

## REGULATORY OVERVIEW

### Laws and Regulations on R&D of Drugs

#### *Regulations on drug development*

The Drug Administration Law of the People’s Republic of China (the “**PRC**”) (《中華人民共和國藥品管理法》) (the “**DAL**”) which was promulgated by the SCNPC on 20 September 1984, and latest amended on 26 August 2019 and took effect as of 1 December 2019 and the State Council referred to as the Regulations for the Implementation 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 “**DAL Implementing Regulation**”), which was latest amended on 6 December 2024 and took effect as of 20 January 2025 provided legal framework for establishment of drug manufacturing enterprises and drug trading enterprises as well as drug administration. The SAMR has its own set of regulations further implementing the DAL; the primary one governing clinical trial applications (referred to individually as a “**CTA**” and collectively as “**CTAs**”), marketing approval, and post-approval amendment and renewal is known as the Drug Registration Regulation (《藥品註冊管理辦法》) which was latest amended on 22 January 2020 and effective from 1 July 2020.

The Biosecurity Law of the PRC (《中華人民共和國生物安全法》) (“**Biosecurity Law**”) promulgated by the SCNPC on 17 October 2020 and latest amended on 26 April 2024, establishes a comprehensive legislative framework for the pre-existing regulations in relevant areas. It stipulates that the clinical research of new biomedical technologies shall pass the ethical review and be conducted in the medical institutions with corresponding qualifications and the operation of human clinical research shall be conducted by the professional medical workers with corresponding qualifications.

#### **Regulations on drug research**

##### *Non-Clinical Research and Animal Testing*

The NMPA requires pre-clinical data to support registration applications for imported and domestic drugs. According to the Drug Registration Regulation, non-clinical safety studies shall be conducted in accordance to the Good Laboratory Practises for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範》) promulgated by the CFDA, which was revised on 27 July 2017 and took effect from 1 September 2017. According to the Administrative Measures for Certification of Good Laboratory Practise for Non-clinical Laboratory (2023 Amendments) (《藥物非臨床研究質量管理規範認證管理辦法》(2023年修訂)) issued by the NMPA on 19 January 2023 and became effective on 1 July 2023, the NMPA is responsible for the certification of non-clinical safety evaluation and research institutions nationwide and the local provincial drug administrative department is in charge of the daily supervision of non-clinical safety evaluation and research institutions.

##### *Clinical Trials Approval*

Clinical trials should be conducted when applying for registration of a new drug. 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. 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 CFDA on 17 March 2017 and taking effect from 1 May 2017, the decision on the approval of clinical trials of drugs enacted by the CFDA can be made by the Centre for Drug Evaluation of NMPA (“**CDE**”) from 1 May 2017.

Clinical trials could not proceed until being approved by the NMPA. According to the latest amended the Drug Registration Regulation, the NMPA now has adopted a system for clinical trials of new drugs where trials can proceed if the applicant has not received any objections from the CDE within 60 days thereafter. After the issuance of the Announcement of the CFDA on Several Policies on the Appraisal and Approval of Drug Registration (《國家食品藥品監督管理總局關於藥品註冊審評審批若干政策的公告》) (“**Announcement on Appraisal and Approval of Drug Registration**”) on 11 November 2015, as for CTAs for new drugs, the one-time approval is implemented and the declaration, appraisal and approval at different levels are replaced. The one-time approval mechanism was restated in the Announcement of the NMPA on Adjusting Appraisal and Approval Procedures for Clinical Trials for Drugs (《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》) (“**Announcement on Adjusting Appraisal and Approval Procedures**”), which was issued on 24 July 2018 by the NMPA. If a new drug clinical trial has been approved to be carried out, after the completion of Phase I and Phase

---

## REGULATORY OVERVIEW

---

If 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. If expanded indications are involved, or the security risks to which subjects are exposed are increased as a result of the alteration to the clinical trials protocols, drastic pharmaceutical changes, or significant security findings for non-clinical research, new applications or supplementary applications of clinical trials might be required, according to the Announcement on Adjusting Appraisal and Approval Procedures.

### ***Drug Clinical Trial Registration***

According to the Drug Registration Regulation, where a clinical trial is approved, the sponsor shall, prior to conducting subsequent phases of the clinical trial, formulate the clinical trial protocol, carry out the trial upon obtaining approval by the ethics committee, and submit the clinical trial protocol and supporting materials on the CDE website. On 6 September 2013, the CFDA released the Announcement on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》), providing that all clinical trials approved by the CFDA and conducted in the PRC shall be registered on and trial information shall be published through the Drug Clinical Trial Information Platform under management of the CDE.

### ***Clinical Trial Process***

According to the Drug Registration Regulation, a clinical development programme consists of Phases I, II, III and IV. Phase I refers to the initial clinical pharmacology and safety evaluation studies in humans. Phase II refers to the preliminary evaluation of a drug candidate’s therapeutic effectiveness and safety for particular indications in patients, to provide evidence and support for the design of Phase III clinical trials and to settle the administrative dose regimen. Phase III refers to clinical trials undertaken to confirm the therapeutic effectiveness of a drug. Phase III is used to further verify the drug’s therapeutic effectiveness and safety in patients with target indications, to evaluate the overall benefit-risk relationships of the drug, and ultimately to provide sufficient evidence for the review of drug registration application. Phase IV refers to a new drug’s post-marketing study to assess therapeutic effectiveness and adverse reactions when the drug is widely used, to evaluate the overall benefit-risk relationships of the drug when used among the general population or specific groups and to adjust the administration dose. In accordance with the revised Administrative Measures for Drug Registration, drug clinical trial shall comprise Phase I clinical trial, Phase II clinical trial, Phase III clinical trial, Phase IV clinical trial as well as bioequivalence test.

According to 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》) (“**Several Policies Circular**”), the CDE grants a one-time approval for clinical trial applications for new drugs and does not require separate declarations, reviews or approvals for the subsequent phases of clinical trials. The CDE review focuses on the scientific nature of clinical trial protocols and the control of safety risks to ensure patient safety. Applicants must promptly communicate with the CDE, to resolve problems during clinical trials and make a supplementary report on the latest research materials as the relevant reviewer requires. Upon the completion of Phase I and Phase II clinical trials, the applicant must submit trial results and the clinical trial protocol for the next phase in a timely manner. Where there is no safety problem, applicants can proceed to Phase III clinical trials after discussion with the CDE. The applicants must report serious adverse events that occur during clinical trials and submit annual research reports. Where clinical trial risks cannot be controlled, the clinical trials must be stopped immediately.

### ***Sampling and Collecting Human Genetic Resources Filing***

The MOST promulgated the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources, or Taking Such Resources out of the PRC (《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》) on 2 July 2015, according to which, the sampling, collection or research activities of human genetic resources by a foreign-invested sponsor fall within the scope of international cooperation, and the cooperating organisation of China shall apply for approval of the China Human Genetic Resources Management Office (“**CHGRMO**”).

---

## REGULATORY OVERVIEW

---

On 28 May 2019, the State Council of the PRC issued the Administrative Regulations of the PRC on Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》) (“**Human Genetic Resource Regulation**”), last amended on 10 March 2024, and took effect from 1 May 2024. The Human Genetic Resource Regulation formalised the approval requirements pertinent to research collaborations between Chinese and foreign-owned entities, under which, a new filing system (as opposed to the advance approval approach originally in place) is put in place for clinical trials utilising the human genetic resources in Chinese Mainland in order to obtain market licence at clinical institutions without involving the export of human genetic resources materials outside of Chinese Mainland. Foreign organisations, individuals and institutions established or actually controlled by foreign organisations and individuals are not allowed to collect or preserve human genetic resources in Chinese Mainland or provide human genetic resources abroad. 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》), which was promulgated by the MOST on 26 May 2023, and took effect from 1 July 2023, further clarify the requirements for administrative licensing, record-keeping, and security review in relation to the collection, conservation, utilisation, and export of human genetic resources, as well as detailing matters relating to the supervisory review and administrative penalties.

### *Priority Evaluation and Approval programmes to Encourage Innovation*

According to the Opinion on Deepening the Reform of the Evaluation and Approval System to Encourage Innovation in 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》) (“**Innovation Opinion**”) promulgated by General Office of the Communist Party of China (“**CPC**”) Central Committee and General Office of the State Council on 8 October 2017, for any drugs or medical devices used for the treatment of severe and life-threatening diseases that cannot be treated in an effective manner and those badly needed for public health, if the early and mid-term indicators in clinical trials show their efficacy and their clinical value are predictable, conditional approval for the marketing of these drugs and medical devices can be granted, and enterprises shall develop the risk control plans to conduct researches according to the requirements.

The Announcement of the NMPA on Promulgating Three Documents Including the Working Procedures for the Evaluation of Breakthrough Therapy Designation Drugs (Trial) (《國家藥監局關於發佈〈突破性治療藥物審評工作程序(試行)〉等三個文件的公告》), which was promulgated and implemented by the NMPA on 7 July 2020, refines the requirements and scope of the fast track, and the Opinions on Encouraging the Prioritised Evaluation and Approval for Drug Innovation was repealed simultaneously.

### *Good Clinical Practises*

Clinical trials must be conducted in accordance with the Good Clinical Practise for Drug Trials (《藥物臨床試驗質量管理規範》) (“**GCP Rules**”) promulgated by NMPA and the National Health Commission of the PRC (“**NHC**”) on 23 April 2020 and effective on 1 July 2020, which stipulates the requirements for the procedures of conducting clinical trials, The GCP Rules also set out the qualifications and requirements for the investigators and centres participating in clinical trials.

### **Laws and Regulations on Drug Registration and Drug Marketing Authorisation Holder**

According to the newly amended DAL the drug marketing authorisation holder means an enterprise or a drug R&D institution that has obtained the drug registration certificate, and this pharmaceutical marketing authorisation holder shall be responsible for non-clinical laboratory studies, clinical trials, production and distribution, post-market studies, and the monitoring, reporting, and handling of adverse reactions in connection with pharmaceuticals in accordance with the provisions of the DAL. According to the Drug Registration Regulation, at the time of application for drug marketing authorisation, the applicant and the manufacturing enterprise shall have held the corresponding drug manufacturing permits.

## REGULATORY OVERVIEW

### Laws and Regulations on Drug Manufacturing and Distribution, Drug Operation and Drug Recalls

According to the Measures for Supervision and Administration of Drug Manufacturing (《藥品生產監督管理辦法》) (“**Drug Manufacturing Measures**”), which was revised by the SAMR on 22 January 2020, and took effect from 1 July 2020, the new drug manufacturer shall be approved and issued with the Drug Manufacturing Licence by the drug supervision and administration department of the province, autonomous region or municipality directly under the central government where it is domiciled.

The Good Supply Practise (“**GSP**”) and Good Manufacturing Practise (“**GMP**”) certification for drugs were cancelled, and the application for GSP and GMP certification for drugs were no longer be accepted, since 1 December 2019, according to the Announcement of the NMPA on Implementation of the Drug Administration Law (《國家藥監局關於貫徹實施〈中華人民共和國藥品管理法〉有關事項的公告》). But the competent regulatory authorities conduct the supervision and regulations through changing from the certification inspection once every five years to the inspection of the implementation of the GMP/GSP from time to time and supervising the compliance of enterprises.

The Administrative Measures for Drug Inspection (Trial) (《藥品檢查管理辦法(試行)》), revised by the NMPA on 19 July 2023, which stipulates that NMPA shall be in charge of the national drug inspection and management work.

As required by the DAL and the Measures for the Quality Supervision and Administration of the Distribution and Use of Medicinal Products (《藥品經營和使用質量監督管理辦法》) which was promulgated by the SAMR on 27 September 2023, which further clarify the procedure, renewal, supervision and inspection of the drug operation licenses.

According to the Announcement on Issuing the Measures for the Administration of Medicinal Product Recalls (《關於發佈〈藥品召回管理辦法〉的公告》) promulgated by NMPA on 24 October 2022 and effective from 1 November 2022, a drug manufacturer should establish and improve its recall system by collecting relevant information about drug safety and conducting investigation and evaluation with respect to the 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.

### Laws and Regulations on Coverage and Reimbursement in the PRC

#### *Medical insurance catalogue*

According to the Notice Regarding 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》) issued by the PRC Ministry of Labour and Social Security (revoked from March 2008), together with other governmental authorities, the above-mentioned authorities have the power to determine the medicines included in the NRDL, which is divided into two parts, Part A and Part B. Patients purchasing medicines included in Part A of the Medical Insurance Catalogue are entitled to reimbursement in accordance with the regulations in respect of basic medical insurance. Patients purchasing medicines included in Part B of the Medical Insurance Catalogue are required to pay a certain percentage of the purchase price and the remainder of the purchase price shall be reimbursed in accordance with the regulations in respect of basic medical insurance.

According to the Interim Measures for the Administration of the Use of Drugs Covered by Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》) issued by the National Healthcare Security Administration on 30 July 2020 and effective from 1 September 2020, the scope of the use of drugs covered by basic medical insurance is administered through the formulation of the Basic Medical Insurance Drug Catalogue. The costs of medicines in line with the Basic Medical Insurance Drug Catalogue are paid by the basic medical insurance fund in accordance with national regulations. The State Council’s administrative department for medical insurance has established a sound dynamic adjustment mechanism, and in principle adjusts the Basic Medical Insurance Drug Catalogue once a year. On the premise of meeting clinical needs, medical insurance designated medical institutions shall give priority to equipping and using drugs in the Basic Medical Insurance Drug Catalogue.

---

## REGULATORY OVERVIEW

---

According to the Interim Measures for the Administration of the Use of Drugs Covered by Basic Medical Insurance, expenses incurred by insured persons for the use of medicines in the Basic Medical Insurance Drug Catalogue can be paid by the basic medical insurance fund if they meet certain conditions. Western medicines and proprietary Chinese medicines in the Basic Medical Insurance Drug Catalogue are divided into “Class A drugs” and “Class B drugs”. The use of “Class A drugs” is paid for by the insured according to the payment standards and sharing methods stipulated by the basic medical insurance; the use of “Class B drugs” is paid for according to the payment standards stipulated by the basic medical insurance, with a certain percentage paid out of pocket by the insured first, and then paid for according to the sharing methods stipulated by the basic medical insurance. The proportion of out-of-pocket payments for “Class B drugs” is determined by the medical insurance administrative departments in provinces or regions subject to overall planning.

### *Medical insurance reimbursement standards*

The State Council promulgated the Opinions on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents (《關於整合城鄉居民基本醫療保險制度的意見》) in January 2016, which required the integration of the urban resident basic medical insurance and the new rural cooperative medical care system and the establishment of a unified basic medical insurance system, which will cover all urban and rural residents other than rural migrant workers and persons in flexible employment arrangements who participate in the basic medical insurance for urban employees. The General Office of the State Council further released the Guidance on Further Deepening the Reform of the Payment Method of Basic Medical Insurance (《關於進一步深化基本醫療保險支付方式改革的指導意見》) in June 2017. The main objectives are to implement a diversified reimbursement mechanism including diagnosis related groups, per-capita caps, and per-bed-day caps. These new reimbursement methods would replace the current reimbursement method that is based on service category and product price.

## **Laws and Regulations on Environmental Protection and Fire Control**

### *Environment protection*

The Environmental Protection Law of the PRC (《中華人民共和國環境保護法》), which was promulgated by the SCNPC on 26 December 1989, came into effect on the same day and last amended on 24 April 2014 and came into effect on 1 January 2015, outlines the authorities and duties of various environmental protection regulatory agencies.

According to the Administration Rules on Environmental Protection of Construction Projects (《建設項目環境保護管理條例》) (“**Construction Environmental Protection Rule**”), which was promulgated by the State Council on 29 November 1998, amended on 16 July 2017 and became effective on 1 October 2017, depending on the impact of the construction project on the environment, a construction employer shall submit an environmental impact report or an environmental impact statement, or file a registration form. According to the Environmental Impact Appraisal Law of PRC (《中華人民共和國環境影響評價法》), which was promulgated by the SCNPC on 28 October 2002, amended on 2 July 2016 and 29 December 2018, for any construction projects that have an impact on the environment, an entity is required to produce either a report, or a statement, or a registration form of such environmental impacts depending on the seriousness of effect that may be exerted on the environment.

For any violation of the Regulation on the Administration of Permitting of Pollutant Discharges and the Measures for Pollutant Discharge Permitting Administration, in accordance with the Environmental Protection Law of the PRC, the Atmospheric Pollution Prevention and Control Law of the PRC (《中華人民共和國大氣污染防治法》), the Water Pollution Prevention and Control Law of the PRC (《中華人民共和國水污染防治法》) and other laws and regulations, the environmental protection authorities have the right to order to make corrections, restrict production, suspend production for rectification, and suspend business and close down, and impose a fine. If a violation of the public security provisions is constituted, it shall be punished for public security violation in accordance with the law. If a crime is established, it shall be investigated for criminal liabilities in accordance with the law. According 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》), entities generating hazardous waste

---

## REGULATORY OVERVIEW

---

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.

### ***Fire control***

Fire control according to the Fire Control Law of the PRC (《中華人民共和國消防法》) last amended on 29 April 2021 and effective therefrom, the design of fire control of a construction project has not been examined according 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 the 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 1 April 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.

### **Laws and Regulations on Intellectual Property Protection**

The Trademark Law of the PRC (《中華人民共和國商標法》) was promulgated by the SCNPC on 23 August 1982, implemented on 1 March 1983, and most recently revised on 23 April 2019, with implementation from 1 November 2019. The Regulations for the Implementation of the Trademark Law of the PRC (《中華人民共和國商標法實施條例》) were issued by the State Council on 3 August 2002, implemented on 15 September 2002, and most recently revised on 29 April 2014, with implementation from 1 May 2014. According to these laws and regulations, the validity period of a registered trademark is 10 years from the date of approval. To continue using a trademark upon the expiry of its validity, renewal procedures must be completed in accordance with the provisions within the 12 months preceding expiration. If renewal procedures are not completed within this period, a six-month extension is allowed. Each renewal extends the validity period for 10 years, starting from the day following the expiration of the last validity period.

The Patent Law of the PRC (《中華人民共和國專利法》) was enacted by the SCNPC on 12 March 1984, implemented on 1 April 1985, and most recently revised on 17 October 2020, with implementation from 1 June 2021. The Detailed Rules for the Implementation of the Patent Law of the PRC (《中華人民共和國專利法實施細則》) were issued by the State Council on 15 June 2001, implemented on 1 July 2001, and most recently revised on 11 December 2023, with implementation from 20 January 2024. According to these laws, regulations and detailed rules, patents in China are categorised into three types: invention patents, utility model patents and design patents. The term of an invention patent right is 20 years, the term of a utility model patent is 10 years, and the term of a design patent is 15 years, all of which are calculated from the filing date.

On 4 July 2021, the NMPA and the National Intellectual Property Administration jointly issued the Implementation Measures for Early Resolution Mechanism of Pharmaceutical Patent Disputes (for Trial Implementation) (《藥品專利糾紛早期解決機制實施辦法(試行)》), which establishes an early resolution mechanism of pharmaceutical patent disputes. Provided there are disputes from the patentee or interested party considering the patent declaration, the pharmaceutical marketing authorisation holder may, within 45 days from the disclosure date of the drug marketing authorisation application by drug evaluation institutions in the PRC, initiate legal proceedings in the People’s Court or apply for an administrative ruling to the patent administration department of the State Council on whether the relevant technical solution of the drug under application falls within the scope of protection of the relevant patent right.

The Administrative Measures for the Internet Domain Name (《互聯網域名管理辦法》) were issued by the Ministry of Industry and Information Technology (“MIIT”) on 24 August 2017, and implemented on 1 November 2017. According to these management measures, the MIIT is the primary regulatory authority for the management of Internet domain names in China.

---

## REGULATORY OVERVIEW

---

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 the SCNPC on 2 September 1993 and last amended on 27 June 2025 and effective from 15 October 2025, business operators are prohibited from infringing others’ trade secrets by, including but not limited to (i) acquiring a trade secret from the right holder by theft, bribery, fraud, coercion, electronic intrusion or any other illicit means; (ii) disclosing, using or allowing other person to use a trade secret acquired from the right holder by any means as specified in the preceding subparagraph.

### Laws and Regulations on Information Security and Data Protection

#### *Personal information protection*

According to the Civil Code, personal information of an individual shall be protected by the law. Any organisation or individual that needs to obtain personal information of others shall obtain such information legally and ensure the safety of such information, and shall not illegally collect, use, process or transmit personal information of others, or illegally purchase or sell, provide or publish personal information of others.

The Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》) (“**Personal Information Protection Law**”), which was promulgated by the SCNPC on 20 August 2021 and became effective on 1 November 2021 requires that the processing of personal information should have a clear and reasonable purpose and should be limited to the minimum scope necessary to achieve the processing purpose, adopt a method that has the least impact on personal rights and interests, and shall not process personal information that is not related to the processing purpose.

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 7 November 2016, effective as of 1 June 2017, and amended by the SCNPC on 28 October 2025, with the amendments taking effect on 1 January 2026, no individual or organisation shall acquire personal information by theft or any other unlawful method, nor shall they engage in the illegal sale or unauthorised provision of personal information to other parties.

#### *Privacy data security and data export*

On 10 June 2021, the SCNPC promulgated the Data Security Law of the PRC (《中華人民共和國數據安全法》) (“**Data Security Law**”) which became effective on 1 September 2021. On 28 December 2021, the Cyberspace Administration of China (“CAC”), jointly with 12 other administrative authorities, promulgated the revised Measures for Cybersecurity Review (《網絡安全審查辦法》) (“**MCR**”), which became effective on 15 February 2022. According to the MCR; (i) that the purchase of cyber products and services by the Critical Information Infrastructure Operator (“CIIO”), and the data processing activities carries out online platform operators which affects or may affect national security, shall be subject to the cybersecurity review by the Cybersecurity Review Office, the department which is responsible for the implementation of cybersecurity review under the CAC; (ii) network platform operators with personal information of more than one million users that seek for listing in a foreign country are obliged to apply for a cybersecurity review by the Cybersecurity Review Office; and (iii) the relevant regulatory authorities may initiate cybersecurity review if such regulatory authorities determine that the issuer’s network products or services, or data processing activities affect or may affect national security. On 24 September 2024, the State Council promulgated the Administration Regulations on Cyber Data Security (《網絡數據安全管理條例》) (“**Data Security Regulations**”), which came into effect on 1 January 2025. The Data Security Regulations reiterate and refine the general regulations for cyber data processing activities, rules of personal information protection, important data security protection, cyber data cross-border transfer management, and the responsibilities of online platform service providers.

On 7 July 2022, the CAC promulgated the Measures for the Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》) (“**Security Assessment Measures**”), which became effective on 1 September 2022. The Security Assessment Measures provides four circumstances, under any of which data processors shall, through the local cyberspace administration at the provincial-level, apply to the national cyberspace administration for security assessment of cross-border data transfer. These circumstances include: (i) where the important data are transferred to an overseas recipient; (ii) where the personal information is transferred to an overseas recipient by a CIIO or a data processor that has

---

## REGULATORY OVERVIEW

---

processed personal information of more than one million individuals; (iii) where a data processor provides personal information to an overseas recipient if such data processor has already provided overseas the personal information of 100,000 individuals or sensitive personal information of 10,000 individuals in total since 1 January of the preceding year; or (iv) other circumstances under which security assessment of outbound data transfer is required as prescribed by the national cyberspace administration. The Measures on the Standard Contract for the Cross-Border Transfer of Personal Information (《个人信息出境标准合同办法》) (“**SCC Measures**”) were promulgated by the CAC on 22 February 2023 and took effect on 1 June 2023. The SCC Measures attach the prescribed template for the standard contract on the cross-border transfer of personal information that could be used as an available option to satisfy the condition for cross-border transfer of personal information under Article 38 of the Personal Information Protection Law. On 22 March 2024, the CAC promulgated the Provisions on Promoting and Regulating Cross-Border Data Flows (《促进和规范数据跨境流动规定》), effective on the date of promulgation. The provisions provide several exemptions from undergoing data security assessment, obtaining personal information protection certification or entering into standard contract for outbound transfer of personal information for businesses. These exemptions include, among others, the scenario where a data processor, other than a CIIO, has cumulatively transferred overseas personal information, excluding sensitive personal information, of fewer than 100,000 individuals since 1 January of the current year. A data processor, other than a CIIO, shall enter into a standard contract with overseas recipients for the cross-border transfer of personal information or obtain certification for personal information protection if since 1 January of the current year, the data processor has cumulatively transferred to overseas recipients (a) personal information of more than 100,000 but less than 1,000,000 individuals, excluding sensitive personal information, or (b) sensitive personal information of less than 10,000 individuals. The provisions also explicitly state that data processors are not required to conduct data security assessments for cross-border transfer of important data if the data has not been notified or published as important data by relevant departments or regions.

### Laws and Regulations on Labour Protection

The Labour Law of the PRC (《中华人民共和国劳动法》) was promulgated by the SCNPC on 5 July 1994, implemented on 1 January 1995, and most recently revised and implemented on 29 December 2018. The Labour Law of the PRC stipulates matters related to promoting employment, labour contracts, working hours, rest and leave, wages, labour safety and hygiene, special protection for female and minor workers, vocational training, social insurance and welfare, labour disputes, supervision and inspection, as well as legal liabilities. The Labour Contract Law of the PRC (《中华人民共和国劳动合同法》) was issued by the SCNPC on 29 June 2007, implemented on 1 January 2008, and most recently revised on 28 December 2012, with the revision taking effect on 1 July 2013. The Implementation Regulation of the Labour Contract Law of the PRC (《中华人民共和国劳动合同法实施条例》) were issued and implemented by the State Council on 18 September 2008. According to the aforementioned law and regulation, a written labour contract shall be established when forming a labour relationship.

The PRC Social Insurance Law (《中华人民共和国社会保险法》) (“**Social Insurance Law**”) issued by the SCNPC in 2010 and latest amended on 29 December 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 (《社会保险费征缴暂行条例》) promulgated by the State Council on 22 January 1999 and most recently amended on 24 March 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.

---

## REGULATORY OVERVIEW

---

On 31 July 2025, the Supreme People’s Court of the PRC has issued the Interpretation II by the Supreme People’s Court of the PRC on Legal Issues in the Trial of Labour Dispute Cases (《最高人民法院關於審理勞動爭議案件適用法律問題的解釋(二)》) (“**Interpretation II**”), which took effect from 1 September 2025. According to the Interpretation II, the agreement between an employer and an employee, or an employee’s commitment to the employer, stipulating that social insurance contributions need not be paid, shall be deemed invalid by the people’s court. If an employer fails to pay social insurance contributions in accordance with the law, and the employee requests to terminate the labour contract and demands the employer to pay economic compensation according to Article 38(3) of the Labour Contract Law, the people’s court shall support such a request in accordance with the law.

According to the Regulations on Administration of Housing Provident Fund (《住房公積金管理條例》), which was promulgated on 3 April 1999 and last revised on 24 March 2019, employers in Chinese Mainland shall provide their employees with housing provident fund. Employers who fail to contribute to the above housing provident funds may be ordered to make full payment within a prescribed time period by the housing provident fund management centre. If an employer fails to make the payment towards the housing provident funds within a prescribed time limit, an application may be made to a people’s court for enforcement.

### **Laws and Regulations on Leasing**

On 1 December 2010, the Ministry of Housing and Urban-Rural Development promulgated the Administrative Measures on Leasing of Commodity Housing (《商品房屋租賃管理辦法》), which became effective on 1 February 2011. According to such measures, the lessor and the lessee are required to complete property leasing registration and filing formalities within 30 days from execution of the property lease contract with the development authorities or real estate authorities of the municipality or county where the leased property is located. If a company fails to do as aforesaid, it may be ordered to rectify within a stipulated period, and if such company fails to rectify, a fine ranging from RMB1,000 to RMB10,000 maybe imposed on each lease agreement.

According to the Civil Code of the PRC (《中華人民共和國民法典》), the relevant parties fail to complete property leasing registration and filing formality in accordance with the laws and regulations, the validity of the lease is not affected.

### **Laws and Regulations on Taxation**

#### ***Enterprise income tax***

According to the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) (“**EIT Law**”) latest amended by the SCNPC and came into effect on 29 December 2018 and the Regulations on the Implementation of the EIT Law (《中華人民共和國企業所得稅法實施條例》) latest amended by the State Council on 6 December 2024 and came into effect on 20 January 2025, a domestic enterprise which is established within Chinese Mainland in accordance with the laws or established in accordance with any laws of foreign countries (regions) but with an actual management entity within Chinese Mainland shall be regarded as a resident enterprise. A resident enterprise shall be subject to a tax rate of 25% of any income generated within or outside Chinese Mainland. A preferential tax rate shall be applicable to any key industry or project which is supported or encouraged by the State.

#### ***Value-added tax***

On 25 December 2024, the SCNPC issued the Value-Added Tax Law of the PRC (《中華人民共和國增值稅法》) (“**VAT Law**”), which became effective from 1 January 2026. According to the VAT Law, any entities and individuals (including individual businesses) engaged in the sale of goods, services, intangible assets and immovables and importation of goods within the territory of the PRC are VAT payers and shall pay VAT in accordance with the VAT Law. Except for taxpayers’ export of goods, the sale of services or intangible assets within the scope as prescribed by the State Council by domestic entities and individuals across national borders and other circumstances specified by the State Council, the rate of VAT for sale of goods, labour services of processing, repair or replacement, or tangible movable property leasing services or import of goods is 13% unless otherwise specified, such as the rate of VAT for sale of agricultural products is 9%, and the rate of VAT for sale of transportation,

---

## REGULATORY OVERVIEW

---

postal, basic telecommunications, construction, or immovable leasing services, sale of immovables, or transfer of the rights to use land is 9%. In addition to the above circumstances, the rate of VAT for sale of services or intangible assets is 6%.

### **Laws and Regulations on Company Establishment and Overseas Investment**

#### ***Regulations relating to corporation***

The establishment, operation and management of corporate entities in the PRC is governed by the Company Law of the PRC (《中華人民共和國公司法》) (“**PRC Company Law**”), which was promulgated by the SCNPC on 29 December 1993 and came into effect on 1 July 1994, and was last amended on 29 December 2023 and became effective on 1 July 2024. The PRC Company Law generally governs two types of companies, namely limited liability companies and joint stock limited companies. Both types of companies have the status of legal persons, and the liability of shareholders of a limited liability company or a joint stock limited company is limited to the amount of registered capital they have contributed. The PRC Company Law shall also apply to foreign invested companies in form of limited liability company or joint stock limited company. Where laws on foreign investment have other stipulations, such stipulations shall prevail.

#### ***Regulations relating to overseas investment***

According to the Measures for the Administration of Overseas Investment of Enterprises (《企業境外投資管理辦法》) promulgated by the NDRC on 26 December 2017 and implemented on 1 March 2018, investors engaging in overseas investment are required to complete formalities for the confirmation or recordation, among others, of an overseas investment project, report the relevant information, and cooperate in supervisory inspection. According to the Measures for the Administration of Overseas Investment (《境外投資管理辦法》) promulgated by the MOFCOM on 16 March 2009, lastly amended on 6 September 2014 and implemented on 6 October 2014, the MOFCOM and the provincial counterparts promulgate regulations providing that overseas investment of enterprises to be subject to recordation or confirmation management, depending on the actual circumstances of investment. Overseas investment involving any sensitive country or region or any sensitive industry shall be subject to confirmation management.

### **Laws and Regulations on Overseas Listing**

On 17 February 2023, the CSRC promulgated the Trial Administrative Measures of the 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》) and relevant five guidelines (“**Overseas Listing Trial Measures**”), which came into effect on 31 March 2023. According to the Overseas Listing Trial Measures, PRC domestic enterprises that seek to offer and list securities in overseas markets, either in direct or indirect means (“**Overseas Offering and Listing**”), are required to fulfill the filing procedure with the CSRC and submit filing reports, legal opinions, and other relevant documents.

On 24 February 2023, the CSRC together with the MOF and National Administration of State Secrets Protection and National Archives Administration of China have promulgated the Provisions on Strengthening the Confidentiality and Archives Administration Concerning the 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》). If domestic enterprises provide or publicly disclose to relevant securities companies, securities service institutions, overseas regulatory agencies and other parties, or provide or publicly disclose documents and materials involving state secrets or state organ work secrets through the issuer, they shall report the matters to the competent authorities for examination and approval, and file them with the department for the administration and management of state secrets at the same level for the record.

---

## REGULATORY OVERVIEW

---

### H Share Full Circulation

“Full circulation” refers to the listing and circulation of the domestic unlisted shares of an H-share listed company on the Stock Exchange, including unlisted domestic shares held by domestic shareholders prior to overseas listing, unlisted domestic shares additionally issued after overseas listing, and unlisted shares held by foreign shareholders. On 14 November 2019, the CSRC issued the Guidelines on the Application of “Full Circulation” of Domestic Unlisted Shares by H-share Companies (Announcement of the CSRC [2019] No. 22) (H股公司境內未上市股份申請“全流通”業務指引) (“**Guidelines on ‘Full Circulation’**”) and last amended on 10 August 2023. According to the Guidelines on “Full Circulation”, provided that the requirements set out in the relevant laws and regulations and in the policies for state-owned assets management, foreign investments and industry regulation are satisfied, the shareholders of domestic unlisted shares may decide at their own discretion through negotiation the amount and proportion of shares applying for circulation, and entrust the H-share Listed Company to submit the application for “full circulation”. The H-share Listed Company shall apply to the CSRC for “full circulation” in accordance with the administrative licensing procedures required for the “examination and approval of overseas public offering and listing of shares (including additional issuance) by joint stock companies”. Upon approval of the application for “full circulation” by the CSRC, the H-share Listed Company shall submit a report to the CSRC within 15 days after completion of the registration of shares involved in the application with the CSDC. According to the Overseas Listing Trial Measures, for a domestic company seeking direct overseas listing, the shareholders holding the domestic unlisted shares of such domestic company who apply for the conversion of the domestic unlisted shares into overseas listed shares shall comply with the relevant provisions of the CSRC and entrust such domestic company to file with the CSRC.

On 31 December 2019, the CSDC and Shenzhen Stock Exchange jointly issued the Implementation Measures for H-share “Full Circulation” Business (H股“全流通”業務實施細則), which applied to the cross-border transfer registration, maintenance of deposit and holding details, transaction entrustment and instruction transmission, settlement, management of settlement participants, services of nominee holders and other businesses in relation to H-share “full circulation” business.

In order to fully promote the reform of H-share “full circulation” and specify the business arrangements and procedures for registration, custody, settlement and delivery of relevant shares, the CSDC Shenzhen Branch issued the Guidance for H-share “Full Circulation” (中國證券登記結算有限責任公司深圳分公司H股“全流通”業務指南) on 7 February 2020, last amended on 27 June 2025, which specified the business preparation, account arrangements, cross-border share transfer registration and overseas centralised custody, etc.