
REGULATORY OVERVIEW

This section sets forth a summary of the principal Hong Kong laws and regulations governing our operations in Hong Kong and the principal PRC laws and regulations relevant to the sale of our products to or in China.

LAWS AND REGULATIONS RELATING TO OUR BUSINESS OPERATIONS IN HONG KONG

Sale of Goods Ordinance

The Sale of Goods Ordinance (Chapter 26 of the Laws of Hong Kong) provides, inter alia, that where a seller sells goods in the course of a business, there is an implied condition that (i) where the goods are purchased by description, the goods must correspond with the description; (ii) the goods supplied are of merchantable quality; and (iii) the goods must be fit for the purpose for which they are purchased. Otherwise, a buyer has the right to reject defective goods unless he or she has a reasonable opportunity to examine the goods.

Pharmacy and Poisons Ordinance and Pharmacy and Poisons Regulations

The Pharmacy and Poisons Ordinance (Chapter 138 of the Laws of Hong Kong) governs the manufacture, labeling, distribution, dispensing, supply, wholesale and retail sale, possession and import and export of pharmaceutical products or medicines in Hong Kong. Under the said ordinance, “pharmaceutical product” is defined as any substance or combination of substances (i) presented as having properties for treating or preventing disease in human beings or animals; or (ii) that may be used in, or administered to, human beings or animals, either with a view to (a) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; or (b) making a medical diagnosis.

Manufacture of pharmaceutical products

Pursuant to the Pharmacy and Poisons Regulations (Chapter 138A of the Laws of Hong Kong), a person must not manufacture any pharmaceutical product on any premises unless he is the holder of a license to manufacture pharmaceutical products on those premises, and the licensing of a manufacturer may be certified by a certificate for manufacturer issued. Furthermore, requirements as to supervision by a registered pharmacist, employment of an authorized person to certify compliance with GMP Guide, labeling, employees’ hygiene, product testing regarding identity, purity and safety, and maintenance of the premises, and record-keeping by the licensed manufacturers are set forth under the said regulations.

Registration of pharmaceutical products

Under the Pharmacy and Poisons Regulations, pharmaceutical products must be registered with the Pharmacy and Poisons Board of Hong Kong before they can be sold, offered for sale, distributed or possessed for the purposes of sale, distribution or other use in Hong Kong. Any person who engages in the sale of unregistered pharmaceutical products commits an offense and is liable on conviction to a fine of HK\$100,000 and imprisonment for two years.

Wholesale sale and supply of poisons or pharmaceutical products

According to the Pharmacy and Poisons Regulations, a person must not, by way of wholesale dealing, sell or supply at or from any premises a pharmaceutical product, or a substance or article consisting of or containing any poison, unless the person: (i) holds a wholesale dealer license; (ii) is an authorized seller of poisons; or (iii) is a licensed manufacturer selling or supplying only pharmaceutical products manufactured by the licensed manufacturer. Furthermore, licensed wholesalers and licensed manufacturers are required to sell or supply a poison only to specified persons and to keep records of transactions in poisons and pharmaceutical products.

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Import and export of pharmaceutical products

Pursuant to the Pharmacy and Poisons Ordinance, a person must not carry on business as an importer or exporter of pharmaceutical products unless the person is a licensed wholesale dealer, or the person is a licensed manufacturer, and (in the case of importation) the products are imported by the person for the purpose of manufacturing the person's own pharmaceutical products or (in the case of exportation) the products to be exported are manufactured by the person.

Distribution and retail of poisons

The Pharmacy and Poisons Ordinance prescribes that only an authorized seller of poisons can carry on a business of retail sale of poisons, provided that the actual sale of poisons is conducted on premises registered in respect of the seller by a registered pharmacist or in his presence and under his supervision. However, exemptions are provided with regard to the sale of poisons by way of wholesale dealing, including the sale of poisons to be exported by a person (where the person is a licensed wholesale dealer, or the person is a licensed manufacturer and the products to be exported are manufactured by the person) to purchasers outside Hong Kong, the sale of a substance to a registered medical practitioner, registered dentist or registered veterinary surgeon for the purpose of his profession, the sale or supply of a substance for use in or in connection with an institution, the sale of a substance by a person carrying on a business, in the course of which poisons are regularly sold to either a person who requires the substance for the purpose of his trade or business, a government department or an officer of the government requiring the substance for the purpose of the public service or a person or institution concerned with education or scientific research, if the substance is required for the purposes of that education or research. Thus, the said exemption applies to our sale of poisons by way of wholesale dealing or otherwise to retail pharmacies, drug stores, chain stores, general practitioners, private hospitals, Hospital Authority hospitals and clinics, Department of Health clinics, as well as our sale of poisons to be exported to purchasers outside Hong Kong in accordance with the said ordinance.

Chinese Medicine Ordinance and Chinese Medicines Regulation

The Chinese Medicine Ordinance makes provisions for the registration of practitioners in Chinese medicines, the licensing of traders in Chinese medicines, and the registration of proprietary Chinese medicines, as defined in the said ordinance, and other related matters. Under the said ordinance, "proprietary Chinese medicine" is defined as any proprietary product that is (i) composed solely of the following as active ingredients: (a) any Chinese herbal medicines and/or (b) any materials of herbal, animal or mineral origin customarily used by the Chinese; (ii) formulated in a finished dose form; and (iii) known or claimed to be used for the diagnosis, treatment, prevention or alleviation of any disease or any symptom of a disease in human beings, or for the regulation of the functional states of the human body. Our proprietary Chinese medicine business is subject to the regulation of the Chinese Medicine Ordinance.

Registration of proprietary Chinese medicines

According to the Chinese Medicine Ordinance, no person shall sell, import or possess any proprietary Chinese medicines unless the proprietary Chinese medicines are registered with the Chinese Medicines Board. A certificate of registration would be issued to the applicant in respect of the relevant proprietary Chinese medicines upon approval of the registration application. Any person who is found guilty of an offense under the said ordinance shall upon conviction be liable to a maximum fine of HK\$100,000 and to imprisonment for two years.

Furthermore, the particulars of a proprietary Chinese medicine, namely Chinese and English name, dose form, name and quantity of each of its active ingredient, name and quantity of each of its excipient (if any), specification, indication (if any), dosage and method of usage, each of its labels to be attached or printed on its package, package insert to be supplied for its sales inside Hong Kong, each of the package inserts to be supplied for its sales outside Hong Kong (if any), name and address of each of its

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manufacturer, and function or pharmacological action, are required by the Chinese Medicines Regulation (Chapter 549F of the Laws of Hong Kong) to be registered.

License to manufacture proprietary Chinese medicines

Pursuant to the Chinese Medicine Ordinance, no person shall manufacture any proprietary Chinese medicines, whether registered or not, without a manufacturer license issued by the Chinese Medicines Board; or at any place other than the premises specified in such license. Furthermore, manufacturers are required to comply with the licensing requirements under the Chinese Medicines Regulation.

License to trade in Chinese medicines and Chinese herbal medicines

According to the Chinese Medicine Ordinance, no person shall sell or distribute by way of wholesale, or possess for the purpose of wholesale, any proprietary Chinese medicines or Chinese herbal medicines without a wholesaler license in proprietary Chinese medicines or Chinese herbal medicines, as applicable, issued by the Chinese Medicines Board, or at any place other than the premises specified in such license. Furthermore, wholesalers of proprietary Chinese medicines and Chinese herbal medicines are required to maintain the premises in suitable condition for storage and to keep transaction records under the Chinese Medicines Regulation.

Labeling and packaging requirements

Pursuant to the Chinese Medicine Ordinance, no person shall sell or have in his possession for the purpose of selling any proprietary Chinese medicines if such proprietary Chinese medicine is without a package label or package insert in the prescribed manner in accordance with the Chinese Medicines Regulation. However, these do not apply to proprietary Chinese medicines imported by a licensed wholesaler for the purpose of re-exporting by the same wholesaler, and the case where a person is in possession of a proprietary Chinese medicine manufactured in Hong Kong for the purpose of exporting the same, according to the said regulation.

Dangerous Goods Ordinance, Dangerous Goods (Application and Exemption) Regulations, and Dangerous Goods (General) Regulations

The Dangerous Goods Ordinance (Chapter 295 of the Laws of Hong Kong) sets forth the regulation relating to “dangerous goods” and shall apply to, inter alia, all explosives, compressed gasses, petroleum and other substances giving off inflammable vapors, substances giving off poisonous gas or vapor, corrosive substances, substances which become dangerous by interaction with water or air, substances liable to spontaneous combustion or of a readily combustible nature and radioactive material.

The Dangerous Goods Ordinance prescribes that no person shall manufacture, store, convey or use any dangerous goods except under and in accordance with the license granted by the Hong Kong Fire Services Department. Notwithstanding any other liability which may arise under the provisions of such ordinance or otherwise, the breach of any term or condition endorsed upon any license issued shall constitute an offense which shall be punishable on summary conviction by a fine not exceeding \$10,000 and imprisonment not exceeding one month. If a company is found guilty of an offense under the said ordinance, the directors and officers concerned in the management of the company shall be guilty of the like offense unless he proves that the act constituting the offense took place without his knowledge or consent.

The Dangerous Goods (Application and Exemption) Regulations (Chapter 295A of the Laws of Hong Kong) set forth the classification of dangerous goods to which the Dangerous Goods Ordinance applies. In particular, alcohol, which is used in the manufacturing process of certain of our proprietary Chinese medicines, falls under category five of dangerous goods, which include, inter alia, substances giving off inflammable vapor, substances having a flash point below 23 degrees Celsius and the substance named “Ethyl Alcohol.”

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According to the Dangerous Goods (General) Regulations (Chapter 295B of the Laws of Hong Kong), no person shall store, or cause or permit to be stored, any dangerous goods in category five in any store together with goods other than dangerous goods in that category, and any dangerous goods in category five which are immiscible with water cannot be stored together with any such goods which are miscible with water. Furthermore, dangerous goods in category five should be packed, conveyed and stored in containers and comply with the requirements of the inner packing, outer packing and label for such dangerous goods. Under these regulations, any person who contravenes the regulations relevant to the conveyance and storage of dangerous goods in category five would be guilty of an offense and would be liable to a fine from HK\$1,000 to HK\$25,000, and imprisonment for one to three months.

Dangerous Drugs Ordinance and Dangerous Drugs Regulations

The Dangerous Drugs Ordinance (Chapter 134 of the Laws of Hong Kong) regulates the import, export, procurement, supply, dealing in or with, manufacture and possession of drugs or substances which are classified as dangerous drugs under the said ordinance. As our business involves the purchase and possession of raw materials, and manufacture, possession and supply of products, which are classified as dangerous drugs, we are subject to the regulation of this ordinance.

Under the Dangerous Drugs Ordinance, licenses are required for the trafficking in (including import, export, procurement, supply, or otherwise dealing in or with), manufacture and possession of dangerous drugs. A person authorized by or licensed under the said ordinance to manufacture a dangerous drug is also authorized to supply that drug, and a person authorized by or licensed under the said ordinance to supply a dangerous drug is also authorized to have that drug in his possession and to procure that drug. Dangerous drugs can only be supplied to persons authorized by or licensed under the said ordinance to be in possession of such drugs.

Furthermore, the Dangerous Drugs Regulations (Chapter 134A of the Laws of Hong Kong) regulates the labeling and record-keeping of dangerous drugs. Any person who contravenes the provisions of the said regulations shall be guilty of an offense and shall be liable on conviction to a fine of HK\$450,000 and to imprisonment for three years.

Public Health and Municipal Services Ordinance and the Regulations thereunder

The Public Health and Municipal Services Ordinance (Chapter 132 of the Laws of Hong Kong) (the “**Public Health Ordinance**”) regulates food and drugs. Under this ordinance, “food” has the same meaning as that under the Food Safety Ordinance (Chapter 612 of the Laws of Hong Kong) as further described in the section headed “— Food Safety Ordinance” below, and “drug” includes any medicine, Chinese herbal medicine or proprietary Chinese medicines for internal or external use by man. As our business involves the sales and distribution of branded healthcare products in Hong Kong, we are subject to the regulation of the Public Health Ordinance.

The Public Health Ordinance makes provision for the safety of food and drugs, and regulates the preparation and sale of adulterated food or drugs, among others. In particular, (i) no person shall add any substance to food, use any substance as an ingredient in the preparation of food, abstract any constituent from food, or subject food to any other process or treatment, so as (in any such case) to render the food injurious to health, with intent that the food shall be sold for human consumption in that state; (ii) no person shall add any substance to, or abstract any constituent from, a drug so as to affect injuriously the quality, constitution or potency of the drug, with intent that the drug shall be sold in that state; and (iii) no person shall sell for human consumption, offer, expose or advertise for sale for human consumption, or have in his possession for the purpose of such sale, any food rendered injurious to health or any drug injuriously affected in its quality, constitution or potency by any operation described above. In determining whether an article of food is injurious to health, the probable effect of that article on the health of a person consuming it as well as the probable cumulative effect of articles of substantially the same composition on the health of a person consuming such articles in ordinary quantities shall be taken into account. Any person who contravenes the said provisions commits an offense.

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Furthermore, the Public Health Ordinance prohibits false labeling and advertisement of food or drugs and provides that: (i) if any person gives with any food or drug sold by him, or displays with any food or drug exposed for sale by him, a label, whether or not the same is attached to or printed on the wrapper or container, which falsely describes the food or drug, or is calculated to mislead as to its nature, substance or quality, he shall be guilty of an offense, unless he proves that he did not know, and could not with reasonable diligence have ascertained, that the label was of such a character as aforesaid; (ii) if any person publishes, or is partly to the publication of, an advertisement, other than a label which falsely describes any food or drug, or is likely to mislead as to the nature, substance or quality of any food or drug, he shall be guilty of an offense, and, in any proceedings against the manufacturer, producer or importer of the food or drug, it shall rest on the defendant to prove (a) that he did not publish, and was not a party to the publication of, the advertisement; or (b) that he did not know, and could not with reasonable diligence have ascertained, that the advertisement was of such a character as is described in that subsection; or (c) that being a person whose business it is to publish, or arrange for the publication of, advertisements, he received the advertisement in the ordinary course of business.

According to the Public Health Ordinance, any person who is guilty of an offense under the ordinance shall be liable on summary conviction to a fine of HK\$10,000 to HK\$50,000 and to imprisonment for three to six months. Furthermore, the regulations made under the Public Health Ordinance make provision for, inter alia, sweeteners in food, metallic contamination of food, composition and labeling of food and drugs, harmful substances in food, and mineral oil in food. Any person who contravenes these said regulations shall be guilty of an offense and shall be liable on summary conviction to a fine of HK\$50,000 and to imprisonment for six months.

Food Safety Ordinance

The Food Safety Ordinance establishes a registration scheme for food importers and food distributors, to require the keeping of records by persons who acquire, capture, import or supply food and to enable food import controls to be imposed. Under this ordinance, “food” is defined to include, inter alia, drink and articles and substances used as ingredients in the preparation of food, which does not include medicine as defined under the Pharmacy and Poisons Ordinance or Chinese herbal medicine or proprietary Chinese medicines as defined under the Chinese Medicine Ordinance.

For the purpose of the Food Safety Ordinance, any food commonly used for human consumption is presumed, unless there is evidence to the contrary, to be intended for human consumption. As such, our consumable health and wellness products, such as vitamins and minerals, insofar as they do not constitute medicines or proprietary Chinese medicines for the purpose of the Pharmacy and Poisons Ordinance and the Chinese Medicine Ordinance, are likely to be considered “food” for the purpose of the Food Safety Ordinance.

Registration as food importer or distributor

The Food Safety Ordinance requires that any person who carries on a food importation business or food distribution business to register with the Food and Environmental Hygiene Department as a food importer or food distributor. Any person who does not register but carries on a food importation or distribution business, without reasonable excuse, commits an offense and is liable to a maximum fine of HK\$50,000 and imprisonment for six months.

Record-keeping requirements relating to movement of food

The Food Safety Ordinance sets forth the record-keeping requirements for local acquisition of food, acquisition of imported food, capture of local aquatic products, and wholesale supply of food. In general, a food importer or food distributor should keep the record, including details such as the date the food was acquired or imported, name and contact details of the supplier or purchaser, and total quantity of the food and description of the food, for the specified period. Any person who fails to comply with the record-keeping requirements, without reasonable excuse, commits an offense and is liable to a maximum fine of HK\$10,000 and imprisonment for three months.

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Waste Disposal Ordinance and Waste Disposal (Chemical Waste) (General) Regulation

The Waste Disposal Ordinance (Chapter 354 of the Laws of Hong Kong) provides for the control and regulation of the production, storage, collection and disposal including the treatment, reprocessing and recycling of waste of any class or description, the licensing and registration of places and persons connected with any such activity, the protection and safety of the public in relation to any such activity and to provide for matters incidental thereto.

Pursuant to the Waste Disposal Ordinance, only licensed or authorized collection service provider can provide any services for the removal and disposal of general waste. The collection and disposal of chemical waste is further regulated by the Waste Disposal (Chemical Waste) (General) Regulation (Chapter 354C of the Laws of Hong Kong) (the “**Chemical Waste Disposal Regulation**”). All of our general waste and chemical waste generated during our manufacturing process during the Track Record Period were collected by licensed waste collecting service providers listed by the Environmental Protection Department.

According to the Chemical Waste Disposal Regulation, a person shall not produce or cause to be produced chemical waste unless he is registered with the Environmental Protection Department as a chemical waste producer. A person who contravenes the requirement for registration commits an offense and is liable on conviction to a fine of HK\$200,000 and to imprisonment for six months. Furthermore, a chemical waste producer shall ensure that chemical waste is properly packed, labeled and stored before disposal and shall keep and furnish records of its chemical waste disposal information for inspection. Any waste producer who fails to comply with any of such requirements commits an offense and is liable to a maximum fine of HK\$100,000 and to imprisonment for six months.

Fire Safety (Buildings) Ordinance

The Fire Safety (Buildings) Ordinance (Chapter 572 of the Laws of Hong Kong) provides for fire safety improvements to be made to certain composite buildings and domestic buildings and to provide for related matters. The purpose of the said ordinance is to provide better protection from the risk of fire for occupants and users of, and visitors to, certain kinds of composite buildings.

As prescribed by the Fire Safety (Buildings) Ordinance, an owner or occupier of a composite building may be directed by the Buildings Department and the Fire Services Department of Hong Kong to comply with fire safety measures in relation to the planning, design and construction of a composite building, and the fire service installation or equipment. An owner or occupier who, without reasonable excuse, fails to comply with a fire safety direction is guilty of an offense and is liable on conviction to a fine of HK\$25,000 and to a further fine of HK\$2,500 for each day or part of a day during which the failure continues after the expiry of the period specified in the direction.

Fire Safety (Commercial Premises) Ordinance

The Fire Safety (Commercial Premises) Ordinance (Chapter 502 of the Laws of Hong Kong) provides better protection from the risk of fire for occupants and users of, and visitors to, certain kinds of commercial premises and commercial buildings.

Similar to the provision under the Fire Safety (Buildings) Ordinance, the owner or occupier of such a commercial building may be directed by the relevant enforcement authorities to comply with fire safety measures in relation to the planning, design and construction of the building, and fire service installation or equipment. An owner or occupier who, without reasonable excuse, fails to comply with the fire safety direction is guilty of an offense and is liable on conviction to a fine at HK\$25,000 and to a further fine of HK\$2,500 for each day or part of a day during which the failure continues after the expiry of the period specified in the direction.

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Boilers and Pressure Vessels Ordinance

The Boilers and Pressure Vessels Ordinance (Chapter 56 of the Laws of Hong Kong) controls the use and operation of boilers and pressure vessels, to provide for the holding of inquiries into accidents in or to boilers and pressure vessels and to provide for matters connected with the purposes aforesaid. Under the said ordinance, no boiler or pressure vessel may be operated until it is registered with the Boilers and Pressure Vessels Authority, and it has been examined and certified (with a certificate of fitness) or it has been granted an exemption by the Boilers and Pressure Vessels Authority. As we use and operate pressure vessels in some of our manufacturing processes, we are subject to the regulation of this ordinance.

In accordance with the Boilers and Pressure Vessels Ordinance, periodic examination of boilers and pressure vessels shall be carried out. Depending on the type of boiler or pressure vessel, after the date of any certificate of fitness issued in respect thereof, each boiler or pressure vessel should be examined by an appointed examiner within 14 or 26 months, or any shorter period as suggested by the appointed examiner and endorsed by the Boilers and Pressure Vessels Authority. Furthermore, the owner of a boiler or pressure vessel shall keep the latest certificate of fitness issued, or a copy thereof, at the premises or place at which the boiler or pressure vessel is installed. The owner of a boiler or pressure vessel who, without reasonable excuse, contravenes these requirements shall be guilty of an offense and shall be liable on summary conviction to a fine of HK\$10,000.

Radiation Ordinance and Radiation (Control of Radioactive Substances) Regulations

The Radiation Ordinance (Chapter 303 of the Laws of Hong Kong) controls, inter alia, the import, export, possession and use of radioactive substances and irradiating apparatus. As we use an x-ray inspection machine to detect foreign matter in aluminum foil sachets during our manufacturing process, we are subject to the regulation of this ordinance.

According to the Radiation Ordinance, no person shall, except under and in accordance with a license issued, deal with or have in his possession or use, any radioactive substance or irradiating apparatus. Any person who contravenes an offense under the said ordinance shall be liable to a fine of HK\$50,000 and to imprisonment for two years, and in the case of continuing offense, be liable to an additional fine of HK\$2,500 for every day during the whole or any part of which such offense is knowingly and willfully continued under the said ordinance.

Pursuant to the Radiation (Control of Radioactive Substances) Regulations (Chapter 303A of the Laws of Hong Kong), every licensee shall cause to be exhibited in a conspicuous place in the premises where the radioactive substance concerned is stored or otherwise dealt with. Any person who fails to comply with the said provision shall be guilty of an offense and be liable on conviction to a fine of HK\$6,000. The licensee shall also comply with the requirements in relation to labeling, storage, disposal of radioactive waste, control of exposure, workplace and equipment, precautions for workers, and supervision under the said regulations.

Protection of Endangered Species of Animals and Plant Ordinance

The Protection of Endangered Species of Animals and Plant Ordinance (Chapter 586 of the Laws of Hong Kong) (the “**Protection of Endangered Species Ordinance**”) regulates the import, introduction from the sea, export, re-export, and possession or control of certain endangered species of animals and plants and parts and derivatives of those species, and provides for incidental and connected matters. As we import artificially propagated *Saussurea costus* (雲木香) which is used as an ingredient for manufacturing one of our proprietary Chinese medicines, and export such proprietary Chinese medicine which contains artificially propagated *Saussurea costus*, we are subject to the regulation of the said ordinance. We are however not required to obtain a license for the possession or control of a specimen of a scheduled species as none of the *Saussurea costus* we imported during the Track Record Period were live plant.

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According to the Protection of Endangered Species Ordinance, a person may obtain a license for the import, export or re-export of a specimen of a scheduled species from the Agriculture, Fisheries and Conservation Department. A person shall not import, export or re-export a specimen of an appendix II species (in our case, *Saussurea costus*) except, inter alia, under and in accordance with a license issued in respect of that specimen prior to the import, and a Convention certifying document showing that (i) the specimen is not a live animal or plant of wild origin, nor is it a live animal or plant that shall be treated as a specimen of an appendix II species, and (ii) the species is not of a population included in appendix I if the species is specified in both appendix I and appendix II. A “Convention certifying document” in this context means a permit, certificate or other document that is issued by a relevant authority of that place in respect of that specimen and remains in force when relied on to show compliance with the said ordinance, and that conforms to the provisions applicable to such a permit, certificate or other document as the case may be issued in respect of that specimen. A person who contravenes an offense under the said ordinance is liable on conviction to a maximum fine of HK\$50,000 and to imprisonment for six months.

Import and Export Ordinance, Import and Export (General) Regulations, and Import and Export (Registration) Regulations

The Import and Export Ordinance (Chapter 60 of the Laws of Hong Kong) regulates and controls, inter alia, the import of articles into and the export of articles from Hong Kong. As we import certain herbs which are toxic herbs in schedule 1 (namely *Aconiti Radix*, *Arisaematis Rhizoma*, *Aconiti Lateralis Radix Praeparata* and *Pinelliae Rhizoma*), dangerous drugs, poisons, non-poisons, antibiotics and controlled chemicals for the manufacturing purposes of our business, and we export our proprietary Chinese medicines and finished goods of dangerous drugs, poisons and non-poisons, we are subject to the regulation of this ordinance.

The Import and Export Ordinance stipulates that no person shall import or export any articles specified in schedule 1 to the Import and Export (General) Regulations (Chapter 60A of the Laws of Hong Kong) without a proper import or export license. The articles in the said schedule 1 include, inter alia, pharmaceutical products and medicines as defined under the Pharmacy and Poisons Ordinance, proprietary Chinese medicines as defined under the Chinese Medicine Ordinance, and certain Chinese herbal medicines, powdered formula and controlled chemicals as defined under the Hazardous Chemicals Control Ordinance (Chapter 595 of the Laws of Hong Kong). Any person who contravenes an offense under the Import and Export Ordinance in respect of pharmaceutical products, medicines, and proprietary Chinese medicines shall be liable on conviction to a fine of HK\$500,000 and to imprisonment for two years.

As dictated by the Import and Export (Registration) Regulations (Chapter 60E of the Laws of Hong Kong), every person who imports or exports any article other than an exempted article shall lodge with the Hong Kong Customs and Excise Department an accurate and complete import or export declaration. Any person who fails or neglects, without reasonable excuse, to lodge the required declaration within 14 days shall be guilty of an offense and shall be liable on summary conviction to a fine of HK\$1,000, and, commencing on the day following the date of conviction, to a fine of HK\$100 in respect of every day during which his failure or neglect to lodge such declaration in that manner continues. Furthermore, any person who knowingly or recklessly lodges any declaration that is inaccurate in any material particular shall be guilty of an offense and shall be liable on summary conviction to a fine of HK\$10,000.

Control of Chemicals Ordinance and Control of Chemicals Regulations

The Control of Chemicals Ordinance controls chemicals related to the manufacture of narcotic drugs or psychotropic substances as set forth in schedules 1, 2 and 3 to this ordinance. A license is required for the import, export, supply, dealing in or with, manufacture, and possession of substance specified in the said schedules. As we import, store and use controlled chemicals for our manufacturing process, we are required to obtain the relevant licenses in accordance with the said ordinance.

Under the Control of Chemicals Regulations (Chapter 145A of the Laws of Hong Kong), a holder of the license or permit shall record the receipt and manufacture of such substances and keep or store them in premises and containers in accordance with such regulations.

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Undesirable Medical Advertisements Ordinance

The Undesirable Medical Advertisements Ordinance (Chapter 231 of the Laws of Hong Kong) aims to protect public health through restricting certain advertisements relating to medical and health matters. The labeling and advertising of certain of our products are subject to the regulation of this ordinance.

The Undesirable Medical Advertisements Ordinance prohibits the publishing of any advertisements likely to lead to the use of any medicine, surgical appliance or treatment for (i) the purpose of treating human beings for, or preventing human beings from contracting, any diseases or condition specified in column 1 in schedule 1 to the said ordinance (including, among others, parasitic diseases, diseases of the heart or cardiovascular system, gastro-intestinal diseases, diseases of the nervous system, diseases of the blood or lymphatic system, diseases of the musculo-skeletal system, diseases of the skin, hair or scalp, and viral, bacterial, fungal or other infectious diseases); or (ii) treating human beings for any purpose specified in schedule 2 to the said ordinance (including (a) the induction of menstruation or relief of amenorrhea or delayed menstruation or any other gynecological or obstetrical disease; (b) the promotion of sexual virility, desire or fertility, or the restoration of lost youth; and (c) the correction of deformity or the surgical alteration of a person's appearance).

According to the Undesirable Medical Advertisements Ordinance, "advertisement" includes any notice, poster, circular, label, wrapper or document, and any announcement made orally or by any means of producing or transmitting light or sound, published in newspapers and magazines, leaflets, on radio, television, and internet, as well as on the label of a container or package containing any medicine, surgical appliance, treatment, or orally consumed product. However, the supply, inside any container or package containing any medicine, surgical appliance or treatment, of information relating to that or any other medicine, surgical appliance or treatment shall not constitute the publication of an advertisement.

Any person who contravenes a provision under the Undesirable Medical Advertisements Ordinance shall be guilty of an offense and shall be liable upon a first conviction to a maximum fine of HK\$50,000 and to imprisonment for six months and upon a second or subsequent conviction for an offense under the same provision to a maximum fine of HK\$100,000 and to imprisonment for one year.

Trade Descriptions Ordinance

The Trade Descriptions Ordinance (Chapter 362 of the Laws of Hong Kong) prohibits false trade description, false, misleading or incomplete information, false marks and misstatements in respect of goods provided in the course of trade or suppliers of such goods. Under the said ordinance, "trade description" in relation to goods is defined as an indication, direct or indirect, and by whatever means given, with respect to the goods or any part of the goods including an indication of the specified matters, including, inter alia, quantity, size or gage, method of manufacture, composition, fitness for purpose, availability, compliance with a standard specified or recognized by any person, price, place or date of manufacture, production, processing or reconditioning, person by whom manufactured, produced, processed or reconditioned. The labeling and advertisements in respect of our products are subject to the relevant provisions therein.

The Trade Descriptions Ordinance formulates that it is an offense to (i) in the course of any trade or business apply a false trade description to any goods, or supply or offer to supply any goods to which a false trade description is applied; or (ii) have in one's possession for sale or for any purpose of trade or manufacture any goods to which a false trade description is applied; (iii) apply a false trade description to a service supplied or offered to be supplied to a consumer; (iv) supply or offer to supply to a consumer a service to which a false trade description is applied; or (v) have the importation or exportation of any goods to which a false trade description or forged trade mark is applied. The Trade Descriptions Ordinance further prescribes that a trader who engages in relation to a consumer in a commercial practice that is (i) a misleading omission; (ii) aggressive; or (iii) constitutes (a) bait advertising, (b) a bait and switch, or (c) wrongly accepting payment for a product, commits an offense.

Any person who commits an offense under the Trade Descriptions Ordinance shall be liable, on conviction on indictment, to a fine of HK\$500,000 and to imprisonment for five years, and on summary conviction, to a maximum fine of HK\$100,000 and to imprisonment for two years.

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Trade Marks Ordinance

The Trade Marks Ordinance (Chapter 559 of the Laws of Hong Kong) provides for the registration of trade marks, the use of registered trade marks and connected matters. Under the said ordinance, “trade mark” is defined as any sign which is capable of distinguishing the goods or services of one undertaking from those of other undertakings and which is capable of being represented graphically. The registration and maintenance of trade marks for our self-manufactured own brand products, and the distribution of products under third-party trade marks are subject to the regulation of this ordinance.

The Trade Marks Ordinance provides territorial protection for trade marks. As such, trade marks registered in other countries or regions are not automatically entitled to protection in Hong Kong. In order to enjoy protection by the laws of Hong Kong, trade marks must be registered with the Trade Marks Registry of the Intellectual Property Department. Upon registration of the trade mark, the owner is conferred exclusive rights in the trade mark which are infringed by use of the trade mark in Hong Kong without his consent. In respect of any infringement of a registered trade mark, the owner is entitled to remedies under the said ordinance, including, inter alia, damages, injunctions, accounts, order for delivery up and order for disposal.

Copyright Ordinance

The Copyright Ordinance (Chapter 528 of the Laws of Hong Kong) makes provisions in respect of copyright and related rights and for connected purposes. As we create artistic and literary works in the course of business (including packaging, instruction and explanation), and import and distribute products with design works which may involve copyright belonging to another person, we are subject to the regulation of this ordinance. Under the said ordinance, an owner of the copyright in a work is conferred a series of exclusive rights, including the right to, inter alia, copy the work, issue copies of the work to the public, and make available copies of the work to the public. In addition, the Copyright Ordinance provides acts that constitute secondary infringement of the copyright in a work, including, inter alia, importing or exporting infringing copies, and possessing or dealing with infringing copies. A person would only be liable for a secondary infringement if he knows or has reasons to believe that the copy in question is an infringing copy of the copyright work. Where a copyright is infringed, the copyright owner is entitled to remedies under the said ordinance, including, inter alia, damages (and, in appropriate cases, additional damages), injunctions, accounts, orders for delivery up, and orders for disposal.

Patents Ordinance

The Patents Ordinance (Chapter 514 of the Laws of Hong Kong) makes provision for the grant, registration and use of patents and related matters. As our business involves the import or export of products that are covered by patents owned by third parties, we are subject to the regulation of this ordinance.

Pursuant to the Patents Ordinance, a patent gives the inventor an exclusive right to use his invention, including, inter alia, the right to make, put on the market, use, import or stock any product which is the subject matter of the patent. Two types of patents may be granted under this ordinance: (i) standard patents; and (ii) short-term patents. The patent registration system of Hong Kong provides territorial protection. Hence, foreign patents have to be registered in Hong Kong to be entitled to protection under such ordinance. In respect of any infringement of a granted patent, the proprietor is entitled to remedies under the said ordinance, including, inter alia, damages, injunctions, accounts, order for delivery up and order for disposal.

Business Registration

The Business Registration Ordinance (Chapter 310 of the Laws of Hong Kong) sets forth the law relating to the registration of businesses in Hong Kong. Under this ordinance, “business” is defined as any form of trade, commerce, craftsmanship, profession, calling or other activity carried on for the purpose of gain and also defined as a club.

REGULATORY OVERVIEW

Under the Business Registration Ordinance, every person carrying on any business or commencing to carry on any business shall make application to the Inland Revenue Department in the manner prescribed for the registration of that business. A business registration application shall be made within one month of the commencement of such business. In addition, any person carrying on business at a branch of business shall make application in the manner prescribed for the registration of that branch within one month of the commencement of business at the branch. The valid business registration certificate or branch registration certificate must be displayed in a conspicuous place at the address where the business is carried on and should be produced for official inspection on demand. Where business registration certificates are issued in electronic form under the one-stop company and business registration service, companies must display a printed copy of such certificates. Any person who fails to make any registration application as required under the said ordinance shall be guilty of an offense and shall be liable to a maximum fine of HK\$5,000 and to imprisonment for one year.

Competition Ordinance

The Competition Ordinance prohibits (i) making or giving effect to agreements, engaging in a concerted practices, or, in the case of associations of undertakings, making or giving effect to decisions, that have as their object or effect the prevention, restriction or distortion of competition in Hong Kong; (ii) unilateral abuses of substantial market power that are engaged in with the object or effect of the prevention, restriction or distortion of competition in Hong Kong; and (iii) mergers of telecommunications carriers that have, or are likely to have the effect of substantially lessening competition in Hong Kong. This ordinance came into effect on December 14, 2015. There will be no retrospective application of these three prohibitions. Therefore, this ordinance applies to the entry into and giving effect of agreements that we concluded after the coming into effect of the Competition Ordinance. The ordinance also applies to agreements that we entered into before the effective date of the Competition Ordinance, insofar as the parties continued to give effect to such agreements after the effective date.

Upon contravention of a competition rule by an offender, the Competition Tribunal may impose penalties including pecuniary penalty, injunctive orders, disqualification orders, costs orders, award of damages, and other orders. If a pecuniary penalty is to be imposed, the maximum amount of such pecuniary penalty imposed in relation to conduct constituting a single contravention is 10% of the turnover of the undertaking concerned for each year the contravention occurred, or, if the contravention occurred in more than three years, 10% of the turnover of the undertaking concerned for the three years in which the contravention occurred that saw the highest, second highest and third highest turnover.

Employees' Compensation Ordinance

The Employees' Compensation Ordinance (Chapter 282 of the Laws of Hong Kong) establishes a no-fault and non-contributory employee compensation system for work injuries and lays down the rights and obligations of employers and employees in respect of injuries or death caused by accidents arising out of and in the course of employment, or by prescribed occupational diseases. This ordinance applies to all full-time or part-time employees who are employed under contracts of service or apprenticeship, but does not apply to casual employees (but still applies to employees employed for the purposes of the employer's trade or business), outworkers, or members of the employer's family who live with him.

According to the Employees' Compensation Ordinance, if an employee sustains an injury or dies as a result of an accident arising out of and in the course of his employment, his employer is in general liable to pay compensation even if the employee might have committed acts of faults or negligence when the accident occurred. Similarly, an employee who suffers incapacity or dies arising from an occupational disease is entitled to receive the same compensation as that payable to employees injured in occupational accidents. We, as an employer, shall report work injuries of our employees to the Labor Department not later than 14 days after the accident, irrespective of whether the accident gives rise to any liability to pay compensation.

REGULATORY OVERVIEW

As imposed by the Employees' Compensation Ordinance, all employers are required to take out insurance policies to cover their liabilities both under such ordinance and at common law for injuries at work in respect of all their employees (including full-time and part-time employees). The minimum insurance cover is: (i) HK\$100 million per event where the number of employees in relation to whom the policy is in force does not exceed 200; and (ii) HK\$200 million per event where the number of employees in relation to whom the policy is in force exceeds 200. An employer who fails to comply with the said ordinance to secure an insurance cover commits an offense and is liable on conviction upon indictment to a fine of HK\$100,000 and imprisonment for two years and on a summary conviction to a fine of HK\$100,000 and to imprisonment for one year.

According to the Employees' Compensation Ordinance, an employer shall not, without the consent of the Labor Department, terminate, or give notice to terminate, the contract of service of an employee (who has suffered incapacity or temporary incapacity in circumstances which entitle him to compensation under such ordinance) before occurrence of certain events. Any person who commits breach of this provision is liable on conviction to a maximum fine of HK\$100,000.

Employment Ordinance

The Employment Ordinance (Chapter 57 of the Laws of Hong Kong) provides for the protection of the wages of employees, regulates general conditions of employment and employment agencies, and for matters connected therewith. Subject to limited exceptions, this ordinance applies to all employees engaged under a contract of employment, to employers of such employees and to the contract of employment between such employers and employees, and makes provision for, inter alia, payment of wages, end of year payment, rest days, holidays, and leave, sickness allowance, maternity protection and paternity leave. An employer who, without reasonable excuse, fails to comply with the relevant provisions, shall be guilty of an offense and shall be liable on conviction to a fine ranging between HK\$10,000 and HK\$350,000.

The Employment Ordinance also requires an employer to keep records of, inter alia, sickness days, annual leave, wage and employment history in relation to each employee. An employer who fails to keep such record is shall be liable on conviction to a fine of HK\$10,000.

Mandatory Provident Fund Schemes Ordinance

The Mandatory Provident Fund Schemes Ordinance (Chapter 485 of the Laws of Hong Kong) (the "**MPF Schemes Ordinance**") specifies that employers shall participate in a registered mandatory provident fund scheme for employees employed under the jurisdiction of the Employment Ordinance.

Under the MPF Schemes Ordinance, employers are required to enroll their regular, employees (full-time and part-time) and self-employed persons, except for exempt persons, who are at least 18 but under 65 years of age within the first 60 days of employment. For both employees and employers, it is mandatory to make regular contributions into a registered mandatory provident fund scheme. For an employee, subject to the maximum and minimum levels of income (HK\$25,000 and HK\$7,100 per month, respectively before June 1, 2014 or HK\$30,000 and HK\$7,100 per month, respectively on or after June 1, 2014), an employer will deduct 5% of the relevant income on behalf of an employee as mandatory contributions to a registered mandatory provident fund scheme with a ceiling of HK\$1,250 before June 1, 2014 or HK\$1,500 on or after June 1, 2014. An employer will also be required to contribute an amount equivalent to 5% of an employee's relevant income to the registered mandatory provident fund scheme, subject only to the maximum level of income (HK\$25,000 per month before June 1, 2014 or HK\$30,000 on or after June 1, 2014).

REGULATORY OVERVIEW

According to the MPF Schemes Ordinance, employers found to have evaded or delayed payment of MPF contributions, deducted employer contributions from an employee's pay, or failed to enroll their employees to a registered mandatory provident fund scheme, may be liable to a financial penalty and potential criminal prosecution.

Occupational Safety and Health Ordinance

The Occupational Safety and Health Ordinance (Chapter 509 of the Laws of Hong Kong) aims to ensure the safety and health of persons when they are at work and provides for related matter. This ordinance and its subsidiary regulations impose general duty of care on employers, occupiers of premises and employees, and formulate basic requirements in accident prevention, fire prevention, working environment, workplace hygiene, first aid, manual handling operation and use of display screen equipment.

Under the Occupational Safety and Health Ordinance, an employer is responsible to ensure the safety and health of its employees, which includes, inter alia: (i) providing or maintaining plant and systems of work that are, so far as reasonably practicable, safe and without risks to health; (ii) making arrangements for ensuring, so far as practicable, safety and absence of risks to health in connection with the use, handling, storage and transport of plant or substances; (iii) providing such information, instruction, training and supervision as may be necessary to ensure, so far as reasonably practicable, the safety and health at work of the employer's employees; (iv) maintaining the workplace in a condition that is, so far as reasonably practicable, safe and without risks to health; (v) providing or maintaining means of access to or egress from the workplace that are, so far as reasonably practicable, safe and without such risks; and (vi) providing or maintaining a working environment for its employees that is, so far as reasonably practicable, safe and without risks to health. An employer who fails to comply with the said provisions commits an offense and is liable on conviction to a fine of HK\$200,000.

LAWS AND REGULATIONS RELATING TO THE SALE OF OUR PRODUCTS TO OR IN CHINA

Import of Dietary Supplements, Pharmaceuticals and Medical Equipment via General Trading Channels

Dietary supplements

In accordance with the Administrative Measures for Dietary Supplements (《保健食品管理辦法》) promulgated by the Ministry of Health (currently known as the National Health Commission) on March 15, 1996 and effective from June 1, 1996, "dietary supplements" refer to supplements with specific healthcare functions, namely such supplements that are suitable for certain groups of people to adjust their bodily functions but not for the purpose of treating diseases.

Pursuant to the Food Safety Law of the PRC (《中華人民共和國食品安全法》) passed by the SCNPC on February 28, 2009 and last amended on December 29, 2018 and the Administrative Measures for the Registration and Recordation of Dietary Supplements (《保健食品註冊與備案管理辦法》) promulgated by China Food and Drug Administration (which has been currently consolidated as the SAMR) on February 26, 2016 and last amended on October 23, 2020, (i) dietary supplements imported for the first time (excluding those that belong to vitamin, minerals and other nutritious substances and nutritional supplements) are subject to application to the SAMR for registration; and (ii) dietary supplements that are imported for the first time and belong to vitamin, minerals and other nutritious substances and nutritional supplements are subject to application to the SAMR for recordation.

REGULATORY OVERVIEW

Pharmaceuticals

Pursuant to the Pharmaceutical Administration Law of the PRC (《中華人民共和國藥品管理法》) (the “**Pharmaceutical Administration Law**”) passed by the SCNPC on September 20, 1984 and last amended on August 26, 2019, “pharmaceutical” refers to substances used for the prevention, treatment or diagnosis of human diseases, for the purpose of regulating human physiological functions and with prescribed indications or efficacies, usages and dosage, including traditional Chinese medicines, medicinal chemicals and biological products.

According to the Pharmaceutical Administration Law and the Regulations for the Implementation of the Pharmaceutical Administration Law of the PRC (《中華人民共和國藥品管理法實施條例》) promulgated by the State Council on August 4, 2002 and amended on February 6, 2016 and March 2, 2019 respectively, any pharmaceutical import is subject to application for registration in compliance with the provisions of the NMPA. Pharmaceutical products from overseas manufacturers may be imported only upon the obtainment of the Import Drug License (《進口藥品註冊證》), while those from manufacturers in Hong Kong, Macau or Taiwan of China may be imported only upon the obtainment of the Pharmaceutical Product License (《醫藥產品註冊證》).

Medical equipment

Pursuant to the Regulations on the Supervision and Administration of Medical Equipment (《醫療器械監督管理條例》) promulgated by the State Council in 2000 and amended on February 12, 2014 and May 4, 2017 respectively, “medical equipment” refers to such instruments, apparatuses, appliances, in-vitro diagnostic reagents and calibrators, materials and other similar or related items, including necessary computer software, used directly or indirectly on the human body, with effect obtained mainly through physical means rather than pharmacological, immunological or metabolic means. Such means are employed but with a supplementary role, for the purpose of (i) diagnosis, prevention, monitoring, treatment or alleviation of diseases; (ii) diagnosis, monitoring, treatment, alleviation or function compensation of injuries; (iii) examination, replacement, regulation or support of physiological structure or process; (iv) life support or maintenance; (v) control of conception; and (vi) provision of information for medical treatment or diagnosis by means of examining samples from the human body.

In accordance with the Regulations on the Supervision and Administration of Medical Equipment, the state employs classified management of medical equipment based on the extent of risk. Class I encompasses low-risk medical equipment, with safety and effectiveness ensured through routine administration; class II covers moderate-risk medical equipment, with safety and effectiveness ensured through rigorous control and administration; and class III involves high-risk medical equipment, with their safety and limitation ensured through strict control and administration. An overseas manufacturer that exports class I medical equipment to China shall, through its representative office in China or the corporate enterprise designated in China as its agent, submit to the NMPA record filings and supportive documents for approval of the market launch of such medical equipment by the competent authorities of the country or region where the filing party is located. An overseas manufacturer that exports class II or class III medical equipment to China shall, through its representative office in China or the corporate enterprise designated in China as its agent, submit to the NMPA registration application documents and supportive documents for approval of the market launch of such medical equipment by the competent authorities of the country or region where the registration applicant is located.

With reference to the Administrative Measures for Registration of Medical Equipment (《醫療器械註冊管理辦法》) promulgated by China Food and Drug Administration (now consolidated as the SAMR) on July 30, 2014 and effective from October 1, 2014, medical equipment for sale and use in China is subject to application for registration or filing with China Food and Drug Administration in accordance with the Administrative Measures of Registration of Medical Equipment.

REGULATORY OVERVIEW

E-commerce

Under the E-Commerce Law of the PRC (《中華人民共和國電子商務法》) promulgated by the SCNPC on August 31, 2018 and effective from January 1, 2019, “e-commerce operators” refer to natural persons, legal persons and unincorporated bodies that sell commodities or provide services via information networks such as the Internet, including e-commerce platform operators, in-platform operators and those that sell commodities or provide services on self-established websites or other network services. Such business operations shall adhere to the principles of voluntariness, equality, equity and integrity and comply with the law and business ethics, in addition to fair participation in market competition, performance of obligations such as protecting consumer rights and interests, the environment, intellectual property rights, cyber security and individual information, assumption of responsibility for product and service quality, and acceptance of supervision by the government and society.

Cross-border e-commerce retail imports

Pursuant to the Notice on Improving Supervision over Cross-border E-commerce Retail Imports (《關於完善跨境電子商務零售進口監管有關工作的通知》) promulgated by MOFCOM, the National Development and Reform Commission, the Ministry of Finance, the General Administration of Customs, the SAT and the SAMR on November 28, 2018 and implemented on January 1, 2019, “cross-border e-commerce retail imports” refer to the consumption behavior in which domestic Chinese consumers purchase goods from abroad through third-party cross-border e-commerce platform operators and have such purchased goods transported into China under the “Bonded Imports via Online Shopping” (網購保稅進口) or “Imports via Direct Purchase” (直購進口). Such imported goods are products that fall within the List of Imported Goods in Cross-border E-commerce Retail (《跨境電子商務零售進口商品清單》) and are limited to personal use only and meet the conditions set forth in the taxation policies for cross-border e-commerce retail imports. Transactions via the e-commerce trading platforms connected to the customs authorities enable comparison among the documents of transactions, payments and electronic logistics information. Alternatively, for transactions not via the e-commerce trading platforms connected to the customs authorities, cross-border express delivery operators and postal enterprises shall accept the entrustment of e-commerce enterprises and electronic payment providers to undertake to assume corresponding legal liabilities, and transmit transaction data, payment data and other electronic information to the customs authorities. Imported goods from cross-border e-commerce retail are subject to supervision as inbound items for personal use and not subject to the requirements of initial import approval, registration or recordation, except for goods from epidemic areas that are expressly but temporarily prohibited from import by relevant authorities and those imposed with emergency response measures due to material quality and safety risks. Cross-border e-commerce enterprises are responsible for ensuring the quality and safety of goods, protecting the rights and interests of consumers, reminding and notifying consumers, establishing a risk prevention and control mechanism for the quality and safety of goods, as well as establishing a sound traceability system for ensuring the quality of bonded imports through online shopping. Such enterprises shall also submit real-time electronic data regarding transactions for cross-border e-commerce retail imports with electronic signature affixed to the customs authorities, report their forms either on themselves or via an entrusted agent to the customs and assume corresponding responsibilities. Cross-border e-commerce enterprises shall appoint a domestic enterprise registered in China to undergo customs registration procedures, assume the responsibility for factual reporting, accept supervision from relevant authorities in accordance with law, and assume joint civil liability.

REGULATORY OVERVIEW

According to the Announcement on Regulatory Matters concerning Cross-Border E-commerce Retail Imports and Exports (《關於跨境電子商務零售進出口商品有關監管事宜的公告》) promulgated by the General Administration of Customs on December 10, 2018 and implemented on January 1, 2019, cross-border e-commerce platform enterprises, logistics enterprises, payment enterprises and other enterprises involved in cross-border e-commerce retail import business shall, in accordance with the regulations on the administration of registration of customs declaration entities, undergo registration procedures with the customs in the places where such enterprises are located. Overseas cross-border e-commerce enterprises shall appoint domestic agents to undergo registration procedures with the customs in the places where the agents are located. Enterprises engaged in cross-border e-commerce retail import and export business and registered with the customs shall be included in customs credit management, with the customs authorities enforcing differentiated customs clearance management measures according to credit levels. Goods imported through “Imports via Direct Purchase” (直購進口) in cross-border e-commerce and those applicable to the import policy of “Bonded Imports via Online Shopping” (網購保稅進口) are subject to the regulation as inbound items for personal use but not subject to the requirements for initial import approval, registration and recordation of relevant goods.

As stated by the Guidelines of the General Administration of Quality Supervision, Inspection and Quarantine on Strengthening the Inspection and Supervision of Consumer Goods in Cross-border E-commerce Import and Export (《質檢總局關於加強跨境電子商務進出口消費品檢驗監管工作的指導意見》) promulgated by the General Administration of Quality Supervision, Inspection and Quarantine (currently consolidated as the SAMR) on June 10, 2015, the responsibilities of cross-border e-commerce enterprises for quality and safety shall be set forth explicitly, with a quality and safety supervision model in place for consumer goods in cross-border e-commerce import and export which centers on recordation, monitoring and traceability.

Advertising of Dietary Supplements, Pharmaceuticals and Medical Equipment

With reference to the Advertising Law of the PRC (《中華人民共和國廣告法》) promulgated by SCNPC on October 27, 1994 and last amended on October 26, 2018, advertisements for pharmaceuticals, medical equipment and dietary supplements shall be reviewed by relevant authorities before their release and are prohibited from release without review.

Pursuant to the Interim Administrative Measures for Review of Advertisements on Pharmaceuticals, Medical Equipment, Dietary Supplements and Formula Food for Special Medical Purposes (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》) promulgated by the SAMR on December 24, 2019 and implemented on March 1, 2020, advertisements on pharmaceuticals, medical equipment and dietary supplements shall be truthful and lawful. The advertisers (including natural persons, legal persons or other organizations that design, prepare and release advertisements for the marketing of products or services or engage others to do so) are responsible for the truthfulness and legality of the content of such advertisements on pharmaceuticals, medical equipment and dietary supplements. The holder of the registration certificate or filing certificate for pharmaceuticals, medical equipment and dietary supplements and authorized manufacturers and operators are the applicants of such advertisements, and the applicants may appoint agents to apply for the review of advertisements on pharmaceuticals, medical equipment, dietary supplements and formula food for special medical purposes.