

REGULATORY OVERVIEW

LAWS AND REGULATIONS RELATING TO MEDICAL DEVICES

Regulations on the Supervision and Administration of Medical Devices

According to the Regulations on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) (the “**Medical Device Regulations**”) which was issued by the State Council on January 4, 2000 and latest amended on December 6, 2024, and came into effect on January 20, 2025, the drug supervision and administration department under the State Council shall be responsible for the supervision and administration of medical devices nationwide. The relevant departments under the State Council shall be responsible for the supervision and administration relating to medical devices within the scope of their respective duties. We are now principally subject to the supervision of the National Medical Products Administration (國家藥品監督管理局) and its local counterparts. The National Medical Products Administration was established in accordance with the Institutional Reform Program of the State Council (《國務院機構改革方案》) promulgated by the National People’s Congress (the “NPC”) on March 17, 2018. The National Medical Products Administration is a newly established regulatory authority responsible for registration and supervision of pharmaceutical products, cosmetics and medical devices under the supervision of the State Administration for Market Regulation (國家市場監督管理總局) (the “**SAMR**”), a newly established institution for supervising and administrating the market in China. The relevant departments of the local people’s governments at the county level and above are responsible for the supervision of medical devices within their respective scope of duties.

In the PRC, medical devices have been classified into three categories based on their risk degree. Class I medical devices refer to those devices with low risks and whose safety and effectiveness can be ensured through routine administration. Class II medical devices refer to those devices with moderate risks and whose safety and effectiveness shall be strictly controlled and administered. Class III medical devices refer to those devices with relatively high risks and whose safety and effectiveness need to be strictly controlled and administered with special measures. The classification of specific medical devices is stipulated in the Medical Device Classification Catalog (《醫療器械分類目錄》), which was issued by the NMPA on August 31, 2017 and became executive on August 1, 2018 and latest amended on December 30, 2025.

The products we currently sell in China are Class I, Class II and Class III medical devices.

Regulations on the Registration of Domestic Medical Devices

According to the Administrative Measures for the Registration and Filing of Medical Devices (《醫療器械註冊與備案管理辦法》) which was promulgated by the SAMR on August 26, 2021 and came into effect on October 1, 2021, for the filings of Class I medical devices, the filing materials shall be submitted to the local branches at the districted city level of the NMPA. In case of any amendments made to matters stated in the filings, such amendments shall be filed with the original filing department. Class II and Class III medical devices must obtain their respective product registrations before they can be marketed and sold in China. Class II medical devices shall be examined by the provincial branches of the NMPA and domestic Class III medical devices shall be examined by the NMPA, and a Medical Device Registration Certificate (醫療器械註冊證) for such medical device shall be issued upon approval. In case of any substantial changes of the designs, raw materials, production technologies, scopes of application and application methods, among other things, of the registered Class II or Class III medical devices, which may affect the safety and effectiveness of such medical devices, the registrants shall submit the application for change of registration with the original registration departments within 30 days.

The Medical Device Registration Certificate is valid for five years and the registrant shall file for renewal with the corresponding medical products administrative department at least six months prior to its expiration date.

REGULATORY OVERVIEW

Clinical Evaluation and Clinical Trials of Medical Devices

According to the Medical Device Regulations and the Administrative Measures for the Registration and Filing of Medical Devices, clinical evaluation is required for the registration and filing of medical devices. Clinical evaluation of medical devices refers to activities in which clinical data are analyzed and evaluated by adopting scientific and reasonable methods to confirm the safety and effectiveness of medical devices within the scope of application. Moreover, pursuant to the Notice on the Implementation of The Administrative Measures for the Registration and Filing of Medical Devices and Measures for the Administration of Registration and Recordation of In-Vitro Diagnostic Reagents (《國家藥品監督管理局關於實施<醫療器械註冊與備案管理辦法><體外診斷試劑註冊與備案管理辦法>有關事項的通告》) issued by the NMPA on September 28, 2021, clinical evaluations are not required for the recordation of Class I medical devices, but are required for the application for the registration of Class II and Class III medical devices. However, clinical evaluation may be exempted under any of the following circumstances:

- the medical devices have clear and definite working mechanisms, finalized designs and mature manufacturing techniques, the marketed medical devices of the same category have been put into clinical application for years with no record of severe adverse event, and their general purposes remain unchanged;
- the safety and effectiveness of such medical devices can be proved through non-clinical evaluation.

Clinical evaluation of medical devices may be carried out through clinical trials or analysis and evaluation of clinical literature materials and clinical data of medical devices of the same kind to prove their safety and effectiveness of medical devices in light of product characteristics, clinical risks, existing clinical data and other circumstances. If the existing clinical literature and data are insufficient to confirm the safety and effectiveness of the medical devices, clinical trials shall be conducted. Pursuant to the Notice of the Catalogue of Medical Devices Exempted from Clinical Evaluation (《關於發佈免於進行臨床評價醫療器械目錄的通告》) (the “**Exemption Catalogue**”) issued by the NMPA on May 12, 2025, for medical devices that are not included in the Exemption Catalogue, clinical evaluations shall be conducted before the registration or filing.

Clinical trials shall be conducted in accordance with the Good Clinical Practice for Medical Device Trials (《醫療器械臨床試驗質量管理規範》) (the “**Good Clinical Practice**”), which was issued by the NMPA and the NHC jointly on March 1, 2016 and latest amended on March 24, 2022 and came into effect on May 1, 2022. The Good Clinical Practice set forth the necessary procedures of clinical trials for medical devices, including, among others, the protocol design, conduct, monitoring, verification, inspection, and data collection, recording, preservation, analysis, conclusion and reporting procedure of a clinical trial. Prior to commencement of a clinical trial, the applicant must ensure the design of the medical device has been finalized and complete the pre-clinical research of the medical device, including product performance verification and confirmation, product inspection report based on the technical requirements, and risk-benefit analysis, etc., the results of which should support the clinical trial. The clinical trial must be conducted in clinical trial organizations that meet the corresponding conditions and have been filed for record as required. Prior to the commencement of a clinical trial, approval by the ethics committees of the relevant clinical trial organization should be obtained and the applicant, the clinical trial organization and the principal investigators must enter into agreements in writing to arrange their rights and obligations during the trial. In the event of inclusion into the catalog of Class III medical devices whose clinical trials are subject to approval, the approval of the NMPA shall also be obtained, and the clinical trials shall be carried out in the qualified Grade IIIA medical organizations.

The clinical trial could be carried out in two or more clinical trial organizations for medical devices under the same clinical trial protocol (the “**Multi-center Clinical Trial**”). When a Multi-center Clinical Trial is carried out in different countries or regions, it is a multi-regional clinical trial. Multi-regional clinical trials for medical devices conducted within the territory of China shall meet the relevant requirements of the Good Clinical Practice.

REGULATORY OVERVIEW

Regulations on the Production and Quality Management of Medical Devices

The Measures on the Supervision and Administration Production of Medical Devices (《醫療器械生產監督管理辦法》) (the “**Measures on Production of Medical Devices**”), which was promulgated on July 20, 2004, and latest amended on February 18, 2022 and came into effect on May 1, 2022, stipulates that manufacturer of medical devices shall satisfy the following conditions:

- it has production sites, environmental conditions, production equipment and professional technicians that are suitable for such medical devices to be produced;
- it has organizations or professional examination staffs and examination equipment for carrying out quality examinations for such medical devices to be produced;
- it has formulated a management system that ensures the quality of such medical devices;
- it has the capability of after-sale services that is suitable for such medical devices to be produced; and
- it satisfies the requirements as prescribed in R&D and production technique documents.

Medical device manufacturers shall be responsible for the quality of medical devices they manufacture. The enterprises engaging in the production of Class I medical devices shall make filings for such Class I medical devices with the local branches at the districted city level of the NMPA and submit materials to prove that it is qualified to engage in the production of such medical devices. The enterprises engaging in the production of Class II or Class III medical devices shall apply for a Manufacture License for Medical Devices (醫療器械生產許可證) with provincial branches of the NMPA, and submit materials proofing it is qualified to engage in the production of such medical devices and a Medical Device Registration Certificate for the production of such medical devices. A Manufacture License for Medical Devices is valid for five years and the registrant shall file for renewal application with the original branch of the NMPA within 90 to 30 working days prior to its expiration date.

Regulations on the GMP Rules for Medical Devices

The Good Manufacturing Practice Rules for Medical Devices (《醫療器械生產質量管理規範》) (the “**GMP Rules for Medical Devices**”) was promulgated on November 4, 2025 and will come effect on November 1, 2026. According to abovementioned rules, an enterprise engaging in the production of medical devices shall establish and effectively maintain a quality control system. The enterprise shall establish its procurement control procedure and assess its suppliers by establishing an examination system to ensure the purchased products are in compliance with the statutory requirements. The enterprise shall record the procurement, production and inspection of raw materials. Such records shall be true, accurate, complete and traceable. The enterprise shall apply risk management to the whole process of design and development, production, sales and after-sale services. The measures being adopted shall apply to risks associated with the related products.

Pursuant to The Notice of Four Guidelines including On-site Inspection Guidelines for the GMP Rules for Medical Devices (《關於印發<醫療器械生產質量管理規範現場檢查指導原則>等四個指導原則的通知》) which was promulgated by the NMPA on September 25, 2015 and came into effect on the same day, during the course of on-site verification of the registration of medical devices and on-site inspection for the issuance of production permit (including the change and renewal of production permit), the inspection team shall, in accordance with the guidelines, issue recommended conclusions for on-site inspections, which include “passed”, “failed” or “to be reassessed after rectification”. During the supervision and inspection, if it is found that the requirements of the key items or ordinary items that may have a direct impact on product quality are not satisfied, the enterprise shall suspend production and be subject to rectification orders. If it is found that the requirements of the ordinary items that do not directly

REGULATORY OVERVIEW

affect product quality are not satisfied, the enterprise shall rectify such issue in a prescribed time. The regulatory authorities shall examine and verify the recommended conclusions and on-site inspection materials submitted by the inspection group and issue the final inspection results.

Regulations on Supervision and Administration of Medical Devices Operation

According to the Measures for the Supervision and Administration of Medical Devices Operation (《醫療器械經營監督管理辦法》) promulgated by the SAMR on March 10, 2022 and came into effect on May 1, 2022, an enterprise engaging in the operation of medical devices shall have business premises and storage conditions suitable for the operation scale and scope, and shall have quality control department or personnel suitable for the medical devices it operates. An enterprise engaged in the operation of Class I medical devices, the license or record is not required for business activities, while an enterprise engaged in the operation of Class II medical devices shall file with the districted city level medical products supervision and administration department and provide materials to provide it satisfies the relevant conditions of engaging in the operation of medical devices, and an enterprise engaged in the operation of Class III medical devices shall apply for a Business Operation License of Medical Devices (醫療器械經營許可證) to the districted city level medical products supervision and administration department and provide materials to provide that it satisfies the relevant conditions of engaging in the operation of such medical devices.

The relevant local department of NMPA which receives operation permit application shall grant the Business Operation License of Medical Devices if the enterprise meets the prescribed requirements. A Business Operation License of Medical Devices is valid for five years and maybe renewed pursuant to the relevant regulations. An enterprise engaging in medical devices operation shall not operate or use any medical device that has not been legally registered or filed, without qualification certificate, outdated, invalid, or disqualified. Moreover, an enterprise engaging in medical devices operation is prohibited to import and sell medical devices that are outdated, invalid, or disqualified, and are used.

A medical device operator shall establish a quality control system and quality control measures covering the entire process including purchase, acceptance inspection, storage, sales, transport and after-sales service, in accordance with laws, regulations and the quality standards for business operations of medical devices, and keep relevant records to ensure continuous compliance in its business conditions and acts.

- A wholesaler of Class II and Class III medical devices and a retailer of Class III medical devices shall establish a system of sale records. Records of quality control and sale shall be authentic, accurate, complete and traceable.
- A medical device operator shall purchase medical devices from legally qualified registrants, record-filing parties or operators of medical devices.
- A medical device operator shall provide after-sale service or enter into an agreement with the supplier or another institution on liability for after-sale service. The operator shall strengthen management to ensure safe use of such devices.
- A medical device operator shall take effective measures to ensure that devices are transported and stored as required in their instructions and labels, and keep records thereof.

Regulations on Advertisements of Medical Devices

The SAMR promulgated the Interim Measures for the Administration of the Examination and Administration of Drugs, Medical Devices, Health Foods, and Formula Foods for Special Medical Purposes (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》) (the “**Examination Interim Measures**”) on December 24, 2019, which came into effect on March 1, 2020. The Examination Interim Measures stipulates that the advertisements for medical devices shall not be released without being reviewed. The contents of a medical device advertisement shall be based on the contents of the registration certificate or filing

REGULATORY OVERVIEW

certificate approved by the drug administrations, or the registered or filed product instructions. Where the medical device advertisement involves the name, scope of application, functional mechanism or structure or composition of the medical device, the information in such advertisement must not exceed that as set out in the product registration or filing certificate. The validity period of the advertisement approval number for medical devices shall not exceed that of its registration certificate, filing certificate or production license, whichever is shorter. If no valid period is prescribed in the product registration certificate, filing certificate or production license, the valid period of the advertisement approval number shall be two years.

The advertisement of a medical device shall be true and lawful, and its content shall not be false, exaggerated or misleading. A publisher of a medical device advertisement shall verify approval documents and their authenticity prior to the publication. If no approval document was obtained or the authenticity of any approval document has not been verified or the content of the advertisement is inconsistent with the approval documents, such medical device advertisement shall not be published.

Regulations on Medical Device Recalls

Pursuant to the Administrative Measures for Medical Device Recalls (《醫療器械召回管理辦法》), which was promulgated on January 25, 2017 and came into effect on May 1, 2017, in terms of the severity of the case, medical device recalls are divided into three classes, namely: (i) Class I recall, where the circumstances leading to the recall may cause or have caused serious harm to health; (ii) Class II recall, where the circumstances leading to the recall may cause or have already caused temporary or reversible harm to health; or (iii) Class III recall, where the circumstances leading to the recall are not likely to cause any harm but a recall is necessary.

Medical device manufacturers shall determine the recall class based on the situation and properly design and implement the recall plan based on the recall class and the sale and use of the medical devices. In terms of Class I recall, the recall notice shall be published on the website of the NMPA and major media. In terms of Class II and Class III recalls, the recall notice shall be published on the website of the provincial level of food and drug administrative authority.

NATIONAL MEDICAL INSURANCE PROGRAM

The national medical insurance program was adopted pursuant to the Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program (《關於建立城鎮職工基本醫療保險制度的決定》) issued by the State Council on December 14, 1998, under which all employers in urban cities are required to enroll their employees in the Urban Employee Basic Medical Insurance Program and the insurance premium is jointly contributed by the employers and employees. Pursuant to the Opinions on the Establishment of the New Rural Cooperative Medical System (《關於建立新型農村合作醫療制度意見的通知》) forwarded by the General Office of the State Council on January 16, 2003, China launched the New Rural Cooperative Medical System to provide medical insurance for rural residents in selected areas which has spread to the whole nation thereafter. The State Council promulgated the Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance (《國務院關於開展城鎮居民基本醫療保險試點的指導意見》) on July 10, 2007, under which urban residents of the pilot district, rather than urban employees, may voluntarily join Urban Resident Basic Medical Insurance. After years of development, in accordance with the 14th Five-Year Plan for Universal Medical Security (《“十四五”全民醫療保障規劃》) promulgated by the General Office of the State Council on September 23, 2021, the National Medical Insurance Program that covers both rural and urban citizens has been comprehensively established.

With regard to reimbursement for medical devices, the Notice of Opinion on the Diagnosis and Treatment Management, Scope and Payment Standards of Medical Service Facilities Covered by the National Urban Employees Basic Medical Insurance Scheme (《關於印發〈城鎮職工基本醫療保險診療項目管理、醫療服務設施範圍和支付標準意見〉的通知》), which was issued on June 30, 1999 and became effective on the same day, prescribes the coverage of diagnostic and treatment devices where part of the fees are paid through the

REGULATORY OVERVIEW

basic medical insurance scheme. It also includes a negative list that precludes certain devices and medical services from governmental reimbursement. Detailed reimbursement coverage and rate for medical devices and medical services (including diagnostic tests and kits) are subject to each province’s local policies. Pursuant to the Notice on Further Promoting the Administration and Assurance of Oral Medical Services (《關於進一步推進口腔醫療服務和保障管理工作的通知》), which was issued on August 25, 2023, eligible oral therapeutic medical services and medical consumables will be incorporated into the scope of Medical Insurance reimbursement according to relevant procedures, subject to the affordability of the Medical Insurance Fund.

REGULATIONS RELATING TO IMPORTATION AND EXPORTATION OF GOODS

According to the Customs Law of the PRC (《中華人民共和國海關法》) which was promulgated by the Standing Committee of the National People’s Congress (the “SCNPC”) on January 22, 1987 and became effective on July 1, 1987, and latest amended and came into force on April 29, 2021, the import of goods throughout the period from the time of arrival in the territory of China to the time of customs clearance, the export of goods throughout the period from the time of declaration to the customs to the time of departure from the territory of China, and the transit, transshipment and through-shipment goods throughout the period from the time of arrival in the territory of China to the time of departure from the territory of China shall be subject to customs control.

According to the Foreign Trade Law of the PRC (《中華人民共和國對外貿易法》) which was promulgated by the SCNPC on May 12, 1994 and became effective on July 1, 1994, and latest amended on December 27, 2025 and will come into force on March 1, 2026, any foreign trade business operator that is engaged in the import and export of goods or technology shall be registered for archival purposes with the administrative authority of foreign trade of the State Council or the institution entrusted thereby, unless it is otherwise provided for by any law, administrative regulation or the foreign trade department of the State Council. Where any foreign trade business operator that fails to file for archival registration according to relevant provisions, the customs may not handle the procedures of customs declarations and release of the import or export goods.

According to the Administrative Provisions on the Filing of Customs Declaration Entities of the PRC (《中華人民共和國海關報關單位備案管理規定》), promulgated by the General Administration of Customs of the PRC on November 19, 2021 and came into effect on January 1, 2022, the consignors or consignees of imported or exported goods or customs declaration enterprises that apply for filing shall obtain market entity qualifications. Also, consignors or consignees of imported or exported goods that apply for filing shall also complete the record-filing formalities for foreign trade business operators.

Pursuant to the Regulations on the Administration of Export Sales Certificates of Medical Devices (《醫療器械產品出口銷售證明管理規定》) promulgated by the NMPA on June 1, 2015 and coming into effect on September 1, 2015, if the registration certificate for a medical device and production permit for a medical device has been obtained in China, or the medical device registration and production recordation have been completed, the food and drug supervision and administration department may issue a Medical Device Product Export Sales Certificate (醫療器械產品出口銷售證明) to the relevant manufacturing enterprise. The validity term of the Medical Device Product Export Sales Certificate should not exceed the earliest deadline for the various documents submitted by the enterprise in the application materials, and the maximum validity term shall also not exceed two years.

PRODUCTION SAFETY AND LIABILITY

Production Safety Law of the PRC

Pursuant to the Production Safety Law of the PRC (《中華人民共和國安全生產法》) which was amended on June 10, 2021 and came into effect on September 1, 2021, an enterprise shall (i) provide production safety conditions as stipulated in this law and other relevant laws, administrative regulations, national and industry standards, (ii) establish a comprehensive

REGULATORY OVERVIEW

production safety accountability system and production safety rules, and (iii) develop production safety standards to ensure production safety. Any entity that fails to provide required production safety conditions is prohibited from engaging in production activities.

Product Quality Law of the PRC

Pursuant to the Product Quality Law of the PRC (《中華人民共和國產品質量法》) which was promulgated by the SCNPC on February 22, 1993, and amended and came into effect on December 29, 2018, producers and sellers shall have their own proper regulations for the management of product quality, rigorously implementing post-oriented quality regulations, quality liabilities and relevant measures for their assessment. Producers and sellers are responsible for the product quality according to the provisions of the laws.

The product quality supervision and administration departments of the State Council are responsible for the supervision and administration of the quality of products of the whole country. All relevant departments of the State Council shall be responsible for the supervision of product quality within their own functions and duties.

Quality of products shall pass standard examinations and it is not allowed to pass off sub-standard products as standard ones. Industrial products which may be hazardous to the health of the people and the safety of lives and property shall conform to the State and trade standards for ensuring the health of the people and safety of lives and property. In absence of such State or trade standards, the products shall conform to the minimum requirements for ensuring the health of the people and the safety of lives and property. It shall be prohibited to produce or sell industrial products that do not meet the requirements and demands for physical health and safety of body and property. Producers or sellers shall be responsible for any compensation arising from their unlawful acts such as production or sales of defective, eliminated or ineffective products, faking the place of origin or quality marks, mixing or adulterating products or passing off imitations as genuine, substandard products as quality ones or non-conforming products as conforming. Proceeds from the sales may be confiscated, the business license may be revoked, and penalties may be imposed. If the case is serious, criminal responsibilities shall be investigated. Producers or sellers shall be liable for any damage to any person or property due to the defects of products resulting from the default of the producers or sellers.

Tort Law of the PRC

According to the Civil Code of the PRC, which replaced the previous Tort Law of the PRC, in the event of product defects which have caused others to suffer damages, the manufacturer shall bear tort liability. In the event of product defects as a result of the seller's negligence which has caused others to suffer damages, the seller shall bear tort liability. Where the seller is unable to specify the manufacturer and the distributor of the defective products, the seller shall bear tort liability. In case of damages caused by product defects, the infringed party may seek compensation from the manufacturer of the products or the seller of the products. Where the product defects are caused by the manufacturer, the seller shall have the right to seek recourse against the manufacturer after the seller has made compensation. In the event of product defects as a result of the seller's negligence, the manufacturer shall have the right to seek recourse against the seller after the manufacturer has made compensation.

REGULATIONS RELATING TO ENVIRONMENTAL PROTECTION

Pursuant to the Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) which was promulgated on December 26, 1989 and became effective on the same day, latest amended on April 24, 2014 and became effective on January 1, 2015, the waste discharge licensing system has been implemented in the PRC and entities that discharge wastes shall obtain a Waste Discharge License (排污許可證). Furthermore, facilities for the prevention and control of pollution at a construction project shall be designed, constructed and put into operation simultaneously with the major construction works of the construction project.

REGULATORY OVERVIEW

Pursuant to the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》) which was promulgated on October 28, 2002, became effective on September 1, 2003 and latest amended on December 29, 2018, the State implements administration by classification on the environmental impact of construction projects according to the level of impact on the environment. The construction unit shall prepare an environmental impact report or an environmental impact form or complete an environmental impact registration form (the “**Environmental Impact Assessment Documents**”) for reporting and filing purposes. If the Environmental Impact Assessment Documents of a construction project have not been reviewed by the approving authority in accordance with the law or have not been granted approval after the review, the construction unit is prohibited from commencing construction works.

Pursuant to Interim Measures on Administration of Environmental Protection for Acceptance Examination Upon Completion of Construction Projects (《建設項目竣工環境保護驗收暫行辦法》) which was promulgated on November 20, 2017 and came into effect on the same day, the construction unit is the responsible party for the acceptance of the environmental protection facilities for the completion of the construction project, and shall, in accordance with the procedures and standards stipulated in relevant regulations, organize the acceptance of the environmental protection facilities, prepare the acceptance report, disclose the relevant information, accept social supervision, ensure that the environmental protection facilities to be constructed for the construction project are put into operation or used at the same time as the main project, and be responsible for the content, conclusion and public information of the acceptance. The construction unit shall be responsible for the truthfulness, accuracy and completeness of the acceptance content, conclusions and information disclosed, and shall not falsify the acceptance process. The major construction works of the construction project cannot be put into operation until the supporting facilities for environmental protection pass the inspection.

The Administrative Measures on Licensing of Urban Drainage (《城鎮污水排入排水管網許可管理辦法》), which was promulgated by the Ministry of Housing and Urban-rural Development on January 22, 2015 and came into effect on March 1, 2015 and latest amended on December 1, 2022 and came into effect on February 1, 2023, provides that enterprises, institutions and individual industrial and commercial households engaging in industry, construction, catering industry, medical industry and discharging sewage into the urban drainage network must apply for and obtain a License for Urban Drainage (《排水許可證》).

REGULATIONS ON FOREIGN INVESTMENT IN THE PRC

Regulations on Foreign Investment

Investment activities in the PRC by foreign investors were principally governed by the Special Administrative Measures (Negative List) for Access of Foreign Investment (2024 version) (《外商投資准入特別管理措施(負面清單)(2024年版)》), or the Negative List, and the Catalogue of Industries for Encouraging Foreign Investment (2025 version) (《鼓勵外商投資產業目錄(2025年版)》), or the Encouraging List. The Negative List, which came into effect on November 1, 2024, sets out special administrative measures (restricted or prohibited) in respect of the access of foreign investments in a centralized manner, and the Encouraging List which came into effect on February 1, 2026, sets out the encouraged industries for foreign investment. The Group’s business is not subject to the foreign investment restrictions as stipulated in the Negative List.

Foreign-Invested Enterprises

On December 29, 1993, the SCNPC issued the PRC Company Law (《中華人民共和國公司法》), or the Company Law, which was last amended on December 29, 2023 and became effective on July 1, 2024. The Company Law regulates the establishment, operation and management of corporate entities in China and classifies companies into limited liability companies and limited companies by shares. According to the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) promulgated by the SCNPC on March 15, 2019 and came into effect on January 1, 2020, the state shall implement the management systems of pre-establishment national treatment and negative list for foreign investment, and shall give

REGULATORY OVERVIEW

national treatment to foreign investment beyond the negative list. Simultaneously, Sino-foreign Equity Joint Ventures of the PRC (《中華人民共和國中外合資經營企業法》), the Wholly Foreign-owned Enterprises Law of the PRC (《中華人民共和國外資企業法》) and Sino-foreign Cooperative Joint Ventures of the PRC (《中華人民共和國中外合作經營企業法》) have been repealed since January 1, 2020.

On December 26, 2019, the State Council promulgated 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》), which came into effect on January 1, 2020. After the Regulations on Implementing the Foreign Investment Law of the PRC came into effect, the Regulations on Implementing the Sino-Foreign Equity Joint Venture of the PRC (《中華人民共和國中外合資經營企業法實施條例》), Provisional Regulations on the Duration of Sino-Foreign Equity Joint Venture (《中外合資經營企業合營期限暫行規定》), the Regulations on Implementing the Wholly Foreign-owned Enterprise Law of the PRC (《中華人民共和國外資企業法實施細則》) and the Regulations on Implementing the Sino-foreign Cooperative Joint Venture of the PRC (《中華人民共和國中外合作經營企業法實施細則》) have been repealed simultaneously.

On December 30, 2019, the Ministry of Commerce of the PRC (the “**MOFCOM**”) and the SAMR issued the Measures for the Reporting of Foreign Investment Information (《外商投資信息報告辦法》), which came into effect on January 1, 2020 and replaced the Interim Measures for the Recordation Administration of the Incorporation and Change of Foreign-Invested Enterprises (《外商投資企業設立及變更備案管理暫行辦法》), for carrying out investment activities directly or indirectly in PRC, the foreign investors or foreign-invested enterprises shall submit investment information to the commerce authorities pursuant to these measures.

Regulations on Overseas Investment

Pursuant to the Measures for the Administration of Overseas Investment (《境外投資管理辦法》) which was issued by the MOFCOM on September 6, 2014 and became effective on October 6, 2014, the MOFCOM and the commerce departments at provincial levels shall subject the overseas investment of enterprises 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. Overseas investment under other circumstances shall be subject to recordation management.

Pursuant to the Measures for the Administration of Overseas Investment of Enterprises (《企業境外投資管理辦法》) which was issued by the NDRC on December 26, 2017 and became effective on March 1, 2018, an enterprise in the territory of the PRC (the “**Investor**”) shall, in overseas investment, undergo the formalities for the confirmation or recordation, among others, of an overseas investment project (the “**Project**”), report the relevant information, and cooperate in supervisory inspection. Sensitive projects conducted by investors directly or through overseas enterprises controlled by them shall be subject to approval management. Non-sensitive Projects directly conducted by Investors, namely, non-sensitive Projects involving Investors’ direct contribution of assets or rights and interests or provision of financing or security, shall be subject to recordation management. The aforementioned sensitive Project means a Project involving a sensitive country or region or a sensitive industry. The NDRC promulgated the Catalogue of Sensitive Sectors for Outbound Investment (2018 Edition) (《境外投資敏感行業目錄(2018年版)》), effective on March 1, 2018, to list the sensitive industries in detail.

LAWS AND REGULATIONS RELATED TO OVERSEAS OFFERING AND LISTING

Pursuant 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》) promulgated by the China Securities Regulatory Commission (the “**CSRC**”) on 17 February 2023, which became effective on 31 March 2023, where a domestic company seeks to directly or indirectly offer and list securities in overseas markets, the issuer or the designated entity shall file with the CSRC within three business days after the application for [REDACTED] is submitted. Any overseas offering and listing made by an issuer that meets both the following conditions will

REGULATORY OVERVIEW

be determined as indirect: (1) 50% or more of the issuer’s operating revenue, total profit, total assets or net assets as documented in its audited consolidated financial statements for the most recent accounting year is accounted for by domestic companies; and (2) the main parts of the issuer’s business activities are conducted in the Chinese Mainland, or its main places of business are located in the Chinese Mainland, or the senior managers in charge of its business operation and management are mostly Chinese citizens or domiciled in the Chinese Mainland. The determination of the indirect overseas offering and listing of PRC domestic companies shall follow the principle of substance-over-form.

Regulations on Employment

The major PRC laws and regulations that govern employment relationship are the Labor Law of the PRC (《中華人民共和國勞動法》), or the Labor Law (issued by the SCNPC on July 5, 1994, came into effect on January 1, 1995 and latest revised on December 29, 2018), the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》) or the Labor Contract Law (promulgated by the SCNPC on June 29, 2007 and became effective on January 1, 2008, and then amended on December 28, 2012 and became effective on July 1, 2013) and the Implementation Rules of the Labor Contract Law of the PRC (《中華人民共和國勞動合同法實施條例》), or the Implementation Rules of the Labor Contract Law (issued by the State Council on September 18, 2008 and came into effect on the same day). According to the aforementioned laws and regulations, labor relationships between employers and employees must be executed in written form. The laws and regulations above impose stringent requirements on the employers in relation to entering into fixed-term employment contracts, hiring of temporary employees and dismissal of employees. As prescribed under the laws and regulations, employers shall ensure their employees have the right to rest and the right to receive wages no lower than the local minimum wages. Employers must establish a system for labor safety and sanitation that strictly abides by state standards and provide relevant education to its employees. Violations of the Labor Contract Law and the Labor Law may result in the imposition of fines and other administrative liabilities and/or incur criminal liabilities in the case of serious violations.

Regulations on Social Insurance

According to the Social Insurance Law of PRC (《中華人民共和國社會保險法》), which was issued by the SCNPC on October 28, 2010 and revised on December 29, 2018, enterprises and institutions in the PRC shall provide their employees with welfare schemes covering pension insurance, unemployment insurance, maternity insurance, occupational injury insurance, medical insurance and other welfare plans. The employer shall apply to the local social insurance agency for social insurance registration within 30 days from the date of its formation. And it shall, within 30 days from the date of employment, apply to the social insurance agency for social insurance registration for the employee. Any employer who violates the regulations above shall be ordered to make correction within a prescribed time limit; if the employer fails to rectify within the time limit, the employer and its directly liable person will be fined. Meanwhile, the Interim Regulation on the Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》), which was issued by the State Council on January 22, 1999 and came into effect on the same day, and last amended and became effective on March 24, 2019, prescribes the details concerning the social insurance.

Apart from the general provisions about social insurance, specific provisions on various types of insurance are set out in the Regulation on Work-Related Injury Insurance (《工傷保險條例》) which was issued by the State Council on April 27, 2003, came into effect on January 1, 2004 and revised on December 20, 2010, the Regulations on Unemployment Insurance (《失業保險條例》) which was issued by the State Council on January 22, 1999 and came into effect on the same day, the Trial Measures on Employee Maternity Insurance of Enterprises (《企業職工生育保險試行辦法》), which was issued by the Ministry of Labor on December 14, 1994 and came into effect on January 1, 1995. Enterprises subject to these regulations shall provide their employees with the corresponding insurance.

REGULATORY OVERVIEW

Regulations on Housing Provident Fund

According to the Regulation Concerning the Administration of Housing Provident Fund (《住房公積金管理條例》), which was implemented on April 3, 1999 and latest amended on March 24, 2019, any newly established entity shall make deposit registration at the housing accumulation fund management center within 30 days as of its establishment. After that, the entity shall open a housing accumulation fund account for its employees in an entrusted bank. Within 30 days as of the date an employee is recruited, the entity shall make deposit registration at the housing accumulation fund management center and seal up the employee’s housing accumulation fund account in the bank mentioned above within 30 days from termination of the employment relationship.

Any entity that fails to make deposit registration of the housing accumulation fund or fails to open a housing accumulation fund account for its employees shall be ordered to complete the relevant procedures within a prescribed time limit. Any entity failing to complete the relevant procedure within the time limit will be fined RMB10,000 to RMB50,000. Any entity that fails to make payment of housing provident fund within the time limit or has a shortfall in payment of housing provident fund will be ordered to make the payment or make up the shortfall within the prescribed time limit, otherwise, the housing provident management center is entitled to apply for compulsory enforcement with the People’s Court.

REGULATIONS ON INTELLECTUAL PROPERTY

Regulations on Trademarks

Pursuant to the Trademark Law of the PRC (《中華人民共和國商標法》) which was promulgated on August 23, 1982 and latest amended on April 23, 2019 and came into effect on November 1, 2019, the Implementation Regulations of the Trademark Law of PRC (《中華人民共和國商標法實施條例》) which was issued on August 3, 2002 and amended on April 29, 2014, the Trademark Office under the State Administration for Industry and Commerce of the PRC (the “**Trademark Office**”) shall handle trademark registrations and grant a term of ten years to registered trademarks, which may be renewed for additional ten-year period upon request from the trademark owner. The Trademark Law of the PRC has adopted a “first-to-file” principle with respect to trademark registration. Where an application for trademark for which application for registration has been made is identical or similar to another trademark which has already been registered or is under preliminary examination and approval for use on the same kind of or similar commodities or services, the application for registration of such trademark may be rejected. Any person applying for the registration of a trademark may not prejudice the existing right of others, nor may any person register in advance a trademark that has already been used by another party and has already gained a “sufficient degree of reputation” through such party’s use. A trademark registrant may, by entering into a trademark licensing contract, license another party to use its registered trademark. Where another party is licensed to use a registered trademark, the licensor shall report the license to the Trademark Office for recordation, and the Trademark Office shall publish it. An unrecorded license may not be used as a defense against a third party in good faith.

Regulations on Patents

According to the Patent Law of the PRC (《中華人民共和國專利法》), promulgated by the SCNPC on March 12, 1984 and latest amended on October 17, 2020 which became effective on June 1, 2021 and the Implementing Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》), promulgated by the China Patent Bureau Council on January 19, 1985, and last amended on December 11, 2023 and effective from January 20, 2024, there are three types of patents in the PRC invention patents, utility model patents and design patents. The protection period of a patent right for invention patents shall be 20 years, the protection period of a patent right for utility model patents shall be 10 years, and the protection period of design patent right is 15 years, both commencing from the filing date.

REGULATORY OVERVIEW

Regulations on Copyrights

According to the Copyright Law of the PRC (《中華人民共和國著作權法》), promulgated by the SCNPC on September 7, 1990 and latest amended on November 11, 2020 which became effective on June 1, 2021, works of non-Chinese nationals or stateless persons which are first published in the territory of PRC shall enjoy copyright under this Law. Unless otherwise provided for by this Law, the copyright in a work shall be owned by its author. An author’s rights of authorship, modification and integrity in respect of his/her work shall continue in perpetuity.

Regulations on Domain Names

According to the Administrative Measures for Internet Domain Names (《互聯網域名管理辦法》), which was promulgated by the Ministry of Industry and Information Technology (the “MIIT”) on August 24, 2017 and became effective on November 1, 2017, the MIIT is responsible for supervision and administration of domain name services in the PRC. Communication administrative bureaus at provincial levels shall conduct supervision and administration of the domain name services within their respective administrative jurisdictions. Domain name registration services shall, in principle, be subject to the principle of “first apply, first register”. A domain name registrar shall, in the process of providing domain name registration services, ask the applicant for which the registration is made to provide authentic, accurate and complete identity information on the holder of the domain name and other domain name registration related information.

REGULATIONS RELATING TO FOREIGN EXCHANGE AND OVERSEAS INVESTMENT

On January 29, 1996, the State Council promulgated the Administrative Regulations on Foreign Exchange of the PRC (《中華人民共和國外匯管理條例》) which became effective on April 1, 1996 and latest amended on August 5, 2008. Foreign exchange payments under current account items shall, pursuant to the administrative provisions of the foreign exchange control department of the State Council on payments of foreign currencies and purchase of foreign currencies, be made using self-owned foreign currency or foreign currency purchased from financial institutions engaging in conversion and sale of foreign currencies by presenting the valid document. Domestic entities and domestic individuals making overseas direct investments or engaging in issuance and trading of overseas securities and derivatives shall process registration formalities pursuant to the provisions of the foreign exchange control department of the State Council.

On November 19, 2012, the State Administration of Foreign Exchange (the “SAFE”) issued the Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment (《國家外匯管理局關於進一步改進和調整直接投資外匯管理政策的通知》), (the “SAFE Circular 59”), which came into effect on December 17, 2012 and latest amended on December 30, 2019. The SAFE Circular 59 aims to simplify the foreign exchange procedure and promote the facilitation of investment and trade. According to the SAFE Circular 59, the opening of various special purpose foreign exchange accounts, such as pre-establishment expenses accounts, foreign exchange capital accounts and guarantee accounts, the reinvestment of RMB proceeds derived by foreign investors in the PRC, and remittance of foreign exchange profits and dividends by a foreign-invested enterprise to its foreign shareholders no longer require the approval or verification of SAFE, as well multiple capital accounts for the same entity may be opened in different provinces. Later, the SAFE promulgated the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》) on February 13, 2015, which was partially abolished on December 30, 2019 and prescribed that the bank instead of SAFE can directly handle the foreign exchange registration and approval under foreign direct investment while SAFE and its branches indirectly supervise the foreign exchange registration and approval under foreign direct investment through the bank.

REGULATORY OVERVIEW

On May 10, 2013, the SAFE issued the Administrative Provisions on Foreign Exchange in Domestic Direct Investment by Foreign Investors (《外國投資者境內直接投資外匯管理規定》) (the “SAFE Circular 21”), which became effective on May 13, 2013 and latest amended on December 30, 2019. The SAFE Circular 21 specifies that the administration by SAFE or its local branches over direct investment by foreign investors in the PRC must be conducted by way of registration and banks must process foreign exchange business relating to the direct investment in the PRC based on the registration information provided by SAFE and its branches.

According to the Notice on Relevant Issue Concerning the Administration of Foreign Exchange for Overseas Listing (《關於境外上市外匯管理有關問題的通知》) issued by the SAFE on December 26, 2014, the domestic companies shall register the overseas listing with the foreign exchange control bureau located at its registered address in 15 working days after completion of the overseas listing and issuance. The funds raised by the domestic companies through overseas listing may be repatriated to China or deposited overseas, provided that the intended use of the fund shall be consistent with the contents of the document and other public disclosure documents.

According to the Notice of the State Administration of Foreign Exchange on Reforming the Management Mode of Foreign Exchange Capital Settlement of Foreign Investment 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”) promulgated on March 30, 2015, coming effective on June 1, 2015 and partially abolished on December 30, 2019 and March 23, 2023, foreign-invested enterprises could settle their foreign exchange capital on a discretionary basis according to the actual needs of their business operations. Whilst, foreign-invested enterprises are prohibited to use the foreign exchange capital settled in RMB (a) for any expenditures beyond the business scope of the foreign-invested enterprises or forbidden by laws and regulations; (b) for direct or indirect securities investment; (c) to provide entrusted loans (unless permitted in the business scope), repay loans between enterprises (including advances by third parties) or repay RMB bank loans that have been on-lent to a third party; and (d) to purchase real estates not for self-use purposes (save for real estate enterprises).

On June 9, 2016, SAFE issued the Notice of 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 came into effect on the same day and partially amended on December 4, 2023. The SAFE Circular 16 provides that discretionary foreign exchange settlement applies to foreign exchange capital, foreign debt offering proceeds and remitted foreign listing proceeds, and the corresponding RMB capital converted from foreign exchange may be used to extend loans to related parties or repay inter-company loans (including advances by third parties).

According to the Notice of the State Administration of Foreign Exchange on Further Facilitating Cross-Board 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》), which promulgated by SAFE on October 23, 2019 and became effective on the same date (except for Article 8.2, which became effective on January 1, 2020) and the Notice of the State Administration of Foreign Exchange on Further Deepening Reform and Promoting Cross-border Trade and Investment Facilitation (《國家外匯管理局關於進一步深化改革促進跨境貿易投資便利化的通知》), which promulgated by SAFE on December 4, 2023 and became effective on the same date, the restrictions on domestic equity investments made with capital funds by non-investing foreign-funded enterprises have been canceled. In addition, restrictions on the use of funds for foreign exchange settlement of domestic accounts for the realization of assets have been removed and restrictions on the use and foreign exchange settlement of foreign investors’ security deposits have been relaxed. Eligible enterprises in the pilot area are also allowed to use revenues under capital accounts, such as capital funds, foreign debts and overseas listing revenues for domestic payments without providing materials to the bank in advance for authenticity verification on an item by item basis, while the use of funds should be true, in compliance with applicable rules and conforming to the current capital revenue management regulations.

REGULATORY OVERVIEW

REGULATIONS RELATING TO TAXATION

Enterprise Income Tax (“EIT”)

Pursuant to the Enterprise Income Tax Law (the “EIT”, 《中華人民共和國企業所得稅法》) amended by the SCNPC and coming into effect on December 29, 2018 and the Implementation Rules of the EIT Law (《中華人民共和國企業所得稅法實施條例》) amended by the State Council on December 6, 2024 and coming into effect on January 20, 2025, a domestic enterprise which is established within the PRC in accordance with the laws or established in accordance with any laws of foreign countries (regions) but with an actual management entity within the PRC shall be regarded as a resident enterprise. A resident enterprise shall be subject to an EIT of 25% of any income generated within or outside the PRC. A preferential EIT rate shall be applicable to any key industry or project which is supported or encouraged by the State. High and new technology enterprises which are supported by the State may enjoy a reduced EIT rate of 15%.

The PRC and the government of Hong Kong entered into the Arrangement between the Mainland of the PRC and Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (《內地和香港特別行政區關於對所得稅避免雙重徵稅和防止偷漏稅的安排》) (the “Arrangement”) on August 21, 2006 and came into effect on December 8, 2006. According to the Arrangement, if a Hong Kong resident company owns at least 25% equity interests in a PRC company and is the beneficial owner of the dividends paid by the PRC company, the PRC withholding tax on the dividends shall not exceed 5% of the gross amount of the dividends.

Pursuant to the Circular of the State Administration of Taxation on Relevant Issues relating to the Implementation of Dividend Clauses in Tax Agreements (《國家稅務總局關於執行稅收協定股息條款有關問題的通知》) (Guo Shui Han [2009] No. 81) which was promulgated by the State Administration of Taxation (the “SAT”) and became effective on February 20, 2009, all of the following requirements shall be satisfied before a fiscal resident of the other party to a tax agreement can be entitled to such tax agreement treatment as being taxed at a tax rate specified in the tax agreement for the dividends paid to it by a PRC resident company: (i) such a fiscal resident who obtains dividends should be a company as provided in the tax agreement; (ii) the equity interests and voting shares of the PRC resident company directly owned by such a fiscal resident reaches a specified percentage; and (iii) the equity interests of the PRC resident company directly owned by such a fiscal resident, at any time during the twelve months prior to receipt of the dividends, reach a percentage specified in the tax agreement.

According to the Announcement on Several Issues concerning the Enterprise Income Tax on Income from the Indirect Transfer of Assets by Non-Resident Enterprises (《關於非居民企業間接轉讓財產企業所得稅若干問題的公告》) (the SAT Public Notice [2015] No. 7) which was promulgated by the SAT on February 3, 2015 and came into effect on the same day), where a non-resident enterprise indirectly transfers equities and other assets of a PRC resident enterprise to avoid the EIT payment obligation by making an arrangement with no reasonable business purpose, such indirect transfer shall be redefined and recognized as a direct transfer in accordance with the provisions of the EIT Law. Where the EIT on the income from the indirect transfer of real estate or equities shall be paid in accordance with the provisions of the SAT Public Notice [2015] No. 7, the entity or individual that directly assumes the obligation to make relevant payments to the transfer or according to the provisions of the relevant laws or as agreed upon in the contract shall be the withholding agent.

REGULATORY OVERVIEW

Value-Added Tax

On December 25, 2024, the SCNPC issued the Value-Added Tax Law of the PRC (《中華人民共和國增值稅法》), or the VAT Law, which shall become effective from January 1, 2026. According to the VAT Law, any entities and individuals (including individual industrial and commercial households) that sell goods, services, intangible assets, or immovables, or import goods within the territory of the PRC are taxpayers of VAT and shall pay the VAT in accordance with the law and regulation. 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 for by the State Council, the rate of VAT for sale of goods, labor 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, 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%.

SANCTIONS LAWS AND REGULATIONS

Our International Sanctions Legal Advisers have provided the following summary of the sanctions regimes imposed by the jurisdictions below. This summary does not intend to set out the laws and regulations relating to US, the EU, the UK, the UN and Australian sanctions in their entirety.

United States

U.S. sanctions generally consist of primary and secondary sanctions. OFAC administers and enforces most U.S. sanctions programs.

U.S. primary sanctions generally prohibits U.S. persons from engaging in any transaction with or providing almost any goods or services for the benefit of the targeted country, entity or individual. U.S. law may also require a U.S. Person to “block” any assets owned, controlled or held for the benefit of a sanctioned country, entity, or individual. A “blocked” asset means no transaction may be undertaken or effected with respect to the asset, except pursuant to an authorisation or license from OFAC. U.S. primary sanctions also prohibit U.S. persons from facilitating any transaction by a foreign person where the transaction by that foreign person would be prohibited if performed by a U.S. Person or within the United States.

The U.S. has also enacted secondary sanctions targeting non-U.S. persons who are engaged in certain defined activities. Secondary sanctions grant broad discretion to the U.S. President and his delegated representatives to deny access to the U.S. economic system to non-U.S. persons who have been determined to engage in the specified transaction. The imposition of penalties under secondary sanctions legislation is a mechanism that the U.S. employs to punish and deter non-U.S. parties from certain behaviour and transactions.

United Nations

The UN can take action to maintain or restore international peace and security under Chapter VII of the UN Charter. It does this by way of resolutions passed by the UN Security Council. UN Security Council sanctions have taken a number of different forms and have measures have ranged from comprehensive economic and trade sanctions to more targeted measures such as arms embargoes, travel bans, and financial or commodity restrictions.

REGULATORY OVERVIEW

European Union

The EU has over 40 different sanctions regimes in place. All EU sanctions apply: (a) within the EU (including its airspace); (b) on board any aircraft or vessel under the jurisdiction of any EU member state; (c) to any EU national, regardless of where they are resident/located; (d) to any legal person, entity or body which is incorporated/constituted under the laws of any EU member state, irrespective of their location, including unincorporated branches, but not entities incorporated outside the EU; and (e) to any legal person, entity or body in respect of any business done in the EU.

United Kingdom

The UK now operates its own sanctions regime. UK sanctions apply: (a) within the territory and territorial waters of the UK and to all UK Persons, wherever they are in the world; (b) to all individuals and legal entities who are within or undertake activities within the UK’s territory; and/or (c) to all UK nationals and UK legal entities established under UK law, including their non-UK branches (but not separately incorporated non-UK subsidiaries), irrespective of where their activities take place.

Australia

Australia has a dual sanctions regime consisting of sanctions measures imposed by the UN, together with Australian autonomous sanctions imposed by the Australian Government as a matter of its foreign policy. Australia’s dual sanctions regime is administered by the Australian Sanctions Office, which sits within the Department of Foreign Affairs and Trade.

The Australian restrictions and prohibitions arising from the sanctions laws apply broadly to (i) any person in Australia; (ii) any Australian anywhere in the world; (iii) activities in Australia; (iv) companies incorporated overseas that are owned or controlled by Australians or persons in Australia; and/or (v) any person using an Australian flag vessel or aircraft to transport goods or transact services subject to UN sanctions.