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CFDA Provides Clarity on Administration of Imported Drug Registration

The China Food and Drug Administration issued the Decision on Adjusting Relevant Matters Concerning the Administration of Imported Drug Registration “《关于调整进口药品注册管理有关事项的决定》” (the Decision) on Oct. 10, 2017, which makes changes to the administration of imported drugs with respect to the following matters:

1. Removing the requirement of having to be registered overseas or entered into a phase II or phase III clinical trial for drugs (except for biological products for prevention) to be subject to an international multi-center clinical trial in China. That is to say, when the international multi-center trial of a drug is conducted in China, phase I of the clinical trial will be allowed to proceed at the same time.

2. Applicants may directly file a registration application for marketing, subject to relevant drug registration rules, upon completing the international multi-center clinical trial.

3. Removing the requirement of having to obtain marketing licenses from the country where the manufacturer is located for imported chemical drugs or innovative therapeutic biological drugs applying for a clinical trial or marketing license.

If an application for the exemption of an imported drug clinical trial supported by data from an IMCCT of the same drug has already been accepted before the issuance of the Decision, then importing the drug could be approved directly, provided that the Administrative Measures for Drug Registration and requirements stated in relevant documents are met.

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CIRC to Standardize Internal Control System for Use of Insurance Funds

The China Insurance Regulatory Commission (CIRC) has formulated and issued the Draft of Guidelines for Internal Control over the Use of Insurance Funds (No.4 through No.6) (the Draft) “《保险资金运用内部控制应用指引（第 4 号－第 6 号）》” which applies to equity investment, real estate investment, and financial product investment by insurance companies.

Equity Investment

Insurance companies are required to establish the following:

- a standard and effective internal control system to guarantee compliance and provide an anti-fraud management mechanism;
- an equity investment management system and business operation guidelines based on solvency;
- investment management capacity, targets, scale, and other factors; and
- a project screening mechanism to define principles when conducting equity investments.

To strengthen the subsequent management of equity investment, insurance companies shall establish a comprehensive process management system taking into account concerns regarding investee operations including the appreciation of asset value and risk management. This also includes tracking the post-investment performance of projects as well as tracking and analyzing the influence of economic situations on projects and fund transfers. Insurance companies shall also establish an emergency handling mechanism and a liability investigation system based on due diligence duties of senior officers.

Real Estate Investment

Insurance companies shall conduct a full evaluation of the real estate project before investment. The evaluation shall focus on:

- the necessary certificates for the project;
- the qualifications of the company investing in real estate;
- the financial capacity of the debtor and the guarantor where real estate is invested by way of a creditor’s right;
- the legal risks regarding registration, payment of consideration, and other transaction arrangements where real estate is invested in by way of property rights.

Financial Products Investment

Insurance companies shall continuously evaluate the financial product operations identifying key concerns, including financing, equity changes, contract performance, external ratings of financing or guarantee subjects, the conditions of underlying assets, the capacity and due diligence of manager and custodian, and information disclosure. Insurance companies shall designate an individual to be in charge of tracking investments in financial products and their credit status.

SZSE Strengthens Information Disclosure for Joint Investment Made by Listed Companies and Specialized Investment Institutions

The Shenzhen Stock Exchange has issued the Memorandum Concerning Information Disclosure on the Mainboard (No.8) “《主板信息披露业务备忘录第 8 号—上市公司与专业投资机构合作投资》” (the Memorandum), SME Board (No.12) “《中小企业板信息披露业务备忘录第 12 号：上市公司与专业投资机

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构合作投资》” and GEM Board (No. 21) “《创业板信息披露业务备忘录第 21 号：上市公司与专业投资机构合作事项》”(the Memorandum) regarding Joint Investment Made by Listed Companies and Specialized Investment Institutions on Oct. 20, 2017. According to the Memorandum, any listed company that makes an investment in collaboration with a specialized investment institution shall disclose its investment to the public in accordance with the Memorandum.

Review Process and Provisional Disclosure

- A listed company that makes an investment jointly with a specialized investment institution shall disclose the investment regardless of the amount and go through relevant review procedure pursuant to provisions regarding external investment of listed companies based on the maximum amount of loss the company will or is likely to bear;
- Listed companies shall disclose relevant information through designated media and submit the announcement, cooperation agreement, or other similar documents regarding the investment, board resolution, and shareholders resolution to the Stock Exchange.
- Listed companies are required to disclose eight types of information, such as the qualifications of other investors and details on the investment fund, if the listed company plans to participate in investment or set up an investment fund with a specialized investment institution.
- Listed companies shall make commitments in the announcement not to use idle raised funds to supplement liquidity funds within 12 months of the investment.
- Listed companies shall not make investments while using idle funds to replenish liquidity, within 12 months of changing the use of raised funds to permanent supplementary liquidity, or within 12 months of using excess funds as permanent supplementary liquidity or returning them to the bank.
- A listed company that enters into a cooperation agreement with a specialized investment institution shall disclose basic information about the cooperation agreement and the detailed service provided by the specialized institution.

Follow-up Information Disclosure

- Listed companies shall disclose in a timely manner any of the following: 1) the completion or failure of fund raising; 2) the completion of the filing process for an investment fund; 3) important transactions by the investment fund; and 4) changes or risks with the fund that may cause material impacts on the listed company.
- Where a listed company purchases assets from the invested fund or purchases assets recommended by the cooperating investment institution, the listed company shall disclose detailed information regarding the target assets; the operation of the investment institution; and the interest relationship among the listed company, the investment institution, and the target asset.
- Where a listed company enters into a cooperation agreement with a specified investment institution, it shall disclose the main plans to implement the agreement, any arrangement causing material impacts on the listed company subject to the agreement, and any material change to or early termination of the agreement.

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CFDA Sought Public Opinions on the Draft Amendments to the Drug Administration Law and the Regulations for Supervision and Administration of Medical Devices

The General Office of the CPC Central Committee and the General Office of the State Council issued the Opinions on Deepening the Reform of the Evaluation and Approval System to Encourage Innovations in Drugs and Medical Devices (the Innovation Opinions) on Oct. 1, 2017, putting forward 36 measures for the reform. To further implement the Innovation Opinions, the China Food and Drug Administration has recently conducted careful studies of certain relevant laws and regulations and has released the Amendments to the Drug Administration Law "《药品管理法》" and the Amendments to the Regulations on Supervision and Administration of Medical Devices "《医疗器械监督管理条例》" for public opinions.

Major Amendments to Drug Administration Law

- Subject to the drug marketing authorization holder system, the party that applies for launching drugs on the market shall be the drug market license holder. The holder may produce drugs on its own or entrust other enterprises to produce or operate the drugs, and the authorized holder shall bear full legal responsibility for studies before drug clinical trials, production and operation, and notification of adverse effects. In addition, foreign authorized holders shall appoint an agent to jointly assume the above-mentioned responsibilities.
- Clinical trial institutions are no longer required to be certified but must file a record in the future; clinical trials for drugs need not be expressly approved; and the regime of having certain standards certified, such as the Good Manufacturing Practice for Drugs and the Good Supply Practice for Pharmaceutical Products, will be cancelled.
- The state will establish a formal drug inspection system, and the drug regulatory department will run the grade-based administration of professional drug inspectors, as well as establish incentive and restriction mechanisms with respect to performance assessment, remuneration, and promotion.
- To develop the responsibility regime under the Drug Administration Law, the Draft also included specific provisions on the liabilities of all drug-related parties, including the drug market license holders, clinical trial institutions, contract research organizations, and other entities. The provisions clarify the legal responsibilities of each party in certain circumstances.

Proposed Updates on Administrative Measures for Drug Registration

Following the Draft of Amendments to Drug Administration Law (the Draft), the Food and Drug Administration has released the Draft of Administrative Measures for Drug Registration "《药品注册管理办法》" which covers basics requirements, clinical trials, marketing authorization, standards and instructions for drug registration, alteration and re-registration of registered drugs, and time limits, etc.

For a party filing for drug registration, it shall have in place a quality management system and risk management system (including a pharmacovigilance management system) linked to the life-cycle management of the drug. The applicant shall specify whether the drug involves any patent for invention recognized by the Chinese government, the ownership of the patent concerned, and whether there is any infringement of patent rights. The applicant is also required within certain time limits to inform patent right owners of the concerned patents that an application is being filed for marketing authorization of related drugs.

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Proposed Amendments to Regulations on Supervision and Administration of Medical Devices

- The Draft specifies requirements and responsibilities for the party applying for registration or filing the record, including keeping an eye on adverse events, performing re-evaluations, and recalling defective products. The holder may produce medical devices on its own or entrust other enterprises to produce or operate. The Draft also requires the agent of a foreign holder to make a filing with the Food and Drug Administration and bear corresponding responsibilities.
- The Draft introduces provisions regarding the acceptance of data generated from clinical tests abroad and the widened use of medical devices in clinical trials, and the approval of the clinical trial of high-risk, third class devices shall be changed from express permission to implied license.
- For unregistered innovative medical devices, overseas sales licenses are no longer needed when applying for registration. For third or second class medical devices, an inspection report may be issued by the applicant or by a qualified medical device inspection institution.
- For second class medical devices whose safety and function can be guaranteed through routine management in the circulation process, the requirements of filing for an operation record may be waived. It is expressly forbidden to operate medical devices that have been used.
- The state will establish a medical device inspection system, and the drug regulatory department will run the grade-based administration of professional inspectors as well as establish incentive and restriction mechanisms with respect to performance assessment, remuneration, and promotion.
- Registrants, record-filing applicants, production and operating enterprises, and users of medical devices who intentionally violate the regulation or have acted with gross negligence are subject to punishments. Additionally, the legal representative, main person in charge, officers directly held liable, and other directly responsible personnel may also be subject to fines of not less than 30 percent but not more than their income of the previous year.

First-Time Amendments to Anti-Unfair Competition Law Issued

The revised Anti-Unfair Competition Law of the People's Republic of China has been adopted at the 30th Session of the Standing Committee of the 12th National People's Congress and entered into force Jan. 1, 2018. These are the first revisions to the Anti-Unfair Competition Law since its promulgation in 1993, which was 25 years ago.

Changes to Commercial Bribery Provisions

In the old version of the Anti-Unfair Competition Law, a payment could be deemed as commercial bribery when two elements were met:

1. the payment was made secretly and off the books;
2. the payment was made to the counterparty or individual.

The old version provided that discounts or commissions enjoyed by the counterparty were not deemed commercial bribery as long as the payment was recorded in the books faithfully. Payments made to the counterparty of the transaction have become the focus of the investigations of the State Administration for Industry and Commerce (SAIC). Previously, SAIC tended to deem sponsorships, bonuses, and rebates paid by a vendor to a purchaser as commercial bribery. However, it is quite common for medical care companies to sponsor hospitals engaged in business with them, as well as for tire companies to give rebates to their distributors.

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The new version of the Anti-Unfair Competition Law defines commercial bribery as payments made to the following parties in exchange for transaction opportunities or competitive advantage:

- any employee of the counterparty in a transaction;
- any entity or individual entrusted by the counterparty in a transaction to handle relevant affairs; or
- any other entity or individual that is to take advantage of powers or influence to affect a transaction.

The recipients of commercial bribery under the new version have changed significantly, and "counterparty" is no longer a qualified recipient of commercial bribery. In other words, rebates, discounts, sponsorships, donations, or payments otherwise made by a business operator to the counterparty of the transaction shall no longer be deemed commercial bribery.

Please note, SAIC's own regulations on commercial bribery, the Interim Regulations of the State Administration for Industry and Commerce on Prohibition of Commercial Bribery (Interim Regulations), have not yet been revised in accordance with the new Anti-Unfair Competition Law. Therefore, it is possible that, before the revision of the Interim Regulations, SAIC will stick to the old criteria of commercial bribery, and payments made to the counterparty of the transaction can still be deemed commercial bribery.

The new Anti-Unfair Competition Law also provides a presumption against business operators, in that it provides that the act of an employee of a business operator bribing any other individual shall be deemed an act of the business operator itself, unless otherwise proven by the business operator by evidence that the act is not related to seeking a transaction opportunity or competitive advantage. Business operators are encouraged to conduct internal anti-bribery training along with other compliance measures in order to defend against any commercial bribery committed by individuals.

Changes to Intellectual Property Protection Provisions

The old version prohibits four types of infringements upon intellectual property:

- counterfeiting the registered trademarks of others;
- using, without authorization, the names, packaging, or decoration unique or similar to well-known goods, causing buyers to mistake them for the well-known goods of others;
- using, without authorization, the enterprise names or personal names of others on their own goods, leading purchasers to mistake them for the goods of others; or
- forging or falsely using symbols of quality, such as symbols of authentication and symbols of famous and high-quality goods, on their goods, falsifying the origin of the goods, and making false or misleading representations of the quality of the goods.

The new version of Anti-Unfair Competition Law prohibits any of the following confusing acts that will cause people to mistake products for another business's products or to believe certain relations exist between the products and another business's products:

- unauthorized use of a mark that is identical or similar to the name, packaging, or decoration of another business's commodity, which has influence to a certain extent;
- unauthorized use of another business's corporate name (including its shortened name, trade name, etc.), the name of a social group (including its shortened name, etc.), or the name of an individual

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(including his or her pen name, stage name, translated name, etc.), which has influence to a certain extent;

- unauthorized use of the main domain name, website name, or webpage, which has influence to a certain extent; and
- other confusing acts that are sufficient to cause people to mistake products for another business's products or to believe certain relations exist between the products and another business's products.

The new version introduces the criteria of "influence to a certain extent" in comparison with the criteria of "well-known" in the old version. Though the new version has not established any detailed elements of the criteria of "influence to a certain extent," it should be noted that the criteria of "well-known" is arguably more difficult to reach. It could be argued that the intellectual protection under the new version is stricter.

In addition, the new version uses the expression "sufficient to enable people to mistake" rather than the old version's "causing buyers to mistake." The old version requires there to be an actual mistake to establish unfair competition. It should be noted that, under Trademark Law, any imminent risk of mistaking goods is sufficient to establish an infringement upon trademark. The new version accords with the provisions of Trademark Law and protects intellectual property more strictly.

NDRC Issues Administrative Measures for Outbound Investment of Enterprises

The National Development and Reform Commission (NDRC) recently issued the Administrative Measures for the Outbound Investment of Enterprises (Order 11), effective from March 1, 2018. Order 11 replaces and varies significantly from the previous Administrative Measures for Approval and Record-filing on Overseas Investment Projects (Order 9), issued by NDRC in 2014.

Expansion of Scope of Regulation Object: From "Legal Persons" to "Enterprises"

Only domestic legal persons are subject to Order 9, while natural persons and other organizations are subject to other regulations to be formulated in light of Order 9. Order 11 provides explicitly that domestic enterprises are regulated by Order 11; therefore, partnerships, as non-legal person entities, are included.

Expanded Scope of Definition of Outbound Investment

Under Order 9, outbound investment refers to investment projects by means of establishment, merger and acquisition, share purchase, capital increase, etc., as well as overseas investment projects implemented by overseas enterprises or establishments controlled by a domestic investor (Controlled Enterprises) through financing or a guarantee provided by investors. "Investment project" refers to where an investor, with such assets and equities as currency, negotiable securities, physical objects, intellectual property rights or technology, shares and creditor's rights, or providing guarantee, obtains:

- overseas ownership;
- management right;
- other related equities through investment.

Investment by overseas enterprises is classified as outbound investment only when a domestic investor provides financing or guarantee for the overseas enterprises. Order 11 has significantly enlarged the scope of outbound investment by including investment activities conducted by a domestic investor either directly or via an overseas enterprise under the investor's control, through making investments with assets and equities or through providing financing or a guarantee in order to obtain overseas ownership,

control rights, business management rights, and other related equities. In other words, an independent decision concerning an investment project conducted by an independent Controlled Enterprise without any financing or guarantee by its domestic parent is still subject to the regulation of Order 11.

Under Order 11, the rights to be obtained through investment projects include the following:

- The acquisition of the ownership of, right to use, or other equities of land abroad;
- The acquisition of the exclusive right or other equities to prospect and exploit overseas natural resources;
- The acquisition of the ownership, business management right, or other equities of overseas infrastructure;
- The acquisition of the ownership, business management right, or other equities of overseas enterprises or assets;
- The new establishment, renovation, or expansion of overseas fixed assets;
- The incorporation of a new enterprise overseas or the additional investment in an existing enterprise overseas;
- The new establishment of or participation in overseas equity investment funds; and
- The control of overseas enterprises or assets by means of an agreement, trust, or otherwise.

It should be noted that rights such as ownership of land, rights of resources exploitation, and control of overseas enterprises or assets by means of an agreement, trust, or otherwise are not previously listed in Order 9.

Sensitive Projects Subject to Approval by NDRC

Similar to Order 9, outbound investment involving sensitive projects is subject to approval by NDRC. This includes projects involving sensitive countries, regions, and industries. Order 11 defines sensitive industries:

- Research, development, manufacturing, and repair of weaponry;
- Exploitation and utilization of water resources across borders;
- News media; and
- Industries involved in outbound investment that shall be restricted according to China’s laws, regulations, and relevant control policies.

The Guiding Opinions on Further Guiding and Regulating Outbound Investment Direction (Guiding Opinions) issued by NDRC, along with three other departments in August 2017, constitute the so-called “relevant control policies.” The Guiding Opinions list several sectors as sensitive, among which investment in real estate, hotel, cinemas, entertainment or sports clubs, and investment in equity investment funds or investment platforms established outside China with no actual industrial project gave rise to widespread concern. After the issuance of Order 11, it is clear that investment projects in these industry sectors are subject to NDRC approval.

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Requirement for the Implementation of Investment Projects

Under Order 9, before entering into an investment agreement, the agreement must be filed or approved by the NDRC. This restriction often could result in delay and uncertainty between parties, as governmental procedures are generally not regarded as preconditions to contracts as an international practice. In contrast, Order 11 requires that investors fulfill the approval or filing obligations before the implementation of the investment projects.

Consequence of Failure to Comply with Order 11

Although Order 11 is issued by NDRC, it requires the foreign exchange administration, the customs office, and other related departments, as well as financial enterprises, to not process relevant procedures with respect to investors that have not yet obtained NDRC approval or filing.

MOF and SAT Improve Tax Credit Policy for Enterprises' Foreign-Sourced Income

On Dec. 28, 2017, the Ministry of Finance (MOF) and the State Administration of Taxation (SAT) issued the Circular on Issues Concerning Improvement of the Tax Credit Policy for Overseas Income of Enterprises (Circular 84), which took effect Jan. 1, 2017.

To further implement the "Going Global" and "One Belt, One Road" strategies, Circular 84 aims to explain the method and number of enterprise tiers of tax credit.

Background

In August 2017, the State Council issued the Circular of the State Council on Several Measures to Boost the Growth of Foreign Investment. It included three taxation support policies, one of which was a tax incentive policy for Chinese resident enterprises (including regional headquarters of multinational companies) with respect to the remittance back to China of their eligible foreign-source income. Circular 84 has put such tax incentive policies into practice.

In 2009, the MOF and SAT jointly issued the Circular on Issues Concerning Tax Credit for Enterprises' Overseas Income (Circular 125), which provides general policies on tax credit of enterprises' overseas income.

Under Circular 125, enterprises' overseas income is subject to a certain amount of tax credit. The tax credit is determined based upon the amount of tax payable on overseas income from various countries and regions, which are subject to tax credit and to the quota of tax credit thereof in the current period. The policies apply to a maximum of three tiers of foreign enterprises in the event of tax credit of overseas dividends.

There are a few potential pitfalls of the above method which are explained in Circular 84. First, the amount of tax credit based upon overseas income from a certain country or region cannot be transferred to and credited by the overseas income from another country or region. Therefore, an enterprise may have enjoyed a high amount of tax credit in a low-tax country or region, the balance of which cannot be transferred to and credited by the overseas income from a high-tax country or region. Second, the equity structure of multinational group companies is increasingly complex, which makes the limit of three tiers of foreign enterprises inadequate for multinationals.

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Tax Credit Based Upon Various Countries or Regions or Comprehensive Tax Credit?

Unlike tax credit based upon various countries or regions, enterprises selecting comprehensive tax credit may calculate the aggregate amount of overseas income from all countries or regions and apply for tax credit based upon the aggregate amount.

This "comprehensive tax credit" is a good fit for multinationals engaging in business in various countries or regions throughout the world in that the tax burden in countries or regions with different levels of taxation could be balanced, and aggregate tax credit would be increased.

However, it should be noted that the selection of either method of tax credit by an enterprise cannot be altered within a period of five years.

Tiers of Tax Credit in Terms of Overseas Dividends

For overseas dividends obtained by an enterprise, there are tiers for calculating the enterprise's overseas income tax amount subject to tax credit and the tax credit limit. For enterprises that hold 20 percent of the equity interest of a foreign enterprise, there are five tiers:

- Tier 1: a foreign enterprise with more than 20 percent of its shares being directly held by a single enterprise;
- Tier 2 to Tier 5: a foreign enterprise with more than 20 percent of its shares being directly held by a single foreign enterprise at the next level, and in which the enterprise holds more than 20 percent of the shares directly or indirectly through one or more foreign enterprises that meet the shareholding method as stipulated in Article 6 of Circular 125.

Circular 125 is not rescinded and substituted by Circular 84, which still governs other issues relating to tax credit.

Profits Distributed to Overseas Investors Exempt from Withholding Tax if Used for Direct Investment

Four authorities, including the MOF, SAT, NDRC, and Reform Commission and Ministry of Commerce, jointly issued the Circular on Policy Issues Concerning Temporarily Not Levying the Withholding Tax on Distributed Profits Used by Overseas Investors for Direct Investment (Circular 88), effective Jan. 1, 2017. Some commentators believe that the Chinese government intends to keep overseas investment in China attractive in the wake of President Trump's tax cut plan aiming to appeal to investors.

Under Circular 88, if an overseas investor makes an investment under the encouraged category directly with the profits it obtains from a Chinese resident enterprise, the tax deferral policy shall apply subject to further conditions, which means the withholding tax is temporarily not levied. The "encouraged category" refers not only to those encouraged industries listed in the Catalog for the Guidance of Foreign Investment Industries, but also to those listed in the Catalog of Priority Industries for Foreign Investment in the Central-Western Region.

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Conditions for the Application of Tax Deferral

- Direct investment in China

  An overseas investor directly invests with the profits it obtains, in the form of capital increase, new establishment, and equity acquisition but excluding investment in listed companies (except for qualified strategic investment), which mainly refers to the following:

  (1) Increasing by transferring the paid-in capital or capital reserves of a Chinese resident enterprise;

  (2) Establishing a new resident enterprise within the territory of China;

  (3) Acquiring equity interest of a Chinese resident enterprise from a non-affiliated party;

  (4) Investment otherwise specified by MOF and the State Administration of Taxation.

- Nature of the profits obtained

  Profits obtained by an overseas investor are returns of equity investment, such as dividends and bonuses, generated from retained income distributed by the Chinese resident enterprise to the investor.

- Direct investment in encouraged industry

  An overseas investor shall invest in an encouraged industry that falls under the following categories:

  (1) encouraged industries in the Catalog for the Guidance of Foreign Investment Industries; or

  (2) the Catalog of Priority Industries for Foreign Investment in the Central-Western Region.

Timing of the Application of the Tax Deferral Policy

Circular 88 came into force Jan. 1, 2017 and applies retroactively to all qualified profits obtained by overseas investors since Jan. 1, 2017. Any qualified overseas investors who have not made use of the tax deferral policy may apply for the application of the tax deferral policy as well as a tax refund for already paid taxes within three years of the tax payment.

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