

REGULATORY OVERVIEW

OVERVIEW OF LAWS AND REGULATIONS IN THE PRC

REGULATIONS ON PHARMACEUTICAL PRODUCT

Drug Regulatory Regime

The Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the “**Drug Administration Law**”) was promulgated by the Standing Committee of the NPC (the “**SCNPC**”), in September 1984, last amended on August 26, 2019 and became effective on December 1, 2019. The Implementation Regulations of the Drug Administration Law of the PRC (《中華人民共和國藥品管理法實施條例》) (the “**Implementation Regulations**”) was promulgated by the State Council in August 2002, and was last amended in January 2026, and became effective on May 2026. The Drug Administration Law and the Implementation Regulations have jointly established the legal framework for the administration of pharmaceutical products in the PRC, including the research, development and manufacturing of drugs. The Drug Administration Law applies to entities and individuals engaged in the development, production, trade, application, supervision and administration of pharmaceutical products, which regulates and provides for a framework for the administration of pharmaceutical manufacturers, pharmaceutical trading companies and medicinal preparations of medical institutions, and the development, research, manufacturing, distribution, packaging, pricing and advertisements of pharmaceutical products. The Implementation Regulations, at the same time, provides the detailed implementation regulations on the Drug Administration Law.

The General Office of the Central Committee of the Communist Party of China and the General Office of the State Council jointly issued an Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on 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》) (the “**Innovation Opinions**”) in October 2017. According to the Innovation Opinions, institutions for drug clinical trials should establish an independent ethics committee and the clinical trial schemes are subject to examination, approval and signing with approval opinions by the ethics committee before implementation, in order to protect the rights and interests of human subjects in clinical trials.

Application for Clinical Trial

According 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 China Food and Drug Administration (currently known as the National Medical Products Administration, the “**NMPA**”) on March 17, 2017, the decision on the approval of clinical trials of drugs shall be made by the Center for Drug Evaluation (“**CDE**”) from May 1, 2017. According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) (the “**Registration Measures**”), which was promulgated on January 22, 2020 and took effect on July 1, 2020, drug clinical trials shall be divided into Phase I clinical trial, Phase II clinical trial, Phase III clinical trial, Phase IV clinical trial, and bioequivalence trial. After the completion of the pharmaceutical, pharmacological and toxicological research of the drug clinical trial, the applicant may submit relevant research materials to CDE for applying for the approval to conduct drug clinical trial. The CDE will organize pharmaceutical, medical and other technicians to review the application and to decide whether to approve the drug clinical trial within 60 days of the date of acceptance of the application. Once the decision is made, the result will be notified to the applicant through the website of the CDE and if no notice of decision is issued within the aforementioned time limit, the application of clinical trial shall be deemed as approval. In accordance with Registration Measures and the Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs (《關於調整藥物臨床試驗審評審批程序的公告》) issued in July 2018, if a clinical trial applicant does not receive any negative or questioned opinions from the CDE within 60 days after the date when the trial application is accepted and the fees are paid, the applicant can proceed with the clinical trial in accordance with the trial protocol submitted to the CDE.

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After obtaining the approval of clinical trial, the applicant must complete the clinical trial registration at the Drug Clinical Trial Information Platform for public disclosure in accordance with the Circular 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. The applicant shall complete the trial pre-registration within one month after obtaining the approval of the clinical trial application in order to obtain the trial’s unique registration number and complete registration of certain follow-up information before the first subject’s enrollment in the trial. If the registration is not completed within one year after the approval, the applicant shall submit an explanation, and if the first submission is not completed within three years, the approval of the clinical trial application shall automatically expire. During the drug clinical trials, the applicant shall update registration information continuously, and register information of the outcome of the drug clinical trial upon completion.

Accelerated Approval for Clinical Trial and Registration

The Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices (《關於改革藥品醫療器械審評審批制度的意見》) issued by the State Council on August, 2015, established a reform framework of the evaluation and approval system for drugs and medical devices, and indicated the tasks of enhancing the standards of approval for drug registration, accelerating the evaluation and approval process for innovative drugs, and improving the approval for clinical trials of drugs, etc.

The China Food and Drug Administration (currently known as the NMPA) released the Circular Concerning Several Policies on Drug Registration Review and Approval (《關於藥品註冊審評審批若干政策的公告》) in November 2015, which clarified the measures and policies regarding simplifying and accelerating the approval process of clinical trials.

The Innovation Opinions established a framework for reforming the evaluation and approval system for drugs, medical devices and equipment.

According to the Announcement on Matters Concerning the Optimization of Drug Registration Review and Approval (《關於優化藥品註冊審評審批有關事宜的公告》) jointly issued by the NMPA and the National Health Commission (the “NHC”) in May 2018, the CDE will prioritize the allocation of resources for review, inspection, examination and approval of registration applications that have been included in the scope of fast track clinical trial approval.

In April 2026, the NMPA issued the Review and Approval Procedures for Conditional Approval of Drug Marketing Applications (《藥品附條件批准上市申請審評審批工作程序》) which came into effect on the date of its promulgation.

In July 2020, NMPA issued the Priority Review and Approval Procedures for Drug Marketing Authorizations (Trial Implementation) (《藥品上市許可優先審評審批工作程序(試行)》), at the time of application for drug marketing authorization, drugs which have obvious clinical value may apply for prioritized review and approval procedures.

Conduct of Clinical Trial

After obtaining clinical trial approval, the applicant shall conduct clinical trials at qualified clinical trial institutions. The qualified clinical trial institution refers to institutions that have the conditions to conduct clinical trials in accordance with the requirements and technical guidelines set forth in the Regulations for the Administration of Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》), which came into effect on December 1, 2019.

The applicant filing an application for clinical drug trial after completing the pharmaceutical research, pharmacological and toxicological research, and other researches supporting clinical drug trial shall submit relevant research materials according to the requirements for the application materials. The applicant who intends to carry out a bioequivalence test shall, after undergoing the

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recordation formalities for bioequivalence test at the website of the CDE as required, carry out relevant research work according to the plan recorded. The applicant who is 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 Center for Drug Evaluation. Where indications (or functions) are intended to be added for a drug approved for clinical drug trial and the use of a drug in combination with other drugs is added, the applicant shall file a new application for clinical drug trial, and may only carry out new clinical drug trial with approval.

According to the Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs (《關於調整藥物臨床試驗審評審批程序的公告》), where the application for clinical trial of new investigational drug has been approved, upon the completion of Phase I and Phase II clinical trials and prior to Phase III clinical trial, the applicant shall submit the application for communication meetings to CDE to discuss with CDE the key technical questions including the design of the Phase III clinical trial protocol. According to the Administrative Measures for Communication on the Research, Development and Technical Evaluation of Drugs (《藥物研發與技術審評溝通交流管理辦法》), revised by the NMPA on December 10, 2020, during the research and development periods and in the registration applications of, among others, the innovative new drugs, the applicants may propose to conduct communication meetings with the CDE. The communication meetings can be classified into three types. Type I meetings are convened to address key safety issues in clinical trials of drugs and key technical issues in the research and development of breakthrough therapeutic drugs. Type II meetings are held during the key research and development stages of drugs, mainly including meetings before submitting the clinical trial application, meetings upon the completion of Phase II trials and prior to the Phase III trials, meetings before submitting the marketing application for a new drug, and meetings for risk evaluation and control. Type III meetings refer to other meetings not classified as Type I or Type II.

Good Clinical Practices

Clinical trials must be conducted in accordance with the Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》) (the “GCP Rules”) promulgated by NMPA and NHC on April 23, 2020 and effective on July 1, 2020, which stipulates the requirements for the procedures of conducting clinical trials, including preclinical trial preparation, trial protocols, protection of testees’ rights and interests, duties of researchers, sponsors and monitors, as well as data management and statistical analysis. According to the GCP Rules, clinical trial means systematical investigation of drugs conducted on human subjects (patients or healthy volunteers) to prove or reveal the clinical, pharmacological and other pharmacodynamic effects, adverse reactions or absorption, distribution, metabolism and excretion of the drug being investigated. In order to ensure the quality of clinical trials and the safety of human subjects, the GCP Rules provides comprehensive and substantive requirements on the design and conduct of clinical trials in the PRC. In particular, the GCP Rules enhances the protection for study subjects and tightens the control over bio-samples collected under clinical trials.

The GCP Rules also set out the qualifications and requirements for the investigators and centers participating in clinical trial.

The GCP Rules also summarizes the role of ethic committee in clinical trial process. An ethic committee shall consist of experts working in the medical, pharmaceutical and other fields. The clinical trial protocol may not be executed unless approved by the ethic committee. Pursuant to the Announcement on Issuing the Guidelines for Ethical Review Work of Drug Clinical Trials (《關於印發藥物臨床試驗倫理審查工作指導原則的通知》) promulgated by State Food and Drug

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Administration (currently known as the NMPA) in November 2010, the ethics committee shall carry out a review on the project of clinical trial on the drug to decide if it is rational in terms of science and ethics, and shall be subject to guidance and supervision under the drug supervisory and administrative departments.

Trial Exemptions and Acceptance of Foreign Data

The NMPA issued the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data (《接受藥品境外臨床試驗數據的技術指導原則》) in July 2018, as one of the implementing rules for the Innovation Opinions, which provides that overseas clinical data can be submitted for the drug marketing registration applications in China. Such applications can be in the form of waivers to China-based clinical trials, bridging trials and direct drug marketing registration. According to the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data, sponsors may use the data of foreign clinical trials to support drug marketing registration in China, provided that sponsors must ensure the authenticity, integrity, accuracy and traceability of foreign clinical trial data and such data must be obtained consistent with the relevant requirements under the Good Clinical Practice of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (the “ICH”). Moreover, sponsors shall ensure the scientific design of overseas clinical trials, the compliance of clinical trial quality management system requirements, and the accuracy and integrity of statistical analysis of data. 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 sponsors may, prior to implementing registrational clinical trials, contact the CDE to ensure the compliance of registrational clinical trials’ design with the essential technical requirements for drug registration in China. Sponsors must also comply with other relevant sections of the Registration Measures when applying for drug marketing registrations in China using foreign clinical trial data.

New Drug Registration

Pursuant to the Registration Measures, upon completion of clinical trials, determination of quality standards, completion of validation of commercial-scale production processes and completion of other related preparation works, the applicant may apply with the NMPA for the marketing authorization. The applicant must obtain the marketing authorization for a new drug before the drug can be manufactured and sold in the China market.

Marketing Authorization Holder Mechanism

Pursuant to the Drug Administration Law, the PRC implements the marketing authorization holder mechanism for management of the drug industry. The drug marketing authorization holder refers to an enterprise or a drug research and development institution that has obtained the drug registration certificate. The drug marketing authorization holder shall be responsible for non-clinical research, clinical trials, production and operation, post-marketing research, adverse reaction monitoring, reporting and processing of drugs in accordance with the provisions of the law.

Approval or Filing of Human Genetic Resources

The Regulations on the Administration of Human Genetic Resources of the PRC (《中華人民共和國人類遺傳資源管理條例》), promulgated by the State Council in May 2019, latest amended in March 2024 and came into effect in May 2024, further stipulates that in order to obtain marketing authorization for relevant drugs and medical devices in China, no approval is required in international clinical trial cooperation using China’s human genetic resources at clinical institutions without export of human genetic resource materials. However, the type, quantity and usage of the human genetic resources to be used shall be filed with the administrative department of health under the State Council before clinical trials. In May 2023, the MST issued the Implementation Rules for the Administrative Regulation on Human Genetic Resources (《人類遺傳資源管理條例實施細

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則》), which came into effect on July 1, 2023, optimizing the scope of administrative licensing and record-keeping, enhancing the operability of the human genetic resources administration system, and implementing the registration and reporting system for the management of human genetic resources.

On October 17, 2020, the SCNPC promulgated the Biosecurity Law of the PRC (《中華人民共和國生物安全法》) (the “**Biosecurity Law**”) which became effective on April 15, 2021 and latest amended on April 26, 2024, establishing a comprehensive legislative framework on the current regulations in the areas including prevention and control of outbreak of major newly-emerged infectious diseases, animal and plant epidemics, security of biotechnology research, development and application, biosafety management of pathogenic microbiology laboratories, security management of human genetic resources and biological resources, prevention of the invasion of alien species and protection of biodiversity, countermeasures against microbial resistance and prevention of bioterrorism and threat of biological weapons.

Two-Invoice System

Pursuant 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.

Pursuant 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. Pharmaceutical companies must comply with the Two-Invoice System in order to engage in procurement processes with public hospitals.

REGULATIONS ON INFORMATION SECURITY AND DATA PROTECTION

Data Security and Data Export

The SCNPC promulgated the Data Security Law of the PRC (《中華人民共和國數據安全法》) on June 10, 2021, which became effective from September 1, 2021, for the establishment of a data classification and grading protection system to conduct classified and hierarchical protection of data. Entities engaged in data processing activities shall, in accordance with laws and regulations, establish a sound full-process data security management system, organize data security education and training, and take corresponding technical measures and other necessary measures to ensure data security.

On December 28, 2021, the Cyberspace Administration of China (the “**CAC**”) and other twelve PRC regulatory authorities jointly revised and promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》) (the “**Cyber Review Measures**”), which came into effect on February 15, 2022. The Cyber Review Measures stipulate that, among others, (i) when the purchase of network products and services by a critical information infrastructures operator (the “**CIIO**”) (關鍵信息基礎設施運營者) or the data processing activities conducted by a network platform operator (網絡平台運營者) affect or may affect national security, a cybersecurity review shall be conducted pursuant to the Cyber Review Measures; (ii) an application for cybersecurity review shall be made by an issuer who is a network platform operator holding personal information of more than one million users before such issuer applies to list its securities abroad; and (iii) the relevant PRC governmental authorities may initiate cybersecurity review if such governmental authorities determine that the issuer’s network products or services, or data processing activities affect or may affect national security.

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According to the Measures on Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》) issued by the CAC on July 7, 2022 and effective 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 CIIO 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.

Personal Information Protection

The Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》) promulgated by the SCNPC 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.

According to the Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》) promulgated by the SCNPC on November 7, 2016 and effective on June 1, 2017, network operators must follow the principles of legality, legitimacy and necessity when collecting and using personal information, 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.

REGULATIONS ON INTELLECTUAL PROPERTY

Pursuant to the Patent Law of the PRC (《中華人民共和國專利法》) latest amended by the SCNPC on 17 October 2020 and came into effect on 1 June 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》) latest amended by the State Council on 11 December 2023 and came into effect on 20 January 2024, patents in China are divided into three types, i.e., invention patent, utility patent and design patent. The duration of a patent right for invention is 20 years, the duration of a patent right for utility model is 10 years, and the duration of a patent right for design is 15 years, all calculated from the date of application.

In accordance with the Trademark Law of the PRC (《中華人民共和國商標法》) which was latest amended by the SCNPC on 23 April 2019, with the latest revision effective on 1 November 2019, and the Implementation Regulations for the Trademark Law of the PRC (《中華人民共和國商標法實施條例》) which was latest amended by the State Council on 29 April 2014, with the latest revision effective on 1 May 2014, trademarks approved and registered by the Trademark Office of the National Intellectual Property Administration are registered trademarks, including commodity trademarks, service marks, collective trademarks, and certification marks; the validity period of a registered trademark is 10 years, calculated from the date of approval of registration.

The PRC Copyright Law (《中華人民共和國著作權法》), which was promulgated by the SCNPC on September 7, 1990 and amended on November 11, 2020, provides that Chinese citizens, legal persons, or other organizations shall, whether published or not, enjoy copyright in their works, which include, among others, works of literature, art, natural science, social science, engineering technology, and computer software.

REGULATIONS ON LEASING

According to the Civil Code of the PRC (《中華人民共和國民法典》) promulgated by the NPC on 28 May 2020 and implemented on 1 January 2021, the creation, modification, transfer, and extinction of real property rights that are subject to registration in accordance with the law shall take effect when they are recorded in the real estate registration book. A real estate ownership

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certificate is the proof that the owner has the right to the real estate. Pursuant to the Administrative Measures for Commodity Housing Leasing (《商品房屋租賃管理辦法》) promulgated by the Ministry of Housing and Urban-Rural Development on 1 December 2010 and came into effect on 1 February 2011, the parties to house leasing shall, within 30 days after the execution of the house leasing contract, go through the house leasing registration and filing formalities with the competent construction (real-estate) departments of the People’s Government of the municipality directly under the Central Government, city or county at the place where the leased house is located. If a violation of the measures occurs, the party shall be ordered to rectify within a prescribed time limit. and if any party fails to do so, it shall be imposed of a fine of more than RMB1,000 and less than RMB10,000.

REGULATIONS ON FIRE PROTECTION AND ENVIRONMENTAL PROTECTION

Fire Control

Pursuant to the Fire Control Law of the PRC (《中華人民共和國消防法》) promulgated by the SCNPC on April 29, 1998, and last amended on April 29, 2021 and effective therefrom, while the fire control and rescue institutions of such people’s governments shall be responsible for implementation. The design of fire control of the construction projects must comply with the national technical standards of fire control. If the design of fire control of a construction project has not been examined pursuant to the relevant laws or failed to pass the examination, the construction of such project is not allowed. If a completed construction project has not gone through the fire safety inspection or failed to satisfy the requirements of fire safety upon inspection, such project is not allowed to be put to use or business. According to **Interim Regulations on Administration of Examination and Acceptance of Fire Control Design of Construction Projects** (《建設工程消防設計審查驗收管理暫行規定》) issued by the Ministry of Housing and Urban-Rural Development on April 1, 2020 and latest amended on 21 August, 2023, an examination system for fire control design and acceptance only applies to special construction projects, and for other projects, a record-filing and spot check system would be applied.

Environmental Protection

The Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) was promulgated and effective on 26 December 1989, and most recently amended on 24 April 2014. Pursuant to the Environmental Protection Law, construction projects that have environmental impact shall be subject to environmental impact assessment.

Environment Impact Assessment

On 28 October 2002, the SCNPC promulgated the Environmental Impact Assessment Law of PRC (《中華人民共和國環境影響評價法》), which was latest amended on 29 December 2018. According to the Environmental Impact Assessment Law, the State Council implemented the environmental impact assessment to classify construction projects according to the impact of the construction projects on the environment. Pursuant to the Interim Measures for Environmental Protection Acceptance of Completed Construction Projects (《建設項目竣工環境保護驗收暫行辦法》) effective as of 20 November 2017 and the Regulations on the Administration Construction Project Environmental Protection (《建設項目環境保護管理條例》), which was revised on 16 July 2017 and implemented on October 1, 2017, after the completion of a construction project for which an environmental impact report or an environmental impact report form is required, the construction entity shall, according to standards and procedures prescribed by the environmental protection administrative authorities, conduct environmental protection completion acceptance check and compile an acceptance check report. A construction project for which an environmental impact report or an environmental impact report form is required shall not be put into production or use until the environmental protection completion acceptance check has been passed.

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Disposal of Hazardous Waste

Pursuant to the Law on the Prevention and Control of Environmental Pollution Caused by Solid Waste of the PRC (《中華人民共和國固體廢物污染環境防治法》), which was promulgated by the SCNPC in 1995 and was latest amended on 29 April 2020, entities generating hazardous waste shall store, utilise and dispose hazardous waste according to the relevant requirements of the state and environmental protection standards, and shall not dump or pile up hazardous waste without authorisation. Furthermore, it is forbidden to entrust hazardous waste to entities without a permit for disposal, or else the competent ecological and environmental authorities shall order it to make rectification, impose fines, confiscate illegal gains, and in serious circumstance, order it to suspend business or close down upon the approval of the government authorities.

REGULATIONS ON EMPLOYMENT AND SOCIAL WELFARE

According to the Labor Law of the PRC (《中華人民共和國勞動法》) promulgated by the SCNPC on 5 July 1994 and last amended on 29 December 2018, the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》) promulgated by the SCNPC on 29 June 2007 and amended on 28 December 2012, and the Implementing Regulations of the Labor Contract Law of the PRC (《中華人民共和國勞動合同法實施條例》) promulgated by the State Council on 18 September 2008 and came into effect on the same day, employers must enter into written labor contracts with full-time employees. All employers shall comply with local minimum wage standards. Employers must establish a system for labor safety and sanitation, strictly comply with national standards, and provide relevant education to their employees. Violations of the Labor Contract Law and the Labor Law may result in fines, and in serious cases, other administrative and criminal liabilities may be incurred.

In accordance with the Labor Contract Law and the Interim Provisions on Labor Dispatching (《勞務派遣暫行規定》) promulgated by the Ministry of Human Resources and Social Security of the PRC on 24 January 2014 and effective on 1 March 2014, it specified the scope and proportion of the usage of the laborer, execution and performance of labor dispatch agreements and legal liability. An employer shall strictly control the number of dispatched laborers which shall not exceed 10% of the total number of its workers. An employer that is in violation thereof shall be ordered to make correction by the labor administrative department. Where no correction is made by the prescribed deadline, the employer shall be subject to a fine ranging from RMB5,000 to RMB10,000 for each dispatched worker.

The Social Insurance Law of the PRC (《中華人民共和國社會保險法》) (the “**Social Insurance Law**”) issued by the SCNPC in 2010 and latest amended on December 29, 2018, has established social insurance systems of basic pension insurance, basic medical insurance, work-related injury insurance, unemployment insurance and maternity insurance and has elaborated in detail the legal obligations and liabilities of employers who fail to comply with relevant laws and regulations on social insurance. According to the Social Insurance Law and the Provisional Regulations on Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》) promulgated by the State Council on January 22, 1999 and most recently amended on March 24, 2019 and effective from the same date, enterprises shall register social insurance with local social insurance and pay or withhold relevant social insurance for or on behalf of its employees. Any employer that fails to make social insurance contributions may be ordered to rectify the non-compliance and pay the required contributions within a prescribed time limit and be subject to a late fee. If the employer still fails to rectify the failure to make the relevant contributions within the prescribed time, it may be subject to a fine ranging from one to three times the amount overdue.

In accordance with the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》) promulgated by the State Council on April 3, 1999, and amended on March 24, 2002, and March 24, 2019, enterprises must register at the designated administrative centers and open bank accounts for depositing employees’ housing provident funds. Employers and employees are also required to pay and deposit housing provident funds, with an amount no less than 5% of the monthly average salary of the employee in the preceding year in full and on time. Where employers fail to make payment within such period, enforcement by the people’s court will be

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applied. In case of failure to register and open accounts for depositing employees’ housing provident funds, the housing fund management center shall order employers to go through the formalities within a specified period, where employers fail to do such formalities within the prescribed time, a fine of not less than RMB10,000 nor more than RMB50,000 shall be imposed.

REGULATIONS ON FOREIGN INVESTMENT

Investment activities in the PRC by foreign investors are principally governed by the Catalog of Encouraged Industries for Foreign Investment (《鼓勵外商投資產業目錄》) (the “**Encouraged Catalog**”), and the Special Administrative Measures (Negative List) for Foreign Investment Access (《外商投資准入特別管理措施(負面清單)》) (the “**Negative List**”), which are promulgated and amended from time to time by the Ministry of Commerce of the PRC (the “**MOFCOM**”) and the National Development and Reform Commission (the “**NDRC**”), and together with the Foreign Investment Law of PRC (《中華人民共和國外商投資法》) (the “**FIL**”) and its respective implementation rules and ancillary regulations.

In March 2019, the FIL was promulgated by National People’s Congress (the “**NPC**”) and came into effect on January 1, 2020, the FIL, by means of legislation, establishes the basic framework for the access, promotion, protection and administration of foreign investment in view of investment protection and fair competition. According to the FIL, foreign investment shall enjoy pre-entry national treatment, except for those foreign invested entities that operate in industries deemed to be either “restricted” or “prohibited” in the “negative list”, and the State Council shall promulgate or approve a list of special administrative measures for access of foreign investments. To ensure the effective implementation of the FIL, the Regulations on Implementing the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》) (the “**Implementation Regulations**”), was promulgated by State Council in December 2019 and came into effect on January 1, 2020.

In December 2019, the MOFCOM and the State Administration for Market Regulation (the “**SAMR**”) promulgated the Measures on Reporting of Foreign Investment Information (《外商投資信息報告辦法》), which came into effect in January 2020. Since January 1, 2020, for foreign investors carrying out investment activities directly or indirectly in China, the foreign investors or foreign-invested enterprises shall submit investment information to the relevant commerce administrative authorities according to the Measure on Reporting of Foreign Investment Information.

According to the Measures for the Security Review of Foreign Investment (《外商投資安全審查辦法》) promulgated by the NDRC and the MOFCOM on December 19, 2020 and became effective on January 18, 2021, any foreign investment that has or possibly has an impact on state security shall be subject to security review in accordance with the provisions hereof. A foreign investor or a party concerned in China shall take the initiative to make a declaration to the working mechanism office prior to making the investment in any important infrastructure, important transportation services and other important fields that concern state security while obtaining the actual control over the enterprises invested in.

REGULATIONS ON FOREIGN EXCHANGE

The principal regulations governing foreign currency exchange in China are the Foreign Exchange Administration Regulations of the PRC (《中華人民共和國外匯管理條例》), most recently amended in August 2008. Under the PRC foreign exchange regulations, payments of current account items, such as profit distributions, interest payments and trade and service-related foreign exchange transactions, can be made in foreign currencies without prior approval from the SAFE, by complying with certain procedural requirements. By contrast, approval from or registration with appropriate government authorities is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital account items, such as direct investments, repayment of foreign currency-denominated loans, repatriation of investments and investments in securities outside of China.

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The SAFE issued the Circular on Reforming of the Management Method of the Settlement of Foreign Currency Capital of Foreign-Invested Enterprises (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》) (the “**SAFE Circular 19**”) on March 30, 2015, and it became effective on June 1, 2015, which was partially repealed on December 30, 2019, and latest amended on March 23, 2023. The SAFE Circular 19 expands a pilot reform of the administration of the settlement of the foreign exchange capitals of foreign-invested enterprises nationwide. In June 2016, SAFE further promulgated the Circular on the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) (the “**SAFE Circular 16**”), which, among other things, amends certain provisions of SAFE Circular 19. Pursuant to SAFE Circular 19 and SAFE Circular 16, the flow and use of the Renminbi capital converted from foreign currency denominated registered capital of a foreign-invested company is regulated such that Renminbi capital may not be used for business beyond its business scope or to provide loans to persons other than affiliates unless otherwise permitted under its business scope.

In October 2019, SAFE issued the Circular on Further Facilitating Cross-border Trade and Investment (《國家外匯管理局關於進一步促進跨境貿易投資便利化的通知》) (the “**SAFE Circular 28**”), which cancels the restrictions on domestic equity investments by capital fund of non-investment foreign invested enterprises and allows non-investment foreign invested enterprises to use their capital funds to lawfully make equity investments in China, provided that such investments do not violate the Negative List and the target investment projects are genuine and in compliance with laws. According to the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business (《國家外匯管理局關於優化外匯管理支持涉外業務發展的通知》) (the “**SAFE Circular 8**”), issued by SAFE in April 2020, under the prerequisite of ensuring true and compliant use of funds and compliance with the prevailing administrative provisions on use of income under the capital account, eligible enterprises are allowed to make domestic payments by using their capital funds, foreign credits and the income under capital accounts of overseas listing, without prior provision of the evidentiary materials concerning authenticity to the bank for each transaction. The handling banks shall conduct spot checks afterwards in accordance with the relevant requirements. The interpretation and implementation in practice of SAFE Circular 28 and SAFE Circular 8 are still subject to substantial uncertainties given they are newly issued regulations.

Pursuant to the Circular on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plan of Overseas Publicly Listed Company (《國家外匯管理局關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》) (the “**SAFE Circular 7**”), promulgated by SAFE in February 2012, employees, directors, supervisors, and other senior management participating in any share incentive plan of an overseas publicly-listed company who are PRC citizens or who are non-PRC citizens residing in China for a continuous period of not less than one year, subject to a few exceptions, are required to register with SAFE through a domestic agency. Moreover, an overseas-entrusted institution must be retained to handle matters in connection with the exercise or sale of stock options and the purchase or sale of shares and interests. The income of foreign exchange PRC residents by selling out the shares according to the equity incentive plan and the dividend distributed by the overseas-listed company shall be distributed to the PRC residents after being remitted to the bank account in China opened by the domestic institutions.

REGULATIONS ON TAXATION

Enterprise Income Tax

The Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) (the “**EIT Law**”), promulgated by the NPC on March 16, 2007, came into effect on January 1, 2008 and amended on February 24, 2017 and December 29, 2018, as well as the Implementation Rules of the EIT Law (《中華人民共和國企業所得稅法實施條例》) (the “**Implementation Rules**”), promulgated by the State Council on December 6, 2007, came into force on January 1, 2008 and amended on April 23, 2019, are the principal law and regulation governing enterprise income tax in the PRC. According to the EIT Law and its Implementation Rules, enterprises are classified into resident enterprises and non-resident enterprises. Resident enterprises refer to enterprises that are

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legally established in the PRC, or are established under foreign laws but whose actual management bodies are located in the PRC. Non-resident enterprises refer to enterprises that are legally established under foreign laws and have set up institutions or sites in the PRC but with no actual management body in the PRC, or enterprises that have not set up institutions or sites in the PRC but have derived incomes from the PRC. A uniform income tax rate of 25% applies to all resident enterprises and non-resident enterprises that have set up institutions or sites in the PRC to the extent that such incomes are derived from their set-up institutions or sites in the PRC, or such income are obtained outside the PRC but have an actual connection with the set-up institutions or sites. Non-resident enterprises that have not set up institutions or sites in the PRC, or have set up institutions or sites but the incomes obtained by the said enterprises have no actual connection with the set-up institutions or sites, shall pay enterprise income tax at the rate of 10% in relation to their income sources from the PRC.

Value-Added Tax

Pursuant to the Value-Added Tax Law of the PRC (《中華人民共和國增值稅法》), which was promulgated by the SCNPC on December 25, 2024 and effective from January 1, 2026, entities and individuals engaging in selling goods, services, intangible assets, or immovables within the territory of the PRC are taxpayers of the value-added tax (“VAT”).

According to the Notice of the Ministry of Finance and the State Taxation Administration on the Adjusting Value-added Tax Rates (《財政部 稅務總局關於調整增值稅稅率的通知》) effective in May 2018, the VAT rates of 17% and 11% on sales, imported goods shall be adjusted to 16% and 10%, respectively.

According to the Announcement of the Ministry of Finance, the State Taxation Administration and the General Administration of Customs on Relevant Policies for Deepening the Value-Added Tax Reform (《財政部 稅務總局 海關總署關於深化增值稅改革有關政策 的公告》) promulgated on March 20, 2019 and effective from April 1, 2019, the VAT rates of 16% and 10% on sales, imported goods shall be adjusted to 13% and 9%, respectively.

REGULATIONS ON OVERSEAS LISTINGS

According to the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) and five relevant guidelines, 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 the Confidentiality and Archives Management of Overseas Securities Offering and Listing by Domestic Enterprises (《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》) (the “Archives Provisions”) promulgated by the CSRC, the Ministry of Finance of the PRC (中華人民共和國財政部), the State Secrets Bureau and the State Archives Administration of the PRC on 24 February 2023 and implemented from 31 March 2023, domestic enterprises, securities companies and securities service institutions providing corresponding services shall strictly comply with the relevant requirements for confidentiality and archives management, establish and improve confidentiality and file management systems, and take the necessary measures to implement confidentiality and archives management responsibilities, in the direct or indirect overseas securities offering or listing activities by domestic enterprises. According to the Archives Provisions, during the process of domestic enterprises conducting offering and listing overseas, if documents or data involving state secrets or adversely affecting national security or the

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public interest need to be provided or publicly disclosed to relevant securities companies, securities service agencies, overseas regulatory authorities and other units and individuals, the relevant approval/filing and other regulatory procedures shall be completed.

OVERVIEW OF U.S. LAWS AND REGULATIONS

U.S. Government Regulation of Drug and Biological Products

In the U.S., the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (the “**FDCA**”) and its implementing regulations, and regulates biologics under the FDCA, the Public Health Service Act (the “**PHSA**”) and their implementing regulations. Drugs and biologics are also subject to other federal, state and local statutes and regulations, including those relating to competition.

Once a product candidate is identified for development, it enters preclinical testing. Preclinical testing is conducted in accordance with the FDA’s Good Laboratory Practice regulations. A sponsor of IND must submit the results of the preclinical testing, 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. The 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 that involve administration of investigational products in humans must be conducted under the supervision of qualified investigators in accordance with GCP regulations, including the requirement that all research subjects provide informed consent in writing before participation. Further, an Institutional Review Board (“**IRB**”) must review and approve the plan for any clinical trial before it commences at any institution and must conduct continuing review and reapprove the study at least annually. Each new clinical protocol and any protocol amendments must be submitted for FDA review and to the IRBs for approval. An IRB can suspend or terminate approval of a clinical trial if the trial is not conducted in accordance with the IRB’s requirements or if the product is associated with unexpected serious harm to subjects.

Clinical trials generally proceed in three phases, which may overlap. Phase I trials generally involve a small number of healthy volunteers or patients, who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose is to assess the metabolism, pharmacologic action, side effects, tolerability and safety of the product candidate. Phase II trials are conducted in patients to evaluate proof of concept and/or determine the dose required to produce the desired benefits. At the same time, safety and further PK and PD information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted. Phase III trials generally involve a larger number of patients across multiple sites and are intended to generate the data necessary to demonstrate safety and efficacy for the product’s intended use, establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling. Sponsors must submit progress reports on clinical trials to the FDA at least annually. They must also submit safety reports to the FDA and investigators within 15 calendar days after determining that the information is reportable and must report any unexpected fatal or life-threatening suspected adverse reaction as soon as possible and no later than 7 calendar days after initial receipt of the information. Sponsors of clinical trials involving FDA-regulated products, including drugs, are also required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov. Concurrently with clinical trials, companies typically complete additional animal studies and finalize manufacturing processes for commercial-scale production in accordance with GMP requirements.

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U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, together with descriptions of the manufacturing process, analytical testing, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA or BLA. Unless deferred or waived, an NDA, BLA or relevant supplement must also include sufficient data 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. Submission of an NDA or BLA is subject to payment of a substantial user fee and an annual prescription drug program fee. Within 60 days after receipt, the FDA reviews an NDA or BLA to determine whether it is sufficiently complete to permit substantive review. Once the application is accepted for filing, the FDA conducts an in-depth review to determine, among other things, whether the product is safe and effective for its intended use. The FDA also evaluates whether the product is manufactured in compliance with GMP requirements to ensure its identity, strength, quality and purity. Before approving an NDA or BLA, the FDA typically inspects the manufacturing processes and facilities to confirm compliance with GMP requirements and the ability to produce the product consistently within required specifications. The FDA may also refer the application to an advisory committee, an expert panel, for recommendations on whether the application should be approved and under what conditions.

The FDA may refuse to approve an NDA or BLA if the applicable regulatory requirements are not met, or it may require additional clinical or other data and information. In that case, the FDA will issue a complete response letter identifying the deficiencies that must be addressed before the application can be approved. These deficiencies may be minor, such as labeling changes, or major, such as the need for additional clinical trials. A complete response letter may also include recommended actions to place the application in condition for approval. The applicant may resubmit the NDA or BLA after addressing the identified deficiencies, withdraw the application or request a hearing. Regulatory approval may also be limited to specific diseases, dosages or other approved conditions of use. In addition, the FDA may require contraindications, warnings or precautions in the product labeling, as well as post-approval studies, including Phase IV clinical trials, and testing and surveillance programs to monitor the safety of commercialized products.

In the U.S., products comprising components that would otherwise be regulated by different FDA centers are referred to as combination products. The FDA’s Office of Combination Products generally assigns a lead center for review based on the product’s primary mode of action. Depending on the type of combination product, approval, clearance or licensure may be obtained through a single marketing application, although the FDA may in some cases require separate applications for individual constituent parts. Even where a single application is used, multiple FDA centers may participate in the review. Applicants must also work with the FDA on the application of relevant premarket and post-marketing requirements, including clinical trial, adverse event reporting and GMP requirements, to the combination product.

Expedited Development and Review Programs

The FDA has various programs intended to facilitate or expedite the development and review of drugs and biologics for serious or life-threatening conditions that may address unmet medical needs.

Fast Track Designation

A drug may be eligible for fast track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. A sponsor may request fast track designation for a specific indication concurrently with or after submission of the IND, and the FDA must respond within 60 days after receiving the request. Fast track designation may provide benefits such as more frequent interactions with the FDA, the potential use of surrogate endpoints and rolling review, under which the FDA may review portions

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of an NDA before the application is complete if the applicant provides, and the FDA accepts, a schedule for the remaining submissions and pays the applicable user fees. However, the FDA’s review clock does not begin until the final portion of the NDA is submitted. The FDA may also withdraw fast track designation if emerging clinical data no longer supports it.

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 breakthrough therapy designation concurrently with, or at any time after, submission of the IND, and the FDA must determine within 60 days after receipt of the request whether the product qualifies. If so designated, the FDA shall act to expedite the development and review of the marketing application, including by meeting with the sponsor throughout development and providing timely advice to ensure that the program for collecting preclinical and clinical data is as efficient as practicable.

Accelerated Approval

Under the 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 over existing treatments where the product demonstrates an effect on either a surrogate endpoint reasonably likely to predict clinical benefit or a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (“IMM”) and 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 requirements, including post-approval clinical trials to confirm clinical benefit. Failure to conduct the required studies or to confirm clinical benefit in post-marketing studies may permit the FDA to withdraw approval on an expedited basis. In addition, promotional materials for products approved under the accelerated approval regulations are subject to prior FDA review.

Priority Review

The FDA may grant priority review to drugs that offers significant improvement in treatment or provide a treatment where no adequate therapy exists. Under priority review, the FDA’s goal is to review an application within six months, compared with ten months for standard review under Prescription Drug User Fee Act guidelines. For NDAs for new molecular entities, these review periods are measured from the filing date rather than the submission date, which generally adds approximately two months to the overall review timeline. Products eligible for fast-track designation are also often eligible for priority review.

Orphan Drug Designation

Under the Orphan Drug Act of 1983, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition that generally affects fewer than 200,000 individuals in the U.S. or for which there is no reasonable expectation that the costs of research and development will be recovered. The first applicant to obtain FDA approval for a drug or biologic with orphan designation for a particular disease or condition is entitled to seven years of marketing exclusivity for that indication. During that exclusivity period, the FDA may not approve another application to market the same product for the same disease or condition, except in limited circumstances.

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Post-Marketing Requirements

Following approval, a product and its manufacturer remain subject to ongoing FDA regulation, including requirements relating to monitoring and record-keeping, adverse event reporting, and promotion and advertising. These 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. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. Prescription drug promotional materials must be submitted to the FDA at the time of first use or publication. In addition, any modifications to the drug or biologic, including changes to indications, labeling, manufacturing processes or facilities may require submission and approval of a new NDA or BLA, or a supplement thereto, and may require additional data, preclinical studies or clinical trials.

The FDA may also impose conditions of approval, including a risk evaluation and mitigation strategy (“REMS”), to ensure safe use of a product. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, or patient registries and could limit the product’s commercial promotion, distribution, prescribing or dispensing. Product approvals may be withdrawn for failure to comply with regulatory requirements or if safety or other issues arise after marketing.

Approved products must be manufactured in approved facilities and in accordance with cGMP requirements. Manufacturers and other entities involved in the manufacture or distribution of approved drugs and biologics must register their establishments with the FDA and certain state agencies and are subject to periodic inspections for compliance with cGMP and other applicable requirements. Failure to comply with these requirements, or the later discovery of safety, manufacturing or other regulatory issues, may result in labeling changes, post-marketing studies or clinical trials, distribution restrictions under a REMS, restrictions on marketing or manufacturing, warning or other enforcement letters, fines, holds on post-approval clinical trials, refusal to approve pending applications or supplements, product recalls, import or export restrictions, seizure, suspension, revocation or withdrawal of approval, injunctions, and civil or criminal penalties.

Optimizing the Dosage of Human Prescription Drugs and Biological Products for the Treatment of Oncologic Diseases

In August 2024, the FDA issued guidance on optimizing the dosage of oncology drugs and biological products during clinical development before submission of a marketing application for a new indication and usage. The guidance encourages sponsors to identify an optimal dosage that maximizes therapeutic benefit while minimizing toxicity, reflecting the FDA’s view that the traditional focus on maximum tolerated dose may be inappropriate for certain modern oncology therapies, particularly targeted therapies, where lower and better tolerated doses may achieve similar efficacy. The guidance notes that unnecessarily high doses may adversely affect quality of life, treatment adherence and clinical outcomes, and encourages early engagement with the FDA, including through formal meetings or the Model-Informed Drug Development paired meeting program, to discuss dosage optimization plans. Sponsors are encouraged to initiate early evaluations of (i) population pharmacokinetics, dose- and exposure-response relationships, the impact of intrinsic factors on pharmacokinetics, pharmacodynamics and safety, and potential drug-drug interactions, supported by sampling plans to characterize drug behavior and variability and consideration of alternative dosing strategies; (ii) trial designs comparing multiple dosages in randomized, parallel or adaptive trials, with trial sizes sufficient to detect meaningful differences in safety and activity, and use of model-informed approaches, including semi-mechanistic or mechanistic methods, to inform dosage selection for current and future indications; (iii) safety and tolerability, including dose modifications, discontinuations and patient-reported outcomes, together with predefined stopping rules for toxicity and strategies such as dose titration for drugs with early-onset toxicities; (iv) dose formulation, including the availability of suitable dose strengths and forms to facilitate evaluation of multiple dosages; and (v) subsequent indications, given that dosage may differ by disease setting and that further dose-finding may be required for subsequent indications or combination therapies. Dose optimization studies are expected to compare multiple

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dosages using relevant clinical endpoints, such as overall response rate or progression-free survival, and may, where appropriate, incorporate data from similar therapies. Features such as blinding to reduce bias, pre-specified crossover analysis plans and intra-patient dose adjustments to improve tolerability are also encouraged.

Patent Term Restoration and Marketing Exclusivity

After approval, the holder of a patent covering a drug or biological product may apply for an extension of up to five years to restore a portion of the patent term lost during product development and FDA review of an NDA or BLA under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, provided that the approval represents the first permitted commercial marketing or use of the product containing the active ingredient. The extension period is calculated as one-half of the testing phase, measured from IND submission to NDA or BLA submission, plus all of the review phase, measured from NDA or BLA submission to approval, subject to a maximum extension of five years, and may be reduced if the applicant did not act with due diligence. In no event may the remaining patent term, as extended, exceed 14 years from the date of FDA approval. Only one patent for each approved product may be extended, and only claims covering the approved product, a method of using it or a method of manufacturing it is eligible. The patent holder must apply within 60 days after approval, and the USPTO, in consultation with the FDA, reviews the application. If an eligible patent may expire before the application is approved, the patent owner may seek an interim extension of up to one year, renewable up to four times, although each interim extension reduces the final extension by one year. Interim extensions are available only if an NDA or BLA has been submitted and the Director of the USPTO determines that approval of the product is likely.

BIOSECURE Act

On December 18, 2025, the U.S. Senate passed the BIOSECURE Act as a part of the National Defense Authorization Act for Fiscal Year 2026, which was signed into law by the U.S. President. The BIOSECURE Act will prohibit the U.S. government from procuring biotechnology equipment or services from designated “biotechnology companies of concern,” and will prohibit government contracts, loans and grants to any entity that uses biotechnology equipment or services from a designated “biotechnology company of concern.” The BIOSECURE Act provides that any entity on the Department of Defense’s section 1260H list of Chinese military companies operating in the U.S., as well as any of the entity’s subsidiary, parent, affiliate, or successor, will qualify as “biotechnology companies of concern.” The U.S. government has the authority to identify additional entities for inclusion as “biotechnology companies of concern,” specifically any entity that is subject to the administrative governance structure, direction, control, or operates on behalf of the government of a foreign adversary (defined by law to be China, Iran, North Korea, and Russia), is involved in the manufacturing, distribution, provision, or procurement of a biotechnology equipment or service, and poses a risk to the national security of the U.S., based on: (i) engaging in joint research with, being supported by, or being affiliated with a foreign adversary’s military, internal security forces, or intelligence agencies; (ii) providing multiomic data obtained via biotechnology equipment or services to the government of a foreign adversary; or (iii) obtaining human multiomic data via the biotechnology equipment or services without express and informed consent. The prohibitions in the BIOSECURE Act will go into effect for new contracts, grants and loans issued 60 days after the Federal Acquisition Regulation is updated for entities drawn from the 1260H list, and within 180 days after the Federal Acquisition Regulation is updated for entities not included on the 1260H list.

OVERVIEW OF EU LAWS AND REGULATIONS

Clinical Trial Approval

The European Medicines Agency (“**EMA**”) is the scientific agency of the EU that coordinates the evaluation and monitoring of medicinal products, including drugs and biologics, and provides technical guidance and scientific advice to sponsors. In the EU, the development of medicinal products generally involves preclinical laboratory, animal and formulation studies conducted in

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accordance with applicable Good Laboratory Practice requirements; submission of a Clinical Trial Application (“CTA”) before human clinical trials may begin; conduct of adequate and well-controlled clinical trials to establish safety and efficacy for the proposed indication; inspection by the relevant authorities of manufacturing facilities, including those of third parties, for compliance with cGMP requirements; potential inspection of the non-clinical and clinical trial sites generating data in support of a Marketing Authorization Application (“MAA”); and approval of the MAA through the applicable EU or member-state procedure before commercial marketing, sale or shipment of the product. Preclinical studies generally include laboratory evaluation of product chemistry, formulation and stability, as well as animal studies assessing potential efficacy and toxicity. The results of these studies, together with relevant manufacturing and analytical information, form part of the CTA and, later, the MAA.

Clinical trials in the EU are governed by the Clinical Trials Regulation (EU) No. 536/2014, which is directly applicable in all EU member states and provides for a single submission through the Clinical Trials Information System (“CTIS”). The EMA does not itself authorize clinical trials but maintains CTIS as the single entry point through which sponsors submit CTAs and through which the relevant member state authorities coordinate review, request further information, authorize or refuse a trial and oversee an authorized trial. Each application is subject to a validation phase, an assessment phase and a decision phase, within defined timelines, and each member state concerned ultimately issues its own decision on whether the trial may proceed in its territory.

Under Regulation (EU) No. 536/2014, the assessment phase is divided into Part I and Part II. Part I covers the elements of the application common across the EU and is led by a reporting member state (“RMS”), with input from the other member states concerned (“MSC”). These Part I elements generally include the scientific and technical aspects of the trial, such as the trial design, the anticipated therapeutic and public health benefits, risk and inconvenience to subjects, investigational medicinal product quality information, manufacturing and import arrangements, and labeling and investigator’s brochure documentation. Part II is assessed separately by each MSC and addresses national, local and ethical aspects, including informed consent, subject recruitment arrangements, compensation, protection of personal data and biological samples, and the suitability of investigators and trial sites. Requests for information (“RFIs”) may be raised by the RMS during Part I or by an MSC during Part II. Each MSC reaches its own national decision based on the coordinated Part I assessment and its own Part II assessment as to whether the clinical trial may be conducted in its territory. A sponsor may apply to one or more MSCs to conduct a clinical trial, including a Phase III or other pivotal trial following completion of earlier trial phases, provided that the applicable procedures and requirements are satisfied.

Clinical Trial Implementation

Article 47 of the Clinical Trials Regulation (EU) No. 536/2014 provides that the sponsor of a clinical trial and the investigator shall ensure that the clinical trial is conducted in accordance with the protocol and the principles of GCP and, in preparing the protocol and conducting the trial, must also take appropriate account of the quality standards and guidelines established by the International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use (“ICH”) on GCP. ICH E6(R3) Guideline for Good Clinical Practice provides that the sponsor may consider establishing a data review team or data monitoring committee to assess the progress of a clinical trial, including the safety data and the efficacy endpoints, at intervals and to recommend to the sponsor whether to continue, modify or stop a trial.

Marketing Authorization

Centralized Procedure

Authorization to market a product in the EU may be obtained through one of four procedures: the centralized procedure, the mutual recognition procedure, the decentralized procedure or the national procedure.

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The centralized procedure enables an applicant to obtain a marketing authorization that is valid in all EU member states on the basis of a single application. It is mandatory for certain categories of products, including medicines derived from biotechnology processes such as genetic engineering, advanced therapy medicinal products such as gene therapies or tissue-engineered products, orphan medicines, and medicinal products containing a new active substance indicated for the treatment of cancer, diabetes, neurodegenerative disorders, autoimmune and other immune dysfunctions, or viral diseases. It is optional for certain other medicinal products, including those containing a new active substance, where the applicant can demonstrate that the product constitutes a significant therapeutic, scientific or technical innovation or that granting authorization would be in the interest of public health in the EU. If granted by the European Commission based on the opinion of the EMA, the authorization is valid in all EU member states.

Under the mutual recognition procedure, a marketing authorization granted in one EU member state is recognized by one or more other member states. The decentralized procedure permits authorization in more than one EU member state in parallel for products that are not required to be authorized through the centralized procedure and have not yet been authorized in any member state. Under the national procedure, the competent authority of an individual EU member state reviews and decides upon a marketing authorization application for that member state.

Administration Procedure

MAAs should first be electronically submitted to the EMA through the eSubmission gateway and must contain the information required under applicable EU legislation., including details of the target patient population, whether the medicine addresses an unmet medical need, and data on the medicine’s quality, including its chemical, physical and biological properties, such as stability, purity and biological activity, as well as evidence of compliance with good laboratory practice, good manufacturing practice and good clinical practice. The MAA must also describe the medicine’s mechanism of action, pharmacokinetic profile and clinical benefits in the intended patient population, set out its safety profile, including in relevant special populations, and describe how risks will be managed and monitored after authorization, including through a risk management plan (“**RMP**”), which is reviewed for suitability by the Pharmacovigilance Risk Assessment Committee (“**PRAC**”). In addition, the applicant must submit the proposed Summary of Product Characteristics (“**SmPC**”), labelling and package leaflet for review by the Committee for Medicinal Products for Human Use (“**CHMP**”). After submission, the EMA performs a technical validation of the MAA to confirm that the application contains the elements required for scientific assessment and may request additional information before the procedure starts. After the MAA is validated by the EMA, it will be referred to the CHMP.

Under the centralized procedure, the CHMP is the EMA committee responsible for rendering the scientific opinion on the safety, efficacy and quality of medicinal products for human use. The CHMP is composed of experts nominated by the national competent authorities of the EU member states, and one or more members are appointed as Rapporteur and, where applicable, Co-Rapporteur to coordinate the evaluation; after approval, the Rapporteur continues to monitor the product throughout its life cycle. The CHMP has 210 active days to adopt an opinion on whether a marketing authorization should be granted, excluding clock-stops when the applicant is asked to provide additional information. For products of major public health interest, particularly from the perspective of therapeutic innovation, the applicant may request accelerated assessment under Article 14(9) of Regulation (EC) No. 726/2004, in which case the timetable may be reduced to 150 days, although the CHMP may revert to the standard timetable if accelerated assessment is no longer considered appropriate. The final CHMP recommendation is reached by a formal vote. The CHMP seeks to reach its recommendation by consensus, but where consensus cannot be reached, the opinion reflects the majority view, and divergent opinions and the names of the members expressing them are attached to the opinion and reflected in the meeting minutes and public assessment materials. Once the procedure is completed, the EMA publishes a European Public Assessment Report (“**EPAR**”). If the CHMP opinion is negative, the grounds for that conclusion are disclosed.

REGULATORY OVERVIEW

After adoption of the CHMP opinion, the European Commission must adopt a decision on the MAA after consulting the EU member states, a process that may take over 60 days. During that consultation period, each member state has 22 days to submit written observations on the draft decision to the European Commission, and a concerned member state may request that the draft decision be discussed at a plenary meeting of the Standing Committee on Medicinal Products for Human Use, stating its reasons in detail. If, in the opinion of the European Commission, a member state’s written observations raise important new scientific or technical questions not addressed by the EMA opinion, the European Commission may suspend the procedure and refer the application back to the EMA for further consideration. Although significant concerns or divergent views raised by member states may be considered within the CHMP and by the European Commission, the final decision rests with the European Commission. An applicant is not required to obtain prior consent or clearance from the member states in which the clinical trial was conducted. A centralized marketing authorization is valid throughout the EU and in the EEA-EFTA states of Iceland, Liechtenstein and Norway, and confers the same rights and obligations in each member state as a marketing authorization granted by that member state. After a drug is authorized and launched, all aspects relating to its quality, safety and efficacy must continue to be kept under review.

Import of Investigational Medicinal Products

In the EU, the manufacture and import of investigational medicinal products (“IMPs”) for clinical trial use are subject to prior authorization, subject to certain exemptions. Such authorization requires the applicant to maintain suitable premises, equipment and quality control facilities that meet prescribed standards, and to have at least one permanently available qualified person meeting the professional requirements under applicable EU legislation. Each batch manufactured or imported into the EU must be certified by the qualified person as meeting the applicable quality and compliance requirements. IMPs must be manufactured in accordance with EU GMP, and imported IMPs must meet quality standards at least equivalent to EU GMP. The European Commission issues detailed GMP guidelines and Member States monitor compliance through inspections. The authorization requirement does not apply to the preparation of medicinal products for use as IMPs, where this process is carried out in hospitals, health centers or clinics legally authorized in the MSC and the IMPs are intended for use exclusively in hospitals, health centers or clinics taking part in the same clinical trial in that member state.

Conditional Approval

In specific circumstances, EU legislation (Article 14(7) Regulation (EC) No. 726/2004 and Regulation (EC) No. 507/2006 on Conditional Marketing Authorizations for Medicinal Products for Human Use) permits the grant of a conditional marketing authorization before comprehensive clinical data required for a full marketing authorization are available. Such authorization may be granted for products, including medicines designated as orphan medicinal products, if (i) the risk-benefit balance is positive, (ii) it is likely that the applicant will be able to provide the required comprehensive clinical trial data, (iii) the product fulfills unmet medical needs, and (iv) the benefit to public health of the product’s immediate availability outweighs the risk inherent in the need for additional data. A conditional marketing authorization may impose specific obligations on the marketing authorization holder, including completion of ongoing or new studies and collection of additional pharmacovigilance data. Conditional marketing authorizations are valid for one year and may be renewed annually if the risk-benefit balance remains positive, following assessment of the need for any additional or modified conditions or specific obligations. The timelines for the centralized procedure described above also apply to the CHMP review of applications for conditional marketing authorization.

Post-Authorization Measures

After obtaining marketing approval in the EU, the applicant may, on a case-by-case basis, be required by the European Medicines Agency (“EMA”) to provide additional post-authorization data, including data relating to the safety and, in certain cases, the efficacy or quality of authorized medicinal products. Such post-authorization measures are intended to support the ongoing assessment of a medicinal product in the post-approval setting. An applicant is generally not notified of any such requirement until after marketing approval has been granted. Under the centralized procedure, individual EU member states do not have unilateral authority to impose a post-authorization study requirement on a product approved by the European Commission.