Regulatory Framework and Main Regulatory Bodies regarding the Radiopharmaceuticals, Medical Devices and Radioactive Articles Industry in China

Regulatory Framework

As we conduct our principal business in China, we shall comply with the relevant laws and regulations of China. These laws and regulations cover areas including radiopharmaceuticals, medical devices, isotope, radioactive sources and radiation devices, recycling and reusing of radioactive articles and environmental protection. Furthermore, our business operations shall be subject to the general laws and regulations of China, such as the Securities Law, and foreign exchange, taxation and foreign investment industrial guidance policy.

As the manufacturer of radiopharmaceuticals and medical devices, we are regulated and inspected by the food and drug supervision and administration authorities at various levels in China. The competent department in charge of national defense science and technology industry under the State Council shall be in charge of the administration work concerning the radiopharmaceuticals. The competent department of environmental protection under the State Council shall be in charge of the supervisory and administrative work concerning the radiation safety and protection of radiopharmaceuticals. The Pharmaceutical Administration Law of the People's Republic of China (《中華人民共和國藥品管理法》) as amended on April 24, 2015, the Regulations for the Implementation of the Pharmaceutical Administration Law of the People's Republic of China (《藥品管理法實施條例》) as amended on February 6, 2016, Measures for the Supervision over and Administration of Pharmaceutical Production (《藥品生產監督管理辦法》) as amended on November 17, 2017 and Measures for the Administration of Radiopharmaceuticals (《放射性藥品管理辦法》) as newly amended in 2017, collectively constitute the main supervision and administration framework for manufacturing and sales of radiopharmaceuticals and medical devices in China, involving the production, marketing, registration, packaging and pricing of pharmaceuticals and other aspects.

In addition, as the manufacturer and distributor of radioactive articles, we are regulated and inspected by the environmental protection authorities at various levels and the transportation, public security and health authorities under the State Council in China. The Law of the People's Republic of China on Prevention and Control of Radioactive Pollution (《中華人民共和國放射性污染防治法》) which came into force as of October 1, 2003, the Regulation on the Administration of Transport Safety of Radioactive Articles (《放射性物品運輸安全管理條例》) which came into force as of January 1, 2010, the Regulation on the Safety and Protection of Radioisotopes and Radiation Devices (《放射性同位素與射線裝置安全和防護條例》) as newly amended on July 29, 2014, the Measures for the Administration of the Safety and Permission of Radioisotopes and Radiation Devices (《放射性同位素與射線裝置安全許可管理辦法》) as newly amended on December 12, 2017, the Measures for the Administration of the Safety and Protection of Radioisotopes and Radiation Devices (《放射性同位素與射線裝置安全和防護管理辦法》) which came into force as of May 1, 2011 and the Classification and Catalog of Radioactive Articles (for Trial Implementation) (《放射性物品分類和名錄》) jointly formulated by the Ministry of Environmental Protection (State Bureau of Nuclear Safety), the Ministry of Public Security, the Ministry of Transport, the Ministry of Railways, the Ministry of Public Health (currently referred to as the National Population and Family Planning Commission), the General Administration of Customs, the Civil Aviation Administration of China and the State Administration of Science, Technology and Industry for National Defense, collectively constitute the main supervision and administration framework for radioactive articles in China, involving the production, sale, transfer, use, recycling and disposal of radioactive articles and other aspects.

Main Regulatory Bodies

(a) State Food and Drug Administration (which has been consolidated to establish The State Administration of Market Regulation in March 2018) and (food) drug supervision and administration authorities in provinces, autonomous regions and municipalities directly under the central government are the main regulatory bodies which are responsible for regulating and supervising the drugs industry and radiopharmaceuticals industry in China.

The State Food and Drug Administration shall be in charge of drafting laws and regulations concerning the supervision and administration of food (including food additives, health food, similarly hereinafter) safety, drugs (including traditional Chinese drugs and ethnic drugs, similarly hereinafter), medical devices and cosmetics, and formulating the police plans and departmental rules. It also shall be responsible for organizing, promulgating and publishing the standards and classification management policies for drugs listed in national pharmacopeia and others and medical devices, and supervising the implementation; responsible for developing the Good Manufacture Practice (GMP) for the research, production, operation and use of drugs and medical devices and supervising the implementation; responsible for registration of drugs and medical devices and supervising the implementation; establishing the monitoring system for adverse drug reactions and medical device administration events, and carrying out monitoring and disposal work. The (food) drug supervision and administration authorities in provinces, autonomous regions and municipalities directly under the central government shall be in charge of supervision and administration of the drug production enterprises within the respective administrative areas, and daily supervision and administration of drug wholesale enterprises within the respective jurisdictions, and shall direct and supervise the lower level organs of (food) drug supervision and administration for carrying out of the work of supervision and administration on the Pharmaceutical Trade License (《藥品經營許可證》).

(b) The Ministry of Ecology and Environment shall be in charge of centralized supervision and administration of safety and protection work of radioisotopes and radiation devices in China.

The Ministry of Ecology and Environment is mainly responsible for the supervision and administration of nuclear security and radiation safety, formulating the relevant policies, plans and standards, participating in the nuclear accident emergency treatment and emergency treatment work of radiation environment accidents; responsible for the supervision and administration of nuclear facilities safety and radioactive source safety, as well as the supervision and administration of pollution prevention during the application of nuclear facilities and nuclear technologies and the development and utilization of electromagnetic radiation and radioactive mineral resources; responsible for the supervision and administration of the control of nuclear materials and the design, manufacturing, installation and non-destructive testing activities of civil nuclear safety facilities.

The competent departments of environmental protection under local People's Government at or above the county level and other relevant departments shall, according to the segregation of duties, implement the supervision and administration of safety and protection work of radioisotopes and radiation devices within the respective administrative areas. The State shall implement the classification administration of radioactive sources and radiation devices. According to the extent of potential hazard of radioactive sources and radiation devices to human health and environment, the radioactive sources can be classified into Categories I, II, III, IV and V; While, the radiation devices can be classified into Categories I, II and III.

(c) The nuclear safety regulatory department under the State Council shall be in charge of supervision and administration of nuclear and radiation safety in the transport of radioactive articles in China.

The Classification and Catalog of Radioactive Articles (《放射性物品分類和名錄》) shall be formulated by the nuclear safety regulatory department under the State Council jointly with the competent departments of public security, health, customs, transport, railways, civil aviation and nuclear industry under the State Council. The radioactive articles shall be classified into Categories I, II and III according to their characteristics and their extent of potential hazard to human health and environment. The nuclear safety regulatory department under the State Council shall conduct supervision and administration of the nuclear and radiation safety in transport of radioactive articles. The public security, transport, railways, civil aviation and other competent departments under the State Council shall, according to the segregation of duties, implement the supervision and administration of safety in the transport of radioactive articles. The competent departments of environmental protection, public security and transport under the local People's Government at or above the county level shall, in accordance with the segregation of duties, implement the supervision and administration of safety in the transport of radioactive articles within the respective administrative areas.

Laws and Regulations concerning the Manufacturing of Pharmaceuticals and Medical Devices

Drug Production License and Approval

The drugs production enterprises shall be approved and granted with the Drug Production License by the drug supervision and administration departments in provinces, autonomous regions and municipalities directly under the central government where the enterprise are located. Any enterprise without the Drug Production License is not allowed to produce drugs. In accordance with the Pharmaceutical Administration Law of the People's Republic of China (《中華人民共和國藥品管理法》) as newly amended on November 17, 2017, the drug supervision and administration departments at the provincial level shall be in charge of the issuance of the Drug Production License. The term of validity of the Drug Production License is five years and is available for renewal at least six months before the expiry of the term of validity, subject to the re-examination of the relevant departments. The relevant departments shall inspect production facilities before granting the Drug Production License and the investigation results with respect to employee wage, surrounding environment, health status, quality assurance system, management framework and facilities shall meet the required standards.

Medical Device Production License and Approval

In accordance with the Regulation on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) which came into force on June 1, 2014 and were newly amended on May 4, 2017, an enterprise engaged in the production of Class II or Class III medical devices shall file an application for the Medical Device Production License with the local food and drug administration of the province, autonomous region, or municipality directly under the Central Government, and submit the required certification materials and the registration certificate of the produced medical devices. A medical device production license shall be valid for five years, and shall be subject to inspection by the relevant institutions before the renewal.

An enterprise engaged in the production of Class I medical devices shall undergo the formalities for the recordation at the local food and drug administration at the level of a districted city, and submit the required certification materials.

GMP for Drugs

GMP is an abbreviation of Good Manufacture Practice for Pharmaceutical Products (《藥品生產質量管理規範》) and represents the pharmaceutical production management and quality control standards, covering the drug quality control, organization and personnel qualifications, personnel hygiene rules, plant and equipment, inspection of materials and products, file management, production management, entrusted production, entrusted inspection, product distribution and recall and other aspects. In accordance with Good Manufacture Practice for Pharmaceutical Products (GMP) newly amended on March 13, 2017, an enterprise must held GMP certificate for the production of each category of drugs. A pharmaceutical operation enterprise shall meet the GSP requirements within the time limit stipulated by the pharmaceutical supervision and administration departments, and obtain the relevant certificate through certification. A newly established pharmaceutical production enterprise or an enterprise enlarging its business scope shall apply for certification. A pharmaceutical production enterprise rebuilding or expanding its existing plant or production lines shall reapply for GMP certificate. The GMP certificate shall be available for renewal at least six months before the expiry of its term of validity. A newly established pharmaceutical production enterprise shall apply for re-examination of its GMP certificate within three months before expiry, and after passing re-examination procedures, shall be granted with a new GMP certificate with a term of validity of five years.

GMP for Medical Devices

In accordance with the Regulation on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) which took effective as of June 1, 2014 and were newly amended on May 4, 2017, the manufacturing enterprises of medical devices shall, depending on their own characteristics of production, set up the quality control system and ensure its effective operation in line with the GMP requirements.

In Vitro Diagnosis Reagents Registration Administration

In Vitro Diagnosis Reagents Registration Administrative Measures (《體外診斷試劑註冊管理辦法》) became into effect in October 2014 and newly amended in January 2017. In vitro diagnosis reagents registration procedures are as follows: the Food and Drug Administration Authorities carry out the systematical assessment regarding to the safety, effectiveness research and its results of the in vitro diagnosis to be launched commercially based on the applications of the registered applicants in accordance with the legal procedures, in order to determine whether approve the application or not. The registered applicants and the filing parties of the in vitro diagnosis shall establish quality management system relating to the R&D and production of the products and ensure its effective operations.

In vitro diagnosis Category I adopts filing management, and in vitro diagnosis Category II&III adopts registration management. For the filing of the domestic in vitro diagnosis Category I, the filing party shall submit relevant filing information to the municipal food and drug administration authorities. The domestic in vitro diagnosis Category II shall be approved by the food and drug administration authorities in provinces, autonomous regions and municipalities directly under the central government, and obtain the medical device registration certificate upon approval. The domestic in vitro diagnosis Category III shall be approved by the CFDA and obtain the medical device registration certificate upon approval.

Special Laws and Regulations concerning the Radioactive Drugs

Production and Operation of the Radioactive Drugs

The Measures for the Control of Radioactive Drugs (《放射性藥品管理辦法》), effective on January 13, 1989 and newly amended in 2017, stipulates that after completion of clinical study of a newly developed radioactive drug, the research unit must submit an application to the pharmaceuticals supervisory and administrative departments under the State Council for examination and approval. The latter shall consult the competent department in charge of national defense science and technology industry under the State Council before granting a New Drug License. Before a newly developed radioactive drug is put to production, the production unit or the research unit that holds a license for the production of radioactive drugs must submit an application together with a copy of New Drug License and sample to the pharmaceuticals supervisory and administrative departments under the State Council. After examination and verification, the pharmaceuticals supervisory and administrative departments under the State Council shall issue them document of approval.

Requirements for the setting up of enterprises to produce or sell radioactive drugs are that they must have the necessary conditions as stipulated in the Pharmaceutical Administration Law and that they must meet the essential standards of radioisotope safety and protection set by the State, and they are also required to fulfill the formalities for examination and approval of environmental impact assessment report. For enterprises engaged in production of radioactive drugs, after the examination and approval by both the competent department in charge of national defense science and technology industry under the State Council and the pharmaceuticals supervisory and administrative departments under the State Council, the pharmaceuticals supervisory and administrative departments in their province, autonomous region or municipality directly under the Central Government shall issue them "License for the Production Enterprise of Radioactive Drugs"; for enterprises engaged in operation of radioactive drugs, after the examination of the pharmaceuticals supervisory and administrative departments under the State Council and seeking advice from and approval by the competent department in charge of national defense science and technology industry under the State Council, the pharmaceuticals supervisory and administrative departments in their province, autonomous region or municipality directly under the Central Government shall issue them "License for the Business Enterprise of Radioactive Drugs". No enterprises without the license shall be permitted to engage in the production or sale of radioactive drugs.

The term of validity of "License for the Production Enterprise of Radioactive Drugs" and "License for the Business Enterprise of Radioactive Drugs" is five years. The enterprises engaged in the production or sale of radioactive drugs shall make a new application six months before the expiry to the pharmaceuticals supervisory and administrative departments.

Sale and Use of the Radioactive Drugs

In accordance with the Measures for the Control of Radioactive Drugs (《放射性藥品管理辦法》), when ordering these articles, the production unit of radioactive drugs must furnish a License for the Production Enterprise of Radioactive Drugs, while the business unit must present a License for the Business Enterprise of Radioactive Drugs issued by the drug supervision administrative departments at the provincial, autonomous regional or municipal (directly under the Central Government) level. As for the medical unit, they must order these drugs with a License for the Use of Radioactive Drugs issued by drug supervision administrative at the provincial, autonomous regional or the municipal (directly under the Central Government) level.

When a medical unit uses radioactive drugs, it must observe the rules formulated by the State concerning the safety and protection of radioisotope. The drug supervision administrative departments at provincial, autonomous regional or municipal (directly under the Central Government) level shall issue a certain grade of License for the Use of Radioactive Drugs according to technical skill and professional level of the radiological personnel and equipment of the medical unit. No medical unit without a license is allowed to use radioactive drugs clinically.

According to Measures for the Supervision and Administration of Circulation of Drugs (《藥品流通監督管理辦法》) which came into effect on May 1, 2017, an enterprise engaged in drug production and operation shall provide its sales personnel with the drug related laws, regulations and professional knowledge training, and establish training records in which the time, place and content of the training and personnel participated in the training shall be recorded. An enterprise engaged in drug production and operation shall or should be aware of the fact that other parties are engaged in drug production and operation without the appropriate license, and shall not provide them with drugs.

Laws and Regulations concerning the Recall Responsibility of Drugs and Medical Devices

Recall Responsibility of Drugs

In accordance with the Measures for the Administration of Drug Recalls (《藥品召回管理辦法》) which came into force as of December 10, 2007, the drug manufacturers shall gather information about the safety of drug, investigate and evaluate drugs with probable hidden safety problems and then recall drugs with hidden safety problems.

Recall Responsibility of Medical Devices

In accordance with the Measures for the Administration of Medical Device Recalls (《醫療器械召回管理辦法》) which will take effect on May 1, 2017, a medical device manufacturer shall establish and improve its medical device recall system, collect information about the safety of medical devices, investigate and evaluate the potential defective medical devices, and issue a timely recall on the defective medical devices in accordance with the provisions of the Measures. According to the severity of medical device defects, the recalls are divided into:

(1) Class I Recall: The use of the medical device is very likely to cause a severe health hazard;

(2) Class II Recall: The use of the medical device may cause or has caused a temporary or irreversible health hazard;

(3) Class III Recall: The use of the medical device is not very likely to cause adverse health consequences, but it is still necessary to recall the device.

The medical device manufacturer shall determine recall classification according to the specific circumstances, and design and implement an appropriate recall plan based on the recall classification and the sale and use of medical device.

Monitoring of the Adverse Events of Medical Devices

In accordance with the Measures for the Administration of Monitoring and Revaluation of Medical Devices Adverse Events (for Trial Implementation) (《醫療器械不良事件監測和再評價管理辦法（試行）》) which came into force as of December 29, 2008, a medical device production and operation enterprise and a medical device use unit shall establish the medical device adverse event

monitoring system, designate the institution and arrange the dedicated personnel to conduct the monitoring work of adverse events of medical devices within the unit. A medical device production and operation enterprise and a medical device use unit shall establish and keep the monitoring records of adverse events of medical devices. The records shall be kept for two years subsequent to the marked term of validity of the medical device, but the term of records retention shall be not less than five years. A medical device production and operation enterprise shall report any medical device adverse events revolving the products it manufactured or operated which caused or may cause serious injury or death. A medical device use unit shall report any medical device adverse events revolving the medical devices it used which caused or may cause serious injury or death. The report of medical device adverse events shall be on a "when in doubt-report" basis.

The Regulatory System concerning the Centralized Procurement and Sales of Drugs and Medical Devices

Centralized Drug Bidding System for the Public Medical Institutions

The Guiding Opinions on the Reform of the Urban Medical and Health Care System (《關於城鎮醫藥衛生體制改革的指導意見》), implemented from February 21, 2000, aims to regulate the drug procurement activities of medical institutions. The centralized drug bidding procurement pilot shall be conducted in accordance with the Bidding Law of the People's Republic of China. The medical institution as the behavioral agent of bidding procurement can entrust bidding agency for the execution of bidding procurement, and the tenderee who has the capacity to formulate bid-invitation documents and organize bid evaluations may organize bidding procurement on its own initiative. There shall not be any relationship of subordination or other interest between the bidding agency, as recognized by the drug supervision and administration department in conjunction with the Ministry of Public Health, and the administrative departments. The centralized bidding procurement activities shall stick to the principles of openness and fairness.

In accordance with the Provisions on Centralized Drug Bidding Procurement Pilot of Medical Instructions (《醫療機構藥品集中招標採購試點工作若干規定》), implemented from July 7, 2000, and Notice concerning the Further Improvement of Centralized Drug Bidding Procurement Work in Medical Instructions (《關於進一步做好醫療機構藥品集中招標採購工作的通知》), implemented from August 8, 2001, the non-profiting medical institutions organized by the People's Government at or above county level must conduct centralized drug bidding procurement activities. For medical institution which independently organize the activities of centralized drug bidding procurement, its qualification of formulating bid-invitation documents and organizing bid evaluations shall be recognized and approved by the health administrative departments at or above the district level. The medical institutions at county level shall participate in the centralized drug bidding procurement activities organized by the relevant departments at the provincial or district level. The Guiding Opinions of the General Office of the State Council on Improving Centralized Drug Bidding Procurement Work in Medical Instructions (《國務院辦公廳關於完善公立醫院藥品集中採購工作的指導意見》), implemented from February 9, 2015, has further clarified the direction of online centralized drug procurement activities with a province (district, municipality) as a unit, and implemented the policies of "one platform, upper and lower linkage, open and transparent, procurement based on classification", and adopted the measures of "production enterprises participated in the bidding, combination of bidding and procurement, quantity-based pricing, double-envelope system and whole-process monitoring", so as to strengthen comprehensive regulation of the whole drug procurement process and ensure the quality and supply of drugs, and further improves the double-envelope evaluation method. The drug bidding enterprises must prepare both the economic and technical bidding document and the commercial bidding document.

Drug Pricing Control

In accordance with the Notice concerning the Improvement of the Pricing Administration of Low-cost Drugs (《關於改進低價藥品價格管理有關問題的通知》), implemented from April 26, 2014, setting the highest retail price of low-cost drugs by the government shall be canceled, and the pricing mode shall be changed to independently pricing by an enterprise within the average daily cost standard, and an enterprise shall set up the low-cost drugs list entry and exit mechanism. The local drug price control departments shall conduct the monitoring of production cost and actual sales price of low-cost drugs, and especially focus on the monitoring of exclusively produced drugs or monopolistic drugs.

In accordance with the Opinions on Promoting the Drug Pricing Reform (《推進藥品價格改革的意見》), implemented from June 1, 2015, save for the narcotic drugs and the psychotropic drugs of category I, the drug price originally set by the government shall be canceled since June 1, 2015. While, the National Development and Reform Commission shall still temporarily implement the highest ex-factory price and highest retail price management for the narcotic drugs and the psychotropic drugs of category I. After the cancelation of pricing control, the drug price is mainly dependent on the market competition. The government shall strength the regulation of medical institutions through establishing the centralized procurement system and medical insurance reimbursement standards.

Two-invoice System

In accordance with the Major Tasks in Deepening the Medical and Health System Reform in 2016 (《深化醫藥衛生體制改革2016年重點工作任務》) promulgated by the State Council on April 21, 2016, we shall comprehensively establish and implement the two-invoice system, i.e. the information traceability mechanism for drug ex-factory price which means issuing an invoice from drug production enterprise to circulation enterprise and issuing an invoice from circulation enterprise to medical institution, with a view to reducing the intermediate links of drug circulation and making the price more transparent.

The Opinions on the Implementation of a Two-invoice System in Public Medical Institutions' Drug Procurement (for Trial Implementation) (《關於在公立醫療機構藥品採購中推行"兩票制"的實施意見（試行）》), implemented from December 26, 2016, has further clarified that a wholly owned or holding commercial company only engaged in the sale of drugs of its own enterprise (group) (only one commercial company across the country), and a domestic general agency for foreign drugs (only one general agency across the country) established by a drug production enterprise or a group enterprise undertaking integrated operation of science, industry and trade shall be regarded as a production enterprise. Drug allocation to its wholly owned (holding) subsidiaries by a drug circulation group enterprise or drug allocation among the wholly owned (holding) subsidiaries shall not be deemed as one invoice, but allowed to issue one invoice at most. The public medical institutions shall constantly implement the "two-invoice system" and other medical institutions are encouraged to implement the "two-invoice system" in the drug procurement activities. The pilot provinces (districts, municipalities) of comprehensive healthcare reform and the pilot cities of the public hospital reform shall take the lead in the implementation of "two-invoice system", and other regions are encouraged to implement the "two-invoice system", thereby fully implementing such system throughout the country by 2018.

The Mechanism of Commercial Bribery Records in the Field of Drug Sales

In accordance with the Provisions on the Establishment of Commercial Bribery Records in the Purchase and Sale of Drugs (《關於建立醫藥購銷領域商業賄賂不良記錄的規定》) which came into force as of March 1, 2014, when a medical and health institution enter into a procurement contract with a pharmaceutical production and operation enterprise and its agent, it shall also enter into a probity purchase and sale contract, which shall clearly state the name of designated sales representative, and stipulate that the commercial bribery behavior is banned, and if breached, the one will be included in the blacklist of commercial bribery. For a pharmaceutical production and operation enterprise and its agent included in the blacklist of commercial bribery for one time, the public medical institutions and the medical and health institutions financed by government funds in local province shall not purchase the drugs, medical devices and medical consumables from it within two years after publishing the blacklist, and the public medical institutions and the medical and health institutions financed by government funds in other regions at provincial level shall conduct score reduction for the breached enterprise in bidding and procurement evaluation within two years. For an enterprise and its agent included in the blacklist of commercial bribery for twice within five years, all public medical institutions and the medical and health institutions financed by government funds shall not purchase the drugs, medical devices and medical consumables from it within two years.

Laws and Regulations concerning the Transport of Radioactive Articles

Transport of Radioactive Articles or Drugs

In accordance with the Regulation on the Administration of Transport Safety of Radioactive Articles (《放射性物品運輸安全管理條例》) which came into force as of January 1, 2010, the units which are involved in the production, sale, use or disposal of radioactive articles may apply for the qualification of non-operational road transport of hazardous goods to the local road transport administration authorities of the People's Government at the level of a districted city according to the requirements of the Regulation of the People's Republic of China on Road Transport (《中華人民共和國道路運輸條例》). The units which are involved in the production, sale, use or disposal of radioactive articles are prohibited from posting the radioactive articles of Category I and Category II. The postage of radioactive articles of Category III must be conducted in accordance with the relevant requirements of the administration departments of postal services under the State Council.

In accordance with the Measures for the Administration of the Safety and Permission of Transport of Radioactive Articles (《放射性物品運輸安全許可管理辦法》) which came into force as of November 1, 2010, the units which independently transport radioactive articles of their own units and the operating units of radioactive wastes at the provincial, autonomous regional or municipal (directly under the Central Government) level which are engaged in the radioactive goods transportation in the process of acceptance and storage of radioactive wastes shall obtain the qualification of non-operational road transport of hazardous goods.

The Classification and Catalog of Radioactive Articles (《放射性物品分類和名錄》) jointly formulated by the Ministry of Environmental Protection (State Bureau of Nuclear Safety), the Ministry of Public Security, the Ministry of Transport, the Ministry of Railways, the Ministry of Public Health (currently referred to as the National Population and Family Planning Commission), the General Administration of Customs, the Civil Aviation Administration of China and the State Administration of

Science, Technology and Industry for National Defense requires that, the following radioactive articles shall be waived from in compliance with the transport regulatory requirements:

(a) Radioactive articles which have become a component of means of transportation;

(b) Radioactive articles which are conducted within the units and not involved in the road or railway transportation;

(c) Radioactive articles which are implanted or injected into the human body or the bodies of live animals for diagnosis or therapy purposes;

(d) Consumer goods containing weak radioactive substance which have been approved by regulatory authorities and sold to end users; natural objects and ore containing natural radionuclides, which are in the natural state or are processed not only for the purpose of the extraction of radionuclide, and are not intended for use after processing. Moreover, the specific radioactivity of such articles is not more than 10 times of the specific radioactivity limit of exempted articles;

(e) Non-radioactive solid materials with surface pollution that meet the following limits: for ß and γ generators and low toxic α generators, its level of radioactivity is less than 0.8Bq/cm2; for all other α generators, its level of radioactivity is less than 0.08Bq/cm2.

Consignment of Radioactive Articles

The consignor shall entrust the carrier with the qualifications of transport of radioactive articles to transport the radioactive articles.

When consigning the radioactive articles of Category I, the consignor shall prepare nuclear and radiation safety analysis report in connection with the transport of radioactive articles and submit the report for examination and approval by the nuclear safety regulatory department under the State Council. The nuclear and radiation safety analysis report in connection with the transport of radioactive articles of Category I shall be valid for five years. When the nuclear and radiation safety analysis report needs to be renewed at the expiry of its, the consignor shall, six months before the expiry of such report, submit a written application for renewal to the nuclear safety regulatory department under the State Council.

Transport Containers for Radioactive Article

In accordance with the Regulation on the Administration of Transport Safety of Radioactive Articles (《放射性物品運輸安全管理條例》), when transporting the radioactive articles, special transport packaging containers for radioactive articles shall be used. For the units which are involved in the production, sale, use or disposal of radioactive articles of Category I, an entity using transport containers for radioactive articles of Category I shall also conduct safety performance evaluation once every two years on the transport containers for radioactive articles of Category I used by it, and file the evaluation results with the nuclear safety regulatory department under the State Council for archival purpose.

Laws and Regulations concerning Isotope, Radioactive Sources and Radioactive Radiation Devices

Warning Signs of Radioactive Substances

The Measures for the Control of Radioactive Drugs (《放射性藥品管理辦法》) stipulates that the radioactive drugs must bear the prescribed mark.

In accordance with the Law of the People's Republic of China on Prevention and Control of Radioactive Pollution (《放射性污染防治法》) which came into force as of October 1, 2003, the obvious radioactivity identification and the warning statements in Chinese shall be set for the radioactive substance and radiation devices. At a place where radioactive substance and radiation devices are produced, sold, used, stored or disposed, and on the means of transportation of radioactive substance and radiation devices containing any radioactive source, an obvious radioactivity mark shall be set.

The Regulation on the Safety and Protection of Radioisotopes and Radiation Devices (《放射性同位素與射線裝置安全和防護條例》), which came into force as of December 1, 2005, stipulates that, an obvious radioactivity mark shall be set for a place where radioisotope and radiation devices are produced, sold, used and stored in accordance with the relevant national regulations, and the safety and protective facilities and necessary protective safety interlock system, alarm device or work signal shall be set for its entrance in accordance with the requirements of the relevant national safety and protection standard. The security measures for prevention of mis-operation and prevention of accidental exposure to radiation of workers and the public shall be adopted for a place for production reconditioning and use of radiation devices. The obvious radioactivity identification and the warning statements in Chinese shall be set for the packaging containers for radioisotope and the equipment and radiation devices containing radioisotope; the radioactivity identification shall also be set for radioactive sources if available. An obvious radioactivity mark or danger signal shall be set for the means of transportation of radioisotope and radiation devices containing any radioactive source in accordance with the relevant national regulations.

Radiation Safety Permit

The Law of the People's Republic of China on Prevention and Control of Radioactive Pollution (《放射性污染防治法》) stipulates that, an entity producing, selling or using radioisotope and radiation devices shall, in accordance with the relevant provisions of the State Council on prevention of radioactivity from the radioisotope and radiation devices, apply to obtain a permit and go through the registration procedures accordingly. An entity transferring or importing radioisotope and radiation devices or an entity equipped with radioisotope instruments shall go through the relevant formalities in accordance with the relevant provisions of the State Council on prevention of radioactivity from the radioisotope and radiation devices.

The Regulation on the Safety and Protection of Radioisotopes and Radiation Devices (《放射性同位素與射線裝置安全和防護條例》) stipulates that, a permit shall be valid for five years. If the term of validity of a permit needs to be renewed at the expiry of it, the entity holding the permit shall, 30 days prior to the expiry of the term of validity of such permit, submit an application for renewal to the original permit-issuing authority.

The Measures for the Administration of the Safety and Permission of Radioisotopes and Radiation Devices (《放射性同位素與射線裝置安全許可管理辦法》), newly amended on December 12, 2017, stipulates that, before the application for a permit, the radiation work unit shall organize the formulation of or fill in environmental impact assessment (EIA) documents, and in accordance with the procedures prescribed by the State, submit the EIA documents to the competent department of environmental protection for approval. The environmental impact report or environmental impact statement described in the EIA documents shall be prepared by the institutions with corresponding qualification of environmental impact evaluation. A unit shall implement classification management for the EIA documents according to the requirements of the safety and protection of radioisotopes and

radiation devices and the extent of impact to the environment. The preparation of the EIA documents is not required for activities of transfer of radioisotopes and radiation devices.

Transfer of Radioactive Sources

The Regulation on the Safety and Protection of Radioisotopes and Radiation Devices (《放射性同位素與射線裝置安全和防護條例》) stipulates that, an entity producing radioisotopes shall maintain an account book of radioisotope products, and in accordance with the coding rules of the competent department of environmental protection under the State Council, uniformly code its produced radioactive sources. The account book of radioisotope products and the coding list of radioactive sources shall be filed with the competent department of environmental protection under the State Council. The produced radioactive sources shall have clear labels and necessary descriptive documents. In particular, the labels of Class I, Class II and Class III radioactive sources shall be engraved on the bodies or the sealed shells of radioactive sources, and the labels of Class IV and Class V radioactive sources shall be recorded in the corresponding descriptive documents. The competent department of environmental protection under the State Council shall be responsible for establishing a radioisotope filing information management system to share information with the relevant departments. The radioisotopes not included in the product account book and uncoded radioactive sources shall not leave factory and be sold.

Recycling of Radioactive Sources

The Law of the People's Republic of China on Prevention and Control of Radioactive Pollution (《放射性污染防治法》) stipulates that, an entity producing or using radioisotope or radiation devices shall, in accordance with the provisions of the competent administrative department of environmental protection under the State Council, collect, pack and store the radioactive wastes it generates. An entity producing radioactive sources shall, in accordance with the provisions of the competent administrative department of environmental protection under the State Council, recycle and utilize waste radioactive sources.

The Regulation on the Safety and Protection of Radioisotopes and Radiation Devices (《放射性同位素與射線裝置安全和防護條例》), which came into force as of December 1, 2005, stipulates that, if an entity engaged in the production or import of radioactive sources sell the radioactive sources of Class I, Class II and Class III to any other entity for use, such entity shall enter into a waste radioactive sources recycling agreement with the entity using them.

Emission and Safety Management of Radioactive Wastes

The Law of the People's Republic of China on Prevention and Control of Radioactive Pollution (《放射性污染防治法》) stipulates that, an entity generating radioactive waste liquid must, in accordance with the requirements of the national standards on the prevention and control of radioactive pollution, dispose or store the radioactive waste liquid which shall not be discharged to the environment. An entity generating radioactive solid wastes shall, in accordance with the provisions of the competent administrative department of environmental protection under the State Council, deliver the radioactive solid wastes it generates to the entity disposing the radioactive solid wastes for disposition after having them treated, and shall assume the disposition expense.

In accordance with the Regulations on the Safety Management of Radioactive Waste (《放射性廢物安全管理條例》) which came into effect on Mach 1, 2012, China adopts the classified

management of radioactive waste. According to the characteristics and the potential hazardous exposure of the human health and environment, radioactive wastes are divided into high-level radioactive waste, medium-level radioactive waste and low-level radioactive waste. Entities of utilization of nuclear technology shall conduct relevant treatment procedures of the liquid radioactive waste (which was generated but couldn't be discharged after purifications), and then transformed to solid radioactive waste. Entities of utilization of nuclear technology shall deliver disused radioactive sources and other solid radioactive wastes generated by them to any qualified entity for centralized storage, or to a solid radioactive waste disposing entity possessing the applicable licenses for disposal.

DESCRIPTION OF SANCTIONS LAWS

United States

The Office of Foreign Assets Control ("**OFAC**") of the US Department of the Treasury is responsible for the administration of a variety of statutes, Executive Orders, and their respective regulations imposing economic sanctions to further the foreign policy and national security objectives of the United States. OFAC works with various federal and state regulatory agencies, as well as foreign governments, to pursue compliance. Generally, US economic sanctions seek to deprive targets of the use of their assets and/or to deny them the benefits of trade and commerce with the United States. UN sanctions are implemented in the United States under the United Nations Participation Act ("**UNPA**").

OFAC programs generally apply globally to "**US Persons**" defined as: (a) US citizens and permanent residents, wherever located; (b) persons within the United States; and (c) entities organized under US law, including foreign branches. The Iran and Cuba sanctions programs also apply to non-US entities that are owned or controlled by US persons. Depending on the facts of the particular transaction, other relevant statutes or legal theories may broaden the jurisdictional reach of OFAC sanctions. Non-US persons also have compliance obligations under OFAC sanctions programs to the extent that they involve US persons, the US financial system, or US-origin goods in transactions involving US Sanctioned Countries or Sanctions Targets.

OFAC's comprehensive jurisdiction-based sanctions programs generally prohibit US Persons from directly or indirectly engaging in or facilitating any transactions that directly or indirectly involve: (i) Sanctioned Countries (ii) governments of Sanctioned Countries, (iii) individuals or entities on an OFAC sanctions list such as the Specially Designated Nationals and Blocked Persons List (the "**SDN List**") other than the entities on OFAC Sectoral Sanctions Identification List (the "**SSI List**").

OFAC also imposes limited jurisdiction-based sanctions on certain companies in specified sectors of the Russian economy. These entities are included in the SSI List. The Russian sectoral sanctions do not impose comprehensive restrictions or blocking requirements on transactions involving the designated companies, but rather only restrict certain specified dealings by US persons or involving the US financial system with these companies, as well as any companies owned 50% or more by them.

The US also imposes extraterritorial sanctions against Iran (and to a lesser extent against Syria and North Korea) under a number of different statutes, executive orders, and regulations that seek to deter non-US persons from engaging in a range of Iran-related activity. The State Department has primary authority for designating (i.e., targeting) non-US individuals and corporations under these sanctions (with the exception of non-US financial institutions, over which OFAC has primary designation authority). These extraterritorial sanctions differ from the other jurisdiction-based OFAC sanctions because they do not impose compliance requirements under the authority of US criminal or

administrative law. In general, US law enforcement jurisdiction does not extend to the type of entirely non-US conduct by non-US persons that the extraterritorial sanctions measures seek to deter. Thus, a non-US person does not violate US law, in any traditional legal sense, by engaging in non-US conduct proscribed by US extraterritorial sanctions measures. Rather, such conduct exposes the non-US person to potential US retaliation, through a range of potential sanctions measures intended to restrict US market access.

In broad general terms, US law authorizes US extraterritorial sanctions measures against Iran in connection with activity related to Iran's energy, petrochemical, automotive, shipping, shipbuilding, port operating, and financial sectors, as well as any activity involving OFAC-listed Iranian SDNs, persons on the United Nations Consolidated List, agents and affiliates of the Islamic Revolutionary Guard Corps, and activity related to weapons of mass destruction proliferation or terrorism. In addition, OFAC has authority to impose sanctions on non-US persons that engage in or facilitate violations of human rights in Iran or conduct deceptive transactions that seek to evade international sanctions against Iran. Under the Joint Comprehensive Plan of Action (the "**JCPOA**"), OFAC has suspended all of the nuclear-related secondary sanctions against Iran, including sanctions targeting Iran's energy, petrochemical, automotive, shipping, shipbuilding, port operating and financial sectors. However, non-nuclear related secondary sanctions targeting Iranian SDNs designated under OFAC's terrorism, ballistic missile proliferation, and human rights-related sanctions programs remain in place. Among other things, the remaining US extraterritorial sanctions against Iran authorize the President to impose sanctions on any non-US entity that knowingly materially assists, sponsors, or provides support for, or goods or services in support of, the Iran's Revolutionary Guard Corps or any of its officials, agents, or affiliates whose property and interests in property are blocked or any non-US entity that engages in significant transactions with IRGC or any of its officials, agents or affiliates. We refer to the activities that create designation risk under US extraterritorial sanctions as "**Sanctionable Activity.**" The impact of a designation can vary depending on the measures authorized and actions taken under the applicable sanctions, but in extreme cases could include an SDN designation blocking the assets not only of the designated person but any entities owned 50 percent or more by the designated person.

On August 2, 2017, the US enacted the Countering America's Adversaries Through Sanctions Act ("**CAATSA**"). In relation to Russia, CAATSA: (i) codifies existing US sanctions against Russia, (ii) modifies the sectoral sanctions to reduce the maximum permissible maturity of new debt that can be extended to certain SSI List entities, (iii) expands the scope of the sectoral sanctions targeting Russian deepwater, Arctic, or shale projects that have the potential to produce oil to also cover projects outside Russian territory if the project is owned by a Directive 4 SSI List entity or such an entity has a 33% or greater non-controlling interest, and (iv) introduces new secondary (*i.e.*, extraterritorial) sanctions targeting certain activity in Russia by non-US persons such as investing in Russian energy export pipelines or in the privatization of Russia state-owned assets in a manner that unjustly benefits Russian government officials or their family members. Although the new secondary sanctions are referred to as "mandatory," in fact, the imposition of the sanctions by the President is discretionary and the President does not have to impose the sanctions if he makes a written determination that the waiver of the mandatory sanctions is in the vital national security interests of the United States.

CAATSA also targets Iran's ballistic missile development program, but does not change the nuclear-related secondary sanctions that were lifted under the JCPOA. Lastly, CAATSA increases the list of activities that can trigger "mandatory" secondary sanctions. For Iran, these include: (i) engaging in activity contributing to Iran's ballistic missile or WMD programs and (ii) engaging in activities contributing to the supply or military materials or related technical advice to Iran.

For North Korea, the additional activities triggering "mandatory" secondary sanctions include: (i) acquiring from North Korea of certain valuable metals or minerals, (ii) providing aviation or jet fuel to North Korea, (iii) providing support involving the operations of designated vessels or aircraft, (iv) facilitating the registration or insurance of vessels controlled by the North Korean government, (v) maintaining correspondent accounts with North Korean financial institutions, and (vi) employing North Korean laborers.

European Union

The EU also imposes economic sanctions in relation to certain countries including, but not limited to, Egypt, Iran, Iraq, Libya, Russia, Sudan, Tunisia and Yemen. EU sanctions apply: (i) within the territory of the EU, including its airspace; (ii) on board any aircraft or any vessel under the jurisdiction of an EU Member State; (iii) to any person inside or outside the territory of the EU who is a national of a Member State; (iv) to any legal person, entity or body, inside or outside the territory of the EU, which is incorporated or constituted under the law of a Member State; and (v) to any legal person, entity or body in respect of any business done in whole or in part within the EU. Persons and entities to whom EU sanctions apply are referred to hereafter as "**EU Persons**."

Under the EU's Common Foreign and Security Policy, the EU may introduce sanctions either on an autonomous basis (to implement an EU Council Decision which defines the EU's approach to a particular matter, such as the imposition of restrictions against a country or group), or to implement sanctions imposed by the UNSC uniformly across all Member States. EU sanctions are imposed through Council and Commission regulations, which are directly applicable in the 28 Member States of the EU.

Under the EU's sanctions regimes, defined activities involving countries, territories, persons, entities or bodies subject to the EU sanctions are either prohibited or require approval from a competent authority of a Member State. EU sanctions typically comprise restrictions on dealings or investment involving certain industrial or business sectors, trade in certain goods and services, embargoes on arms and related technology, asset freezes, and prohibitions on making funds or economic resources available, directly or indirectly, to or for the benefit of listed individuals and entities specifically identified by the EU sanctions. EU sanctions may also prohibit the provision of technical assistance, brokering services and/or financing or financial assistance in support of prohibited activities. EU sanctions prohibitions are generally defined by reference to both direct and indirect activity. In addition, EU sanctions generally include anti-circumvention provisions, which prohibit EU Persons from participating, knowingly and intentionally, in activities the object or effect of which is, directly or indirectly, to circumvent the EU sanctions measures.

The EU imposes sanctions in relation to all of the Sanctioned Countries with the exception of Cuba. The EU also imposes sanctions in relation to other Targeted Countries. In general, all of the EU's sanctions regimes contain at least some of the above-mentioned categories of restrictions, in particular, asset freezes, and prohibitions on making funds or economic resources available to or for the benefit of listed persons and entities.

With effect from January 16, 2016 ("**Implementation Day**"), most of the EU's nuclear-related sanctions against Iran were lifted and others were amended. EU Sanctions imposed in light of the human rights situation in Iran, support for terrorism and the Iranian ballistic missile program remain in place. Moreover, in the event of a significant non-performance by Iran of its commitments under the JCPOA, the EU could reintroduce the lifted EU Sanctions (i.e. there would be a "snapback").

EU sanctions relating to Ukraine and Russia contain some of the categories of restrictions described above, but also EU Sectoral Sanctions which include (i) restrictions on access to the capital markets for listed Russian financial institutions and military and energy companies, and defined entities associated with them; (ii) a prohibition on the provision of certain new loans or credit to listed Russian financial institutions and military and energy companies, and defined entities associated with them; (iii) restrictions on the sale, supply, transfer or export, directly or indirectly, of listed items relating to the oil industry, to Russia or for use in Russia; (iv) a prohibition on the sale, supply, transfer or export, directly or indirectly, of dual-use goods and technology, to Russia, or for use in Russia, if the items are or may be intended for military use or for a military end-user; and (v) restrictions on the provision, directly or indirectly, of certain services related to the supply of arms and military equipment to Russia or for use in Russia. There are also prohibitions on the provision of technical assistance, brokering services, financing and financial assistance in support of certain prohibited activities.

Whilst EU sanctions regulations are directly applicable in Member States, each Member State sets the penalties for breaches of EU sanctions, generally through national legislation. In some Member States, national legislation creates criminal offenses and may further elaborate on activities which will be regarded as being contrary to the EU regulations. In the UK, for example, breaches of EU sanctions prohibitions will generally be criminal offenses; in addition, the circumvention of a prohibition in the EU regulations will also be a criminal offense, as will participating in activities which "enable" or "facilitate" a contravention.

In order to fully assess EU sanctions risk, it would be necessary to consider not only the terms and effect of EU sanctions regulations, but also the domestic legislation in a relevant Member State defining offenses and governing penalties for breaches of EU sanctions, as well as enforcement policy and practice in a relevant Member State. It would also be necessary to consider applicable Member State legislation which may be engaged by the particular circumstances of a transaction or activity (for example, export controls, anti-money laundering regulations etc.). Only EU sanctions regulations are discussed in this prospectus.

Australia

Australia operates a dual sanctions regime implementing the UNSC sanctions regimes under the *Charter of the United Nations Act 1945* (Cth) and regulations ("**Australian UN Sanctions**") and imposing its own autonomous sanctions as a matter of foreign policy under the *Autonomous Sanctions Act 2011* (Cth) and *Autonomous Sanctions Regulations 2011* ("**Autonomous Sanctions**"). The Autonomous Sanctions regime may operate independently to, or complement, the UNSC sanctions regime.

The Australian sanctions regimes have extraterritorial reach and apply broadly to activities in Australia, conduct by Australian citizens overseas, conduct by Australian registered bodies corporate overseas, foreign bodies corporate owned or controlled by Australian citizens and to activities (whether by Australian citizens or not) onboard Australian flagged vessels and aircraft.

The Australian sanctions regimes are administered by the Minister for Foreign Affairs who may grant a permit authorizing an activity that would otherwise contravene an Australian sanction law. It is a serious criminal offense under Australian sanction laws to contravene sanctions measures.

Australia fully implements the UNSC sanctions regime relating to Iran as well as applying the autonomous sanctions regime. The regimes prohibit or restrict, inter alia, (i) the export of specified goods, including arms, certain metals and certain software ("**export sanctioned goods**"), (ii) the provision of technical assistance, brokering services, financing and financial assistance relating to export sanctioned goods, (iii) the provision of technology related to export sanctioned goods which could contribute to the development of nuclear weapon delivery systems, (iv) the import of arms or related materials, (v) the sale or otherwise making available of an interest in a sensitive commercial activity, and (vi) the use or dealing with an asset owned or controlled by a person or entity designated by the Australian government.

Australia fully implements the UNSC sanctions regime in relation to Iraq. There is no autonomous sanctions regime for Iraq.

Australia implements an autonomous sanctions regime in relation to Russia. The autonomous sanctions regime prohibits or restricts, inter alia, (i) the supply of arms or related materiel and items suited to specified oil exploration and production projects, (ii) the provision of technical assistance, financial assistance or financing relating to military activities and arms or related materiel, (iii) the provision of investment services relating to sanctioned commercial activity, (iv) the import of arms or related material, and (v) dealing with certain financial instruments issued by Russian state-owned banks or other specified entities.

In addition to the sanctions outlined above, Australia implements (i) UN sanctions regimes for, inter alia, Sudan, North Korea and Libya, and (ii) autonomous sanctions regimes for, inter alia, North Korea, Libya, Crimea and Sevastopol, and Ukraine.

United Nations

Under Chapter VII of the UN Charter, the UNSC may impose economic sanctions through UNSC resolutions. As at the Latest Practicable Date, there were UNSC Resolutions relating to certain countries including, but not limited to: Iran, Iraq, Libya, Sudan and Yemen. UNSC Resolutions are addressed to UN Member States, who are required under the UN Charter to give effect to the provisions of the resolutions. The manner in which UNSC resolutions are given effect in a particular jurisdiction depends on the constitutional position in that jurisdiction. In some instances, national legislation is required before the requirements of a resolution will become binding on private parties in the jurisdiction. Accordingly, the means of implementation, the interpretation and the enforcement of UN sanctions may differ among UN Member States. In order to fully assess UN sanctions risk, it would be necessary to consider applicable domestic laws of any relevant UN Member State concerning the implementation and enforcement of UN sanctions.

UN sanctions may contain a range of measures. For example, UNSC resolutions typically call upon UN Member States to take measures such as: (i) freeze any funds or other financial assets or economic resources that belong to specified persons, governments, state bodies, entities, or agencies, in the country targeted by the sanctions; (ii) prevent the supply, sale or transfer of defined categories of goods or services to, or for use in or benefit of countries, territories, entities, groups or persons targeted by the sanctions; (iii) to prevent the supply, sale or transfer of arms and related materiel to the countries, territories, entities, groups or persons targeted by the sanctions.

UN Sanctions also apply to economic sanctions implemented and enforced in Hong Kong under the United Nations Sanctions Ordinance (Cap 537) (the "**UN Ordinance**") and the United

Nations (Anti-Terrorism Measures) Ordinance (Cap 575), and their subsidiary regulations (collectively, "**Hong Kong Sanctions**"). The UN Ordinance provides for the imposition of Hong Kong Sanctions arising under UN Sanctions and matters incidental to or connected with UN Sanctions, with the exception of sanctions adopted under Chapter VII of the UN Charter targeting the PRC.