound investment activities, including record-filing, information reporting and cross-border capital management.

Pursuant to the Regulations on the Administration of Foreign Exchange of the PRC (《中華人民共和國外匯管理條例》) promulgated by the State Council on January 29, 1996, and last amended and effective on August 5, 2008, any domestic organization or individual that seeks to make a direct investment overseas or engage in the issuance or trading of negotiable securities or derivatives overseas shall make the appropriate registrations in accordance with State Council foreign exchange administrative department provisions.

The Circular of the State Administration of Foreign Exchange on Further Improving and Adjusting Foreign Exchange Administration Policies on Direct Investment (《國家外匯管理局關於進一步改進和調整直接投資外匯管理政策的通知》) (hereinafter referred to as the “Circular 59”), which was promulgated by the State Administration of Foreign Exchange (the “SAFE”) on November 19, 2012, and last amended on October 10, 2018, part of which was abolished on December 30, 2019, substantially amends and simplifies the foreign exchange procedures. In February 2015, the SAFE promulgated the Notice on Further Simplifying and Improving Foreign Exchange Administration Policies on Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》), part of which was abolished in December 2019. It stipulates that banks shall, on behalf of the SAFE, directly examine and handle foreign exchange registration under domestic direct investment and overseas direct investment, and the SAFE and its branches shall exercise indirect supervision over foreign exchange registration of direct investment through banks. On April 3, 2024, the SAFE promulgated the Guidelines of Capital Account Foreign Exchange Business (2024 Version) (《資本項目外匯業務指引(2024年版)》), which came into effective on May 6, 2024, and stipulates guidelines for the capital account foreign exchange business.

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Regulations in Relation to Product Liability

The Product Quality Law of the PRC (《中華人民共和國產品質量法》), promulgated by the SCNPC on February 22, 1993 and latest amended on December 29, 2018 (the “Product Quality Law”), is the principal governing law relating to the supervision and administration of product quality. According to the Product Quality Law, manufacturers shall be liable for the quality of products produced by them and sellers shall take measures to ensure the quality of the products sold by them.

Pursuant to the PRC Civil Code (《中華人民共和國民法典》) promulgated by the NPC on May 28, 2020 and coming into effect on January 1, 2021, where a patient suffers damage due to defects in drugs, he may seek compensation from the drug marketing authorization holder, producer or also from the medical institution. Where the patient seeks compensation from the medical institution, the medical institution, after it has made the compensation, shall have the right to recover the compensation from the liable drug marketing authorization holder.

The Law of the PRC on the Protection of the Rights and Interests of Consumers (《中華人民共和國消費者權益保護法》) was promulgated on October 31, 1993 and latest amended on October 25, 2013 and came into effect on March 15, 2014 to protect consumers’ rights when they purchase or use goods and accept services.

Regulations in Relation to Production Safety

The Production Safety Law of the PRC (《中華人民共和國安全生產法》), promulgated by the SCNPC on June 29, 2002 and latest amended on June 10, 2021 and came into effect on September 1, 2021, is the basic law for governing production safety. It provides that, any entity whose production safety conditions do not meet the requirements may not engage in production and business operation activities.

Regulations in Relation to Environmental Protection and Fire Safety

According to the Environmental Protection Law of the PRC (《中華人民共和國環境保護法》), promulgated by the SCNPC on December 26, 1989 and latest amended on April 24, 2014 and came into effect on January 1, 2015, the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》), promulgated by the SCNPC on October 28, 2002 and latest amended on December 29, 2018, and the Administrative Regulations on the Environmental Protection of Construction Project (《建設項目環境保護管理條例》), promulgated by the State Council on November 29, 1998 and latest amended and came into effect on October 1, 2017, enterprises which plan to construct projects shall engage qualified professionals to provide the assessment reports, assessment form, or registration form on the environmental impact of such projects.

According to the Administrative Measures on Pollutant Discharge Permit issued by the Ministry of Ecology and Environment on April 1, 2024 and came into effect on July 1, 2024, enterprises, public institutions and other producers and operators that are subject to the administration of pollutant discharge permits shall apply for pollutant discharge permit and discharge pollutants in accordance with the requirements of the pollutant discharge permit; and those who have not obtained the pollutant discharge permits shall not discharge pollutants.

According to the Fire Safety Law of the PRC (《中華人民共和國消防法》) promulgated by the SCNPC in April 1998, last amended and effective on April 29, 2021, and the Interim Provisions on Administration of Fire Protection Design Review and Acceptance of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》) (the “Interim Provisions”) promulgated by the Ministry of Housing and Urban-Rural Development on April 1, 2020, and last amended on August 21, 2023, the fire protection design or construction of a construction project must conform to the national fire protection technical standards for project construction and construction projects shall undergo the fire protection design review and acceptance system. The special construction projects as defined

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in the Interim Provisions must apply to the fire control department for fire protection design review, and complete the fire protection acceptance procedures after the completion of the construction project. The construction unit of other construction projects must complete the fire protection filing of the fire protection design and the completion acceptance within five (5) business days after the completion acceptance of the construction project. If a construction project fails to pass the fire safety inspection before it is put into use, or does not meet the fire safety requirements after the inspection, it will be ordered to suspend the construction and use of such project, or suspend production and business, and be imposed a fine.

Regulations in Relation to Prevention and Control of Occupational Diseases

The Prevention and Control of Occupational Diseases Law of the PRC (《中華人民共和國職業病防治法》), which was promulgated by the SCNPC on October 27, 2001 and latest amended on December 29, 2018 (the “Prevention and Control of Occupational Diseases Law”), is the basic law for the prevention and control of occupational diseases. According to the Prevention and Control of Occupational Diseases Law, budget for facilities for the prevention and control of occupational diseases of a construction project shall be included in the budget of the project and those facilities shall be designed, constructed and put into operation simultaneously with the main body of the project. The entity that takes charge of the project should carry out the assessment of the effectiveness of measures for the prevention and control of occupational diseases before the final acceptance of the construction project. In addition, employers shall take required administrative measures to prevent and control occupational diseases in work.

Regulations in Relation to Employment and Social Securities

Pursuant to the Labor Law of the PRC (《中華人民共和國勞動法》), promulgated by the SCNPC on July 5, 1994 and latest amended on December 29, 2018 and the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》), promulgated by the SCNPC on June 29, 2007 and latest amended on December 28, 2012 and came into effect on July 1, 2013, employers shall execute written labor contracts with full-time employees. All employers shall comply with local minimum wage standards.

According to Social Security Law of the PRC (《中華人民共和國社會保險法》), which was promulgated on October 28, 2010 and amended on December 29, 2018, an employer is required to make contributions to social insurance schemes for its employees, including basic pension insurance, basic medical insurance, unemployment insurance, maternity insurance and work-related injury insurance.

According to the Notice on Conducting the Relevant Work Concerning the Administration of Collection of Social Insurance Premiums in a Steady, Orderly and Effective Manner (《關於穩妥有序做好社會保險費徵管有關工作的通知》) promulgated by the General Office of the State Administration of Taxation on September 13, 2018 and the Urgent Notice on Implementing the Spirit of the Executive Meeting of the State Council in Stabilizing the Collection of Social Security Contributions (《關於貫徹落實國務院常務會議精神切實做好穩定社保費徵收工作的緊急通知》) promulgated by the General Office of the Ministry of Human Resources and Social Security on September 21, 2018, all the local authorities responsible for the collection of social insurance are strictly forbidden to conduct self-collection of historical unpaid social insurance contributions from enterprises. The Notice on Implementing Measures to Further Support and Serve the Development of Private Economy (《關於實施進一步支持和服務民營經濟發展若干措施的通知》), promulgated by the State Taxation Administration on November 16, 2018, repeats that tax authorities at all levels may not organize self-collection of arrears of taxpayers including private enterprises from the previous years. The Notice of General Office of the State Council on Promulgation of the Comprehensive Plan for the Reduction of Social Insurance Premium Rate (《國務院辦公廳關於印發降低社會保險費率綜合方案的通知》), promulgated on April 1, 2019, requires steady advancement of the reform of the system of social security collection.

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According to the Administrative Regulations on Housing Provident Funds (《住房公積金管理條例》), which was promulgated on April 3, 1999 and latest amended on March 24, 2019, employers are required to make contribution to housing provident funds for their employees.

Regulations in Relation to Information Security and Data Privacy

Data Security and Export

The NPCSC promulgated the Data Security Law of the People’s Republic of China (《中華人民共和國數據安全法》), on June 10, 2021 (effective from September 1, 2021), for the establishment of a data classification and grading protection system to conduct classified and hierarchical protection of data.

According to the Measures for Security Assessment of Data Export (《數據出境安全評估辦法》) issued by the Cyberspace Administration of China on July 7, 2022 and came into effect on September 1, 2022, a data processor that provides data overseas under any of the following circumstances shall apply to the national cyberspace administration for the security assessment of the outbound data transfer through local provincial cyberspace administration: (i) a data processor provides important data abroad; (ii) the critical information infrastructure operator or the data processor that has processed the personal information of more than 1 million people provides personal information abroad; (iii) the data processor that has provided the personal information of over 100,000 people or the sensitive personal information of over 10,000 people cumulatively since January 1 of the previous year provides personal information abroad; and (iv) any other circumstance where an application for the security assessment of outbound data transfer is required by the national cyberspace administration.

According to the Measures for Standard Contract for Outbound Transfer of Personal Information (《個人信息出境標準合同辦法》) issued by the Cyberspace Administration of China on February 22, 2023 and effective from June 1, 2023, to provide personal information to an overseas recipient through the conclusion of the standard contract, a personal information processor shall meet all of the following circumstances: (i) it is not a critical information infrastructure operator; (ii) it has processed the personal information of less than one million individuals; (iii) it has cumulatively provided the personal information of less than 100,000 individuals to overseas recipients since January 1 of the previous year; and (iv) it has cumulatively provided the sensitive personal information of less than 10,000 individuals since January 1 of the previous year.

According to the Provisions on Facilitating and Regulating Cross-border Data Flows (《促進和規範數據跨境流動規定》), a data handler that is not a critical information infrastructure operator, will be exempted from declaring for security assessment for outbound data transfer, signing a standard contract with overseas recipient or passing the personal protection certification, if such data handler accumulatively transfers overseas ordinary personal information of less than 100,000 individuals since the January 1 of the current year.

Personal Information Protection

According to the Civil Code (《民法典》), personal information of natural persons is protected by law. If any organization or individual needs to obtain other people’s personal information, they should obtain it in accordance with the law and ensure the security of the information. The Personal Information Protection Law of the People’s Republic of China (《中華人民共和國個人信息保護法》) promulgated by the NPCSC on August 20, 2021 and implemented on November 1, 2021, further emphasizes the obligations and responsibilities of processors for the protection of personal information, and requests higher level of protective measures on the processing of sensitive personal information.

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According to the Cybersecurity Law of the People’s Republic of China (《中華人民共和國網絡安全法》) promulgated by the NPCSC on November 7, 2016, lastly amended on October 28, 2025 and came into effect on January 1, 2026, network operators must follow the principles of legality, legitimacy and necessity when collecting and using personal information, and publicly disclose the rules for collection and use, clearly state the purpose, method and scope of collecting and using information, and obtain the consent of the person whose data is being collected. Network operators shall not collect personal information unrelated to the services they provide. Network operators are not allowed to leak, tamper with, or damage the personal information they collect; they are not allowed to provide personal information to others without the consent of the person whose data is being collected. However, this does not apply to cases where a specific individual cannot be identified and the identity cannot be recovered after processing. Network operators should take technical measures and other necessary measures to ensure the security of the personal information they collect and prevent leakage, damage and loss of information.

Laws and Regulations in Relation to Anti-Bribery

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》) promulgated by SCNPC, lastly amended on June 27, 2025 and came into effect on October 15, 2025, and the Interim Provisions on the Prohibition of Commercial Bribery (《關於禁止商業賄賂行為的暫行規定》) promulgated by the SAIC on November 15, 1996, any business operator shall not provide or promise to provide economic benefits (including cash, other property or by other means) to a counter-party in a transaction or a third party that may be able to influence the transaction, in order to entice such party to secure a transactional opportunity or competitive advantages for the business operator. Any business operator breaching the relevant anti-bribery rules above-mentioned may be subject to administrative punishment or criminal liability depending on the seriousness of the cases.

Pursuant to the Provisions on the Establishment of Adverse Records of Commercial Briberies in the Medicine Purchase and Sales Industry (《關於建立醫藥購銷領域商業賄賂不良記錄的規定》), which was promulgated by the National Health and Family Planning Commission (currently the NHC) and came into effect on March 1, 2014, any medicine production and operation enterprises or agents that are involved in criminal, investigational or administrative procedures for commercial bribery will be listed in the adverse records of commercial bribes by the relevant government authorities, as a result of which, for two years from the date the list of adverse records of commercial bribes is published, (i) their products cannot be purchased by public medical institutions or medical and health institutions receiving financial subsidies within the relevant provinces, and (ii) the scores of their products in the centralized tender processes of public medical institutions or medical and health institutions receiving financial subsidies in other provinces will be reduced. As for those enterprises or agents listed in adverse records twice within five years, their products cannot be purchased by public medical institutions or medical and health institutions receiving financial subsidies throughout China for two years from the date the list of adverse records of commercial bribes is published.

Regulations in Relation to Overseas Securities Offering and Listing by Domestic Companies

According to the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Enterprises (《境內企業境外發行證券和上市管理試行辦法》) issued by the China Securities Regulatory Commission (the “CSRC”) on February 17, 2023 and effective from March 31, 2023 (hereinafter referred to as the “Trial Measures”), where a domestic company seeks overseas securities issuance and listing, the issuer shall file with the CSRC in accordance with the Trial Measures. If an issuer procures an overseas initial public offering or listing, it shall file with the CSRC within three (3) business days after submitting application documents for overseas securities issuance and listing.

According to the Provisions on Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》) jointly issued by the CSRC and other departments on

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February 24, 2023 and effective on March 31, 2023, in the overseas offering and listing activities of domestic enterprises, domestic enterprises, and securities companies and securities service institutions that provide corresponding services shall strictly comply with the applicable laws and regulations of the People’s Republic of China and satisfy the requirements of these Provisions, enhance the legal awareness of safeguarding state secrets and strengthening archives administration, establish and improve the confidentiality and archives work system, and take necessary measures to fulfill the confidentiality and archives administration obligations, and shall not divulge state secrets or work secrets of state organs, or harm the interests of the state or the public.

OVERVIEW OF LAWS AND REGULATIONS IN THE UNITED STATES

This section summarizes the principal laws and regulations in the United States that are relevant to our business.

U.S. Government Regulation of Drug and Biological Products

In the United States, the FDA regulates drugs under the Federal Food Drug and Cosmetic Act (the “FDCA”), its implementing regulations, and biologics implemented under the FDCA and the Public Health Service Act (the “PHSA”) and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations, such as those related to competition.

Once a product candidate is identified for development, it enters preclinical testing, which includes laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. Preclinical testing is conducted in accordance with FDA’s Good Laboratory Practice regulations. A sponsor of an IND must submit the results of the preclinical tests, manufacturing information, analytical data, the clinical trial protocol, and any available clinical data or literature to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions and places the trial on a clinical hold within that 30-day period. FDA may also impose clinical holds or partial clinical holds at any time during clinical trials due to safety concerns or non-compliance.

All clinical trials, which involve the administration of the investigational product to humans, must be conducted under the supervision of one or more qualified investigators in accordance with Good Clinical Practice regulations, including the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial. Further, an Institutional Review Board (the “IRB”), must review and approve the plan for any clinical trial before it commences at any institution, and the IRB must conduct continuing review and re-approve the study at least annually. Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. An IRB can suspend or terminate approval of a clinical trial at its institution if the trial is not being conducted in accordance with the IRB’s requirements or if the product has been associated with unexpected serious harm to subjects.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. Safety reports must be submitted to the FDA and the investigators 15 calendar days after the trial sponsor determines that the information qualifies for reporting. The sponsor also must notify FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than 7 calendar days after the sponsor’s initial receipt of the information. Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov.

Concurrent with clinical trials, companies usually complete additional animal studies and must also finalize a process for manufacturing the product in commercial quantities in accordance with current Good Manufacturing Practice (“cGMP”) requirements. The process of obtaining

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regulatory approvals and compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements may subject an applicant to administrative or judicial sanctions.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the product, proposed labeling and other relevant information, are submitted to the FDA as part of a biologics license application ("BLA"). Unless deferred or waived, BLAs, or supplements must contain data adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The submission of a BLA is subject to the payment of a substantial user fee and an annual prescription drug program fee.

Within 60 days of its receipt, the FDA reviews the BLA to ensure that it is sufficiently complete for substantive review before it accepts the BLA for filing. After accepting the BLA filing, the FDA begins an in-depth substantive review to determine, among other things, whether a product is safe and effective for its intended use. The FDA also evaluates whether the product's manufacturing is cGMP-compliant to assure the product's identity, strength, quality and purity. Before approving the BLA, the FDA typically will inspect whether the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA may refer the BLA to an advisory committee, a panel of experts, for review whether the application should be approved and under what conditions and considers such recommendations when making decisions.

The FDA may refuse to approve the BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. The FDA will issue a complete response letter describing all of the specific deficiencies that the FDA identified in the BLA that must be satisfactorily addressed before it can be approved. The regulatory approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including phase IV clinical trials, to further assess a product's safety and effectiveness after BLA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Expedited Development and Review Programs

The FDA has various programs that are intended to expedite or streamline the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs.

Fast-track Designation

To be eligible for a fast-track designation, the FDA must determine, based on the request of a sponsor, that a drug is intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and demonstrates the potential to address an unmet medical need for the disease or condition. Under the fast-track program, the sponsor of a drug candidate may request FDA to designate the product for a specific indication as a fast-track product concurrent with or after the filing of the IND for the drug candidate. The FDA must make a fast-track designation determination within 60 days after receipt of the sponsor's request. In addition to other benefits, such as the ability to use surrogate endpoints and have greater interactions with FDA, FDA may initiate review of sections of a fast-track product's NDA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the

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submission of the remaining information and the applicant pays applicable user fees. However, FDA’s time period goal for reviewing a fast-track application does not begin until the last section of the NDA is submitted. In addition, the fast-track designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Priority Review

The FDA may give a priority review designation to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under the Prescription Drug User Fee Act (the “PDUFA”) guidelines. These six- and ten-month review periods are measured from the “filing” date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast-track designation are also likely to be considered appropriate to receive a priority review.

Accelerated Approval

Under FDA’s accelerated approval regulations, the FDA may approve a drug or biologic candidate for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments and demonstrates an effect on either a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (“IMM”), that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the disease or condition and the availability or lack of alternative treatments. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of post-approval clinical trial to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Breakthrough Designation

Another program available for sponsors is the breakthrough therapy designation. A drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A sponsor may request that a product be designated as a breakthrough therapy concurrently with, or at any time after, the submission of an IND, and the FDA must determine if the candidate qualifies for such designation within 60 days of receipt of the request. If so designated, the FDA shall act to expedite the development and review of the product’s marketing application, including by meeting with the sponsor throughout the product’s development, providing timely advice to the sponsor to ensure that the development program to gather preclinical and clinical data is as efficient as practicable.

Orphan Drugs

Under The Orphan Drug Act of 1983, the FDA may grant orphan drug designation to drugs or biologic candidates intended to treat a rare disease or condition generally affecting fewer than 200,000 individuals in the U.S. or for which a manufacturer has no reasonable expectation of recovering drug treatment research and development costs. The first applicant to receive FDA

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approval for the disease or indication for which it has orphan drug designation is entitled to a seven-year exclusive marketing period. During the exclusivity period, the FDA may not approve any other applications to market the same product for the same disease or condition except in limited circumstance.

Post-Marketing Requirements

Following the approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations, known as “off-label use,” and limitations on industry-sponsored scientific and educational activities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for a risk evaluation and mitigation strategy (the “REMS”), to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve the BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Product approvals may be withdrawn for noncompliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved BLA, including recall.

Patient Protection and Affordable Health Care Act

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the “ACA”), became law in the United States in March 2010, and have driven healthcare reform in the United States by extending health insurance coverage and substantially changing the way healthcare financed by both governmental and private insurers in the United States. With regard to pharmaceutical products specifically, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit. Among other things, the ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, and mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies’ share of sales to federal health care programs. Since its enactment, there have been judicial and congressional challenges to certain aspects of the ACA, and there may be additional challenges and amendments to the ACA in the future.

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Patent Term Restoration and Marketing Exclusivity

After approval, owners of relevant drug or biological product patents may apply for up to a five-year patent extension to restore a portion of patent term lost during product development and FDA review of a BLA if approval of the application is the first permitted commercial marketing or use of a biologic containing the active ingredient under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The allowable patent term extension is calculated as one-half of the product’s testing phase, which is the time between IND and BLA submission, and all of the review phase, which is the time between BLA submission and approval, up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration, only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended, and the patent holder must apply for restoration within 60 days of approval. The United States Patent and Trademark Office (the “USPTO”), in consultation with the FDA, reviews and approves the application for patent term restoration. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and the patent owner may apply for no more than four subsequent interim extensions. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug candidate covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug candidate for which a BLA has not been submitted.