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Foreign Direct Investment

China Releases Second Draft of Foreign Investment Law to Boost Market

《外商投资法（草案）征求意见》公布

On Dec. 26, 2018, the Standing Committee of the National People's Congress of China released the second draft of the *Foreign Investment Law* (2018 Draft) (the first draft was released by the Ministry of Commerce in 2015 (2015 Draft)), and announced collection of public comments through Feb. 24, 2019. The 2018 Draft expands the development of China's market, protects the legitimate rights and interests of foreign investment, commits to considering the views of foreign investors regarding related laws and regulations, and replaces the three existing laws that regulate Sino-foreign equity joint ventures, wholly foreign-owned enterprises, and Sino-foreign cooperative enterprises.

Highlights of the 2018 Draft:

- The 2018 Draft is significantly different from the 2015 Draft, particularly in level of detail and tolerance on violation of access permission: (1) The 2018 Draft has 39 articles (general regulations), far fewer than the 170 articles of the 2015 Draft (regulations with detailed specifications). For example, the 2015 Draft defines as a "foreign investment" the scenario in which controlling or holding rights in a

domestic enterprise are made via contract or trust (such as a variable interest entity, or VIE), while the 2018 Draft leaves more leeway for foreign investors to use an investment vehicle, and does not define such use of investment tools as "foreign investment"; (2) The 2018 Draft is more forgiving than the 2015 draft of foreign investors' violations of provisions on access permission. The 2018 Draft only requires the cessation of investment activities, restoration of prior status, and confiscation of illegal gains (if any), while the 2015 Draft imposes a fine.

- The 2018 Draft provides a five-year grace period for the three types of regulated enterprises to modify their organizational form and structure after replacing the three existing laws.
- To better protect the intellectual property rights of foreign investors, the 2018 Draft forbids the mandatory transfer of technology via administrative means.
- All levels of local government in China and their relevant departments must strictly keep their lawfully binding promises on foreign investment policy and all lawfully entered agreements with the foreign investors and/or foreign-funded enterprises. Any damage suffered by the foreign investors and/or foreign-funded enterprises due to the change of such policy or agreement for the sake of country or public interest shall be justly compensated.
- The 2018 Draft provides foreign investors pre-established national treatment and various means for fundraising in China (such as public offering of shares and corporate bonds), and promises equal treatment to foreign investors as domestic investors.

CBIRC Seeks Comments on Proposed Revisions to the Implementing Rules of the Administrative Regulations on Foreign-invested Banks

银保监会就修改外资银行管理条例实施细则征询意见

On Nov. 28, 2018, following the decision on amending the Administrative Regulations of the People's Republic of China on Foreign-invested Banks (Regulation), the China Banking and Insurance Regulatory Commission (CBIRC) further issued the Decision on Amending the Implementing Rules of the Administrative Regulations of the People's Republic of China on Foreign-invested Banks (Draft for Comment) (Draft), the supporting measures of the Regulation, for public consultation by Dec. 27, 2018.

The Draft, in line with the Regulation, sets forth that a foreign bank may hold a wholly-owned subsidiary or joint venture bank, and a branch in China at the same time, and further stipulates requirements including that the branch can only conduct wholesale business (i.e., business with entities), and the subsidiary/JV and the branch shall have distinguished functions, structure, management, and business and risk segregation mechanisms to ensure the independent operation of the subsidiary/JV and the branch. In addition, any transaction between the subsidiary/JV and the branch shall be subject to the business principles, and the terms of such transaction shall not be more favorable than that offered to other third parties.

The Regulation has lowered the minimum limit of each deposit of a PRC citizen in a foreign bank from RMB 1 million to 500,000, and the Draft further stipulates that a foreign bank shall inform clients of whether the foreign bank deposit is insured when offering deposit business.

Other amendments include reporting requirements on foreign banks, procedures for operation of RMB business and regular supervision and review systems.

Health Care

Public Comment Request for Vaccine Management Law

疫苗管理法草案向社会征求意见

On Nov. 11, 2018, the State Administration for Market Regulation promulgated the first *draft Vaccine Administration Law of the People's Republic of China* (Vaccine Administration Law), aiming to strengthen the regulation on the development, manufacture, distribution, application, adverse reaction monitoring, safeguard, and supervision of vaccine products. The comment period for the first draft closed Nov. 25. Seeking public comment, the second draft of the Vaccine Administration Law was published on the PRC National People's Congress website Jan. 4, 2019.

Highlights of the Vaccine Administration Law:

- Establishes the Marketing Authorization Holder System (MAH System) for vaccines. The new rule clarifies that vaccine marketing authorization holders (MAHs) will be permitted to produce vaccines. To ensure the safety of vaccine production, the MAH System will also include the following: (i) a prohibition on commissioned manufacturing to a third party to produce vaccines; (ii) MAHs of vaccines must establish and perform necessary improvements to their vaccine quality control system and report to competent authorities any change in manufacturing technique, location, and critical equipment; and (iii) if the manufacturing technique or quality control is obviously below the standards of other vaccines of the same kind and cannot satisfy the requirements within the time limit prescribed by the regulator, the MAHs of vaccines must proactively apply for cancellation of the marketing authorization.
- Establishes digital whole-process tracing system for vaccines. At the government level, the department of drug supervision and management shall, in concert with the health administrative department, formulate uniform vaccine traceability standards and norms, set up a national electronic traceability collaboration platform to chart the whole process, including the manufacture, distribution, and application of vaccines. At the company level, vaccine MAHs shall establish a vaccine information traceability system, which shall be linked with the national vaccine information traceability and collaboration platform. In this way, the whole-course traceability and verifiability of the production, storage, transportation, and use of vaccines in the minimum packaging unit can be gradually realized.

Public Comments Sought on Revision of Drug Administration Law

药品管理法修正案向社会征求意见

Seeking public comment, on Nov. 1, 2018, the *Drug Administration Law of the People's Republic of China* (Amended Draft) was posted to the website of the PRC National People's Congress. The Amended Draft focuses on implementing the MAH System and promoting examination and approval reform.

Highlights of the Amended Draft:

- Replaces the GMP and GSP certifications with the MAH System. The Amended Draft formally abolishes the certification of Good Manufacturing Practice (GMP certification) and simultaneously promotes the MAH System, a mechanism for separating and managing drug marketing and production licenses. Pursuant to Article 33 of the Amended Draft, MAHs can manufacture and supply drugs by themselves, or outsource to third parties. As the GMP certification is being abolished, the Good Supply

Practice certification (GSP Certification) is also cancelled by the Amended Draft. Additionally, if any noncompliant behaviors relating to drug price, commercial bribery, false advertising, etc. occur during the drug supply process, MAHs are liable as the parties in charge.

- Clarifies the filing management system and compliance requirements for clinical drug trial institutions. According to Article 30 of the Amended Draft, the management of clinical drug trial institutions is changed from a licensing to a recording mechanism. Further, according to Article 89 of the Amended Draft, penalties for noncompliant behavior of drug trial institutions, whether clinical or non-clinical, are increased. For those institutions failing to implement necessary regulations, they shall be prohibited from market participation entry for five years, and responsible principals shall be punished. In cases of gross violation, such principals may be permanently banned from the Chinese medical industry.
- Establishes the drug recall system. Pursuant to Article 81 of the Amended Draft, if there is any quality problem or other hidden danger in marketed drugs, in addition to reporting to the competent authorities, MAHs shall immediately suspend production and sales; notify the relevant manufacturers, distributors, and medical institutions of cessation of the production, distribution, and use of such drugs; recall the drugs that have been marketed for sale; and disclose the recall information in a timely manner.

Quick Channel Established for Expedited Approval of Foreign New Drugs

《临床急需境外新药审评审批工作程序》出台

On Oct. 23, 2018, the *Working Procedures for the Evaluation, Examination and Approval of Foreign New Drugs Urgently Needed in Clinical Treatment* (Working Procedures) was issued by the National Medical Products Administration and National Health Commission, a detailed procedure to enforce the previously issued (on July 6, 2018) *Technical Guiding Principles for Acceptance of Overseas Clinical Trial Data for Domestic Medicine Registration*.

The Working Procedures provide a special pass for the evaluation, examination, and approval for foreign new drugs urgently needed in clinical treatment, and any new drugs introduced into the U.S., EU, or Japanese markets in the past decade but not launched in the Chinese market can be fast-tracked if qualified under any of the following three standards: (1) the drug can be used to treat a rare disease; (2) the drug can be used to prevent and treat a life-threatening disease where an effective treatment or prevention method is not available; (3) the drug can be used to prevent and treat a life-threatening disease, with apparent clinical advantages. The Working Procedures also point out that if the applied drugs are already circulated in the markets of Japan, Hong Kong, Macao, or Taiwan with sufficient clinical use, then the applicant may initially not provide research materials on racial differences for the application research report.

The National Medical Products Administration and National Health Commission will follow a four-step procedure to select from the aforementioned drugs: (1) conduct a preliminary screening; (2) invite the experts for discussion and selection; (3) publish the selected drugs and collect public comments; (4) produce an official and final release of the list of drugs selected. Accordingly, on Nov. 1, 2018, the Center for Drug Evaluation of China Food and Drug Administration (previously referred to as CFDA, now the National Medical Products Administration) published the first list of 48 foreign new drugs which are in urgent clinical need in China, of which eight had been approved for market circulation and 40 were published as part of the final and official release of the first list.

Tax

The State Administration of Taxation Announces No. 53 for the Enforcement of Circular No. 102

国家税务总局发布53号文《关于扩大境外投资者以分配利润直接投资暂不征收预提所得税政策适用范围有关问题的公告》

On Oct. 29, 2018, the State Taxation Administration released the *Announcement of the State Administration of Taxation on Matters concerning Expanding the Applicable Scope of the Policy of Temporarily Not Levying Withholding Tax on Distributed Profits Used by Overseas Investors for Direct Investments* (Announcement No. 53), for further guidance on the enforcement of the *Circular on Expanding the Applicable Scope of the Policy of Temporarily Not Levying the Withholding Tax on Distributed Profits Used by Overseas Investors for Direct Investment* (Circular No. 102), which was issued on Sept. 29, 2018. On Nov. 19, 2018, the corresponding official interpretation for Announcement No. 53 was released for supplementary measures/guidance.

Highlights of Announcement No. 53 (and the official interpretation) and Circular No. 102:

- Announcement No. 53 and Circular No. 102 (effective since Jan. 1, 2018) serve the same purpose as Announcement No. 88 and Circular No. 3 (effective in 2017) – to temporarily not levy the 10 percent withholding tax on distributed profits gained by overseas investors if used for direct investments in China.
- Announcement No. 53 and Circular No. 102 expand the scope of the application of the policy – from the encouraged investment projects (in 2017) to the permitted foreign invested projects/sectors (from 2018).
- The policy is not applied to the increase, conversion, and acquisition of a listed company's shares (except for qualified strategic investments stipulated in the Administrative Measures for Strategic Investment by Foreign Investors in Listed Companies), and equities acquired from a resident enterprise in China as a related/affiliated party.
- Announcement No. 53 requires strict adherence to the time limit for the funds transfer. If transfer of the funds from the overseas investor's special deposit RMB account (for re-investment purpose) to the invested account is not completed **the same day** of the transfer of the funds from the account of the enterprise distributing profits to the overseas investor's special deposit RMB account (for re-investment purpose), then the overseas investor may lose the tax benefit created by the policy.
- In practice, due to foreign exchange control, 2018's Announcement No. 53 and Circular No. 102 appear unable to efficiently solve the problems reflected in the application and enforcement of the previously effective Announcement No. 88 and Circular No. 3.

New Energy

NDRC Unveils Administrative Provisions on Investment in the Automobile Industry

国家发改委发布《汽车产业投资管理规定》

On Dec. 10, 2018, the National Development and Reform Commission (NDRC) issued the *Administrative Provisions on Investment in the Automobile Industry* (Provisions), which aim to regulate auto industry investments, enhance control over and increase the production capacity for fossil-fueled vehicles, and promote development of electric vehicles. The Provisions have been in effect since Jan. 10, 2019.

Following are key points of the Provisions:

- Expanded scope of automobile projects. The Provisions are intended to cover every aspect of automobile industry investment projects. Compared with former policies, in addition to the original whole vehicle projects, the Provisions also apply to investment projects in automobile components.
- Reform of approval system for investment projects. According to the Provisions, the approval system is changed to a filing system which applies to all vehicle and component investment projects, and the local authority replaces the central authority to implement the filing system.
- Restrict investment in fossil-fueled vehicles. The Provisions expressly forbid any investment in fossil-fueled vehicles producers, and set higher requirements for fossil-fueled vehicles producers which intend to increase production capacity.
- Encourage investment in electric vehicles. Electric Vehicles are encouraged; however, the Provisions set forth challenging requirements which include the following: (1) the location of new projects shall be limited to provinces where the utilization rate of automobile capacity over the last two years is higher than the industry average of the same product category, and all existing projects of the same product category have been completed and the annual output has reached the construction scale; (2) investors of new projects shall possess IP and production capacity for key automobile parts, and shall have no other uncompleted projects or any projects for which annual output fails to reach its construction scale; (3) the major foreign investors shall have cumulative sales of 30,000 electric vehicles or achieve cumulative sales of RMB three billion over the previous two years; and (4) new projects shall have proposed output of no less than 100,000 electric passenger vehicles, or no less than 5,000 electric commercial vehicles.

Employment

Ministry of Human Resources and Social Security Collects Public Comments for the Interim Measures for Hong Kong, Macao, and Taiwan Residents to Participate in the Social Insurance Scheme on Mainland

人力资源社会保障部关于《香港澳门台湾居民在内地（大陆）参加社会保险暂行办法（征求意见稿）》公开征求意见

On Oct. 25, 2018, the Ministry of Human Resources and Social Security published the *Interim Measures for Hong Kong, Macao and Taiwan Residents to Participate in the Social Insurance Scheme in Mainland* (Draft for Comment), and collected public comments with a Nov. 25, 2018 deadline. The Draft

for Comment would enable Hong Kong, Macao, and Taiwan residents who are employed, legally engaged in individual business, or study in the university in the mainland to participate in the social insurance scheme on the mainland.

Highlights of the Draft for Comment:

- The procedure for issuing social security cards for residents from Hong Kong, Macao, and Taiwan, the five types of basic social insurance, and the scope and conditions of applicable insurance should be consistent with those for mainland residents.
- Qualified residents are entitled to enjoy social insurance benefits, but the contribution for basic old-age insurance must reach 15 years. If the contribution is less than 15 years when the resident reaches the statutory age of retirement, alternatives are available for the resident to extend the contribution period by five years, or make a one-time payment.
- Residents from Hong Kong, Macao, and Taiwan may participate only in their local social security scheme to avoid double participation in both the mainland and other places.

Compliance

PBC and 2 Financial Regulators Release Regulation on Anti-Money Laundering and Counter-Terrorism Financing by Internet Finance Service Agencies

一行两会发文规范互金机构反洗钱和反恐怖融资

On Oct. 10, 2018, the People's Bank of China (PBC), the China Banking and Insurance Regulatory Commission, and the China Securities Regulatory Commission jointly issued the *Administrative Measures for Anti-Money Laundering and Counter-Terrorism Financing by Internet Finance Service Agencies (for Trial Implementation)* (the Measures), effective Jan. 1, 2019. The Measures apply to the operation of internet finance service agencies in PRC.

Highlights of the Measures:

- Scope of internet finance service agencies. Internet finance service agencies refer to entities which incorporated upon approval or after filing a record with competent PRC authorities. Such agencies engage in finance businesses such as payment, investment, and information intermediary services based on internet technology and information communication technology.
- Obligations of internet finance service agencies.
    i. Internet finance service agencies shall establish internal control systems for anti-money laundering and counter-terrorism financing; report to the relevant authorities; and institute unified compliance management policies for the operations of their affiliates and branches.
    ii. Internet finance service agencies shall take reasonable measures to verify the identity of clients, and determine and adjust client risk class based on information obtained from reliable sources.
    iii. Internet finance service agencies shall implement a reporting system for large-amount and suspicious transactions and develop a monitoring system for such transactions. An Internet finance service agency needs to report to the PBC when it finds a single transaction

amounting to over RMB 50,000 (USD 10,000) or a series of transactions with an aggregate amount of over RMB 50,000 (USD 10,000) in a day.

iv. Internet finance service agencies shall monitor the terrorist organizations and individuals listed by relevant authorities, and report suspicious transactions where there is any justified cause to suspect a client is involved with those on the lists.

v. Internet finance service agencies shall properly preserve information, data, and materials generated by anti-money laundering and counter-terrorism finance work to ensure that each transaction can be traced.

- Supervision and regulatory punishments. The Measures stipulate that internet finance service agencies shall accept inspection and investigation by the PBC and will be subject to administrative punishment of PBC in case of any violation of the Measures.

MIIT Releases the Administrative Regulation on Admission of Road Motor Vehicle Manufacturer and Products

工信部发布道路机动车辆生产企业和产品准入新规

On Dec. 6, 2018, the Ministry of Industry and Information Technology of the People's Republic of China (MIIT) released the *Administrative Regulation on Admission of Road Motor Vehicle Manufacturer and Products* (Administrative Regulation), which will take effect June 1, 2019. As the first unified rule to regulate the Manufacturer Admission and Product Admission in the auto industry, a series of changes have been introduced by the Administrative Regulation to reform the regulatory regime for the market admission of automobile manufacturer (Manufacturer Admission) as well as the admission of auto vehicle products (Product Admission).

Highlights of the Administrative Regulation:

- Simplifies the admission procedures. Pursuant to Article 2 of the Administrative Regulation, the current 19 sub-categories of on-road vehicles have been re-grouped into six categories (i.e., passenger cars, trucks, buses, special vehicles, motorcycles, and trailers). Accordingly, if a company receives the Manufacturer Admission for a certain category, it can manufacture any vehicles within this category without additional approval from MIIT with respect to each sub-category within the approved category.
- Permits the contract manufacture of automotive vehicles. Article 28 of the Administrative Regulation explicitly encourages cooperation between auto manufacturers as well as cooperation between an auto manufacturer and an auto R&D company. Also, qualified R&D companies may apply for access for road motor vehicle manufacturing companies and their products by borrowing the manufacturing companies' production capacity.
- Potentially waives admission conditions applicable to innovative vehicles and manufacturers. In order to encourage technological innovation of auto manufacturers (e.g., autonomous driving and internet of vehicles), Article 24 of the Administrative Regulation allows an auto manufacturer to apply for a waiver of the related access conditions required for the Manufacturer Admission or Product Admission that cannot be met because of use of any new technology, new method, or new materials. MIIT will assess the necessity and adequacy and make a decision on a case-by-case basis to approve the access, possibly subject to restrictions and conditions (e.g., geographical area, term of effectiveness of admission).

Cyberspace Administration of China Releases Administrative Provisions for Blockchain Information Services

国家网信办发布《区块链信息服务管理规定》

On Jan. 10, 2019, the Cyberspace Administration of China promulgated the *Administrative Provisions for Blockchain Information Services* (Administrative Provisions), effective from Feb. 15, 2019.

Highlights of the Administrative Provisions:

- Clarifies the concepts of "blockchain information services" and "blockchain information service providers." According to the Article 2(2) of the Administrative Provisions, blockchain information services refer to the information services provided for the public based on blockchain technology or systems through internet sites, application programs, or otherwise. Namely, the underlying technology to support blockchain information services must be blockchain technology, which means the Administrative Provisions do not apply to blockchain media based solely on Internet technology (including websites and apps). In addition, According to Article 2 (3) of the Administrative Provisions, blockchain information service providers refer to the subjects or nodes providing the public with blockchain information services, as well as the institutions or organizations providing the subjects of blockchain information services with technical support.
- Clarifies the safety requirements. According to the Administrative Provisions, a blockchain information service provider shall be responsible for content-security management, and establish a series of security management systems. If a blockchain information service provider develops and launches new products, application programs or functions, it shall report to the competent authority for safety assessment. Also, if there is any risk regarding information security in the blockchain information service, the service provider shall rectify the risk and may continue to provide services only after complying with applicable laws and regulations.
- Establishes the filing management system. According to the Administrative Provisions, the blockchain information service is subject to filing management. A blockchain information service provider shall, within 10 working days of its provision of such service, fill in such information as the name, service category, form of services, and address of the server, via the record-filing system.

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