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Foreign Direct Investment

China Unveils 2019 Version of Negative Lists for Access of Foreign Investment

中国公布 **2019** 年版外商投资准入负面清单

On June 30, 2019, the State Development and Reform Commission and the Ministry of Commerce jointly issued the 2019 Version of the Special Administrative Measures for Access of Foreign Investment, the so-called "Negative List," updating access restrictions and conditions for foreign investors. The Negative List came into effect July 30, 2019. The 2019 Negative List replaces the 2018 Negative List and further relaxes constraints on foreign investment on certain industries. Details are as follows:

- Mining Industry: Foreign investors are now permitted to wholly own businesses engaged in exploration and exploitation of oil and natural gas. Foreign investors are also permitted to invest in businesses engaged in exploration and exploitation of varieties of minerals, except for rare earth, radioactive minerals, and tungsten.
- Manufacturing Industry: Foreign investors are now permitted to invest in the production of rice paper and ingot.
- Transportation Industry: Foreign investors can now wholly own domestic shipping agencies.

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- Infrastructure Industry: Foreign investors are permitted to wholly own businesses engaged in building and the operation of gas pipeline networks and heating pipe networks.
- Value-Added Telecommunications Industry: Foreign investors can wholly own businesses engaged in domestic communication service, call center service, and store-and-forward service business.
- Culture Industry: Foreign investors can wholly own businesses engaged in the creation and operation of cinemas, in addition to talent agencies.

Drug Administration

China Adopts New Drug Administration Law

新《药品管理法》出台

The most recently revised Drug Administration Law of the People's Republic of China (the New DAL) was formally passed by the Standing Committee of the National People's Congress on Aug. 26, 2019, and entered into force Dec. 1, 2019. Compared to the previous version of Drug Administration Law passed in 2015 (2015 DLA), the New DAL adopts a set of new administrative rules and several updated systems, which are becoming more in line with international standards.

Key focuses of the New DAL:

- Launches the Drug Marketing Authorization Holder System (MAH System). The pilot program for the MAH system was implemented in 2016 on an experimental basis in 10 cities. The MAH system was formally adopted by the New DAL across China, signifying the end of the "drug registration/manufacturer bundling" system, which had been in place for over three decades. Under the New DAL, MAHs refer to companies, drug research institutions, and others that have obtained the drug registration certificates. A MAH is allowed to contract out drug production to a third-party manufacturer, if approved by National Medical Products Administration (NMPA). The New DAL stipulates that a MAH is responsible for the non-clinical research, clinical trials, production and sales, post-market research, adverse reaction monitoring, reporting, and handling of drugs. If a MAH is a foreign company, its designated business entity in China will perform its MAH obligations and bear several joint liability with the foreign MAH. Also, a MAH may transfer its drug marketing license to a qualified third party upon approval of the NMPA; in this case the third party will perform the MAH's obligations.
- Cancels Generalized System of Preferences (GSP) and Good Manufacturing Practices (GMP) certificates and strengthens post-event supervision. Under the 2015 DLA, drug administration authorities assessed drug manufacturing and trading enterprises, and issued assessment certificates. The New DAL eliminates the requirement for GMP and GSP certificates, implementing a stricter form of supervision. Drug manufacturing and trading enterprises will need to establish and improve the quality management systems of production and trade of drugs to continually meet the requirements of the GMP and GSP, and ensure the full manufacturing process and trading of drugs is in complete compliance with the laws and regulations. As stipulated by the New DAL, failure to comply with such statutory obligations may result in more penalties.
- Redefines the scope of counterfeit drugs and inferior drugs. Under the 2015 DLA, drugs imported to China without approval from the NMPA were deemed "counterfeit drugs." The New DAL redefines the

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scope of “counterfeit drugs” and “inferior drugs.” There is a separate provision provided that prohibits the manufacture and import of drugs without approval. Manufacturers and importers of unapproved drugs may be subject to fines, confiscation of illegal gains, or even detention. However, if only a “small amount” of drugs legally marketed overseas are imported into China without approval, there may be a lesser punishment or an exemption.

- Permits Online Sales of Prescription Drugs. The New DAL lifts the restrictions of online sales of prescription drugs. Prescription drugs may be sold online by MAHs, drug distributors, except for vaccines, blood products, and other high-risk drugs under special control.

Land Administration

NPC Standing Committee Revises Land Administration Law

全国人大常委会修改土地管理法

On Aug. 26, 2019, the Standing Committee of the National People’s Congress (NPC) passed the Amendment to the Land Administration Law (the Amendment), which went into effect Jan. 1, 2020.

The Amendment brings significant changes to the exploitation and development of collectively owned construction land. Collectively owned construction land is owned by a rural community, normally a village. Before the Amendment, only the land-use rights of state-owned land could be leased and sold on the market; for collectively owned construction land, the land-use rights could only be transferred among a limited group of individuals or entities that were part of the community that owned the land. The Amendment provides that the collectively owned land can be invested directly on market.

Highlights of the Amendment:

- Marketization of collectively owned construction land. The Amendment removes the article which requires construction to be conducted on state-owned land, and clarifies that collectively owned construction land can be used by individuals and entities through transfer or lease of land-use rights, and land-use rights for collectively owned construction land acquired can be further transferred, exchanged, contributed, donated, or mortgaged, subject to the separate regulation on the management of transfer of collectively owned construction land, which has not been published yet.
- Improvement of land expropriation system. To limit government power in the process of land expropriation, the Amendment details the formalities for the process of land expropriation and defines the scope of “public interests” for the first time. According to the Amendment, the collectively owned construction land can be expropriated under the following circumstances: (i) the land is required for military and diplomatic use; (ii) the land is required for a public infrastructure project implemented by governments for energy, traffic, communication, postal service, etc.; (iii) the land is required for public utilities organized by governments for technology, education, hygiene, environment, social warfare, veteran benefit, etc.; (iv) the land is required for governments’ poverty alleviation and resettlement projects; (v) the land is included in the overall land utilization plan subject to approval of governments at or above the provincial level; and (vi) other circumstances of “public interests” stipulated in laws.
- Protection of permanent basic farmland. To enhance the public awareness of protecting farmland, the Amendment replaces the term “basic farmland” with “permanent basic farmland,” and clarifies that permanent basic farmland cannot be used for any other purpose, and any conversion or expropriation

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of farmland must be subject to approval of the State Council. The Amendment further provides that a national database on permanent basic farmland will be set up to promote effective management.

Compliance

China Issues Three Sets of New Rules on Anti-Monopoly Compliance

三部反垄断法的配套规定正式施行

On Sept. 1, 2019, three new sets of anti-monopoly rules and regulations took effect, as (1) the *Interim Provisions on Prohibiting Monopoly Agreements* (the *Provisions Prohibiting Monopoly Agreements*), (2) the *Interim Provisions on Prohibiting Abuse of Dominant Market Positions* (the *Provisions Prohibiting Abuse of Dominant Market Positions*), and (3) the *Interim Provisions on Stopping the Acts of Eliminating or Restricting Competition by Abuse of Administrative Power* (the *Provisions Stopping Abuse of Administrative Power*).

The above provisions were issued by China's newly formed competition authority, the State Administration for Market Regulation (the SAMR), which is the successor to the previous antitrust enforcement bodies (the National Development and Reform Commission, the State Administration for Industry and Commerce, and Ministry of Commerce), since the "three-in-one" integration of China's anti-monopoly law enforcement authorities. Although the new provisions largely restate existing law, they replace and update the previously dispersed department rules, and provide clarity and transparency. Such provisions, for example, specify that the SAMR is responsible for cases of national significance, while provincial administrations are responsible for anti-monopoly law enforcement within their jurisdictions (unless otherwise clarified, the SAMR at a national level and the provincial administrations are collectively referred to as the "SAMR"). They also specify that various forms of monopoly agreements are banned, and more clearly define what constitutes abuse of administrative powers that limits competition.

The *Provisions Prohibiting Monopoly Agreements* (《禁止垄断协议暂行规定》)

Under the new regulations, SAMR presumes that the monopoly agreements specified in Articles 7 to 12 of the *Provisions Prohibiting Monopoly Agreements* have anti-competitive effects and therefore condemns such agreements as per se illegal. Articles 7 to 12 prohibit price fixing, limiting production/sales volume, segmenting markets, restricting new technologies, boycotting, and maintaining resale prices (which are deemed as "core monopoly agreements"). Faced with the core monopoly agreements, SAMR may directly determine such monopoly agreements are illegal without performing a competition analysis, unless the "suspect" operator can prove that the exemption situations under Article 15 of the *Anti-Monopoly Law* apply to the investigated action. Article 13 of the *Provisions Prohibiting Monopoly Agreements* includes a catchall provision that prohibits "any other agreements, decisions or concerted actions that fall beyond the scope of the situations set forth in Articles 7 to 12 …", when evidence show[s] abovementioned agreements eliminate or restrict competition and the "reasonable analysis" principle is adopted (where a few general factors, such as the degree of competition in the market, market shares, impact on prices, market entry, etc.), but unlike an earlier draft of the provisions, the implemented provisions do not provide a market share safe harbor.

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A commitment system is conducive to saving law enforcement resources and improving law enforcement efficiency – where an operator promises to correct its behavior and take the initiative to eliminate the consequences of its behavior, SAMR may decide to suspend the investigation. SAMR may further terminate the investigation if it determines that the operator has fulfilled its commitments. However, such suspension/termination is not applicable to certain "core monopoly agreements", for (i) fixing prices, (ii) restricting the number of goods produced or sold, or (iii) segmenting the market.

The leniency system is refined and further clarified, that the important evidence (including the identity of the operators involved in the monopoly agreement, the commodities involved, the content of the agreement, the method of reaching agreement, and how the agreement is implemented) provided voluntarily by an operator may exempt or reduce the penalties for the operator. The exemption or reduction from the penalties will be decided by SAMR according to the time sequence of the voluntary reporting by the operator, the significance of the evidence provided, and the relevant information on the conclusion or implementation of the monopoly agreement. From the perspective of time sequence, the first applicant for leniency may exempt or mitigate penalties by a minimum of 80%. The second may reduce the fine amount by 30% to 50%. The third may be reduced by 20% to 30%.

The *Provisions Prohibiting Abuse of Dominant Market Position* (《禁止滥用市场支配地位行为暂行规定》)

An increasing number of anti-monopoly concerns have been raised via the growing internet and intellectual property fields. In response to such concerns, the *Provisions Prohibiting Abuse of Dominant Market Position* clarifies the special factors to be considered in determining the dominant market position of operators in these two areas. For internet and similar businesses, the dominance assessment considers the industry specificity, business models, user volume, network effects, foreclosure effects, technological features, capabilities of market innovation, mastery and processing of relevant data, the data control and processing, and any associated market power. For the intellectual property field, the substitutability of the intellectual property concerned, the degree of dependence of downstream market, and the licensee's bargaining position in a cross-licensing context are taken into consideration for determining whether an operator holds a dominant market position.

Further details are added to the factors commonly considered when finding the collective dominant positions held by more than two operators. The regulation intends to assess the market structure, market transparency, the degree of homogeneity of products, and the operators' concerted conduct.

The *Provisions Prohibiting Abuse of Dominant Market Position* provides additional guidance on certain abusive conduct such as predatory pricing, by for the first time using "average variable cost" (i.e., the cost per unit that varies with the volume of commodities produced) as the benchmark. Exemption may be given to the free internet model or other emerging areas, considering the overall pricing model (which combines the free commodities and relevant priced commodities). On the other hand, the SAMR goes at length to illustrate defense as "justifiable reasons" when determining whether a suspected act constitutes an abuse of dominant market position. Using "tied sale" as an example, the justifications include: (i) the practice is consistent with industrial norms and transactional traditions, (ii) the practice is necessary for product safety reasons, (iii) the products cannot be produced or sold in the absence of the practice, and (iv) other justifiable reasons.

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The *Provisions Stopping Abuse of Administrative Power* (《制止滥用行政权力排除、限制竞争行为暂行规定》)

As the shortest among the three new provisions, the *Provisions Stopping Abuse of Administrative Power* is distinguished from the others, as demonstrated by the Chinese titles of the provisions. SAMR is faced with more restrictions when dealing with administrative abuse of power in restricting or eliminating competition. SAMR is responsible for the acceptance of cases and conducting investigations under its jurisdiction, and may make a public announcement about the monopoly conduct, but may not directly order to stop illegal conduct, confiscate illegal gains, or impose a fine. From the perspective of rectifying the authority's misconduct, SAMR can only issue recommendations to such authority's hierarchically superior body.

CAC Releases Provisions on Protecting Children's Personal Information in Cyberspace

国家互联网信息办公室发布儿童个人信息网络保护规定

On Aug. 23, 2019, the Cybersecurity Administration of China (CAC) issued the *Provisions on Protecting Children's Personal Information in Cyberspace* (the Provisions), which entered into force Oct. 1, 2019. The highlights of the Provisions are as follows:

- Clarifies the definition of "children." The Provisions for the first time provide a legal definition of children, specifically in relation to the network. As stipulated in the Provisions, "for the purpose of this law, children means minors under the age of 14." This corresponds to the definition in the national "Information Security Technology – Personal Information Security Specification."
- Establishes special protection measures for children's personal information. The Provisions stipulate that network operators will set up special rules and user agreements on the protection of children's personal information, and appoint a specific person responsible for the protection of children's personal information. Also, if personal information of children is collected, used, transferred, or disclosed, the children's guardians will be informed in an obvious and clear way, and the consent of the children's guardians will be obtained.
- Specifies network's processing requirements. The Provisions specify various new requirements including informed consent of a guardian, meaning that guardians must be informed about (i) why the children's personal information is collected, shared, kept secure; (ii) how to correct or delete children's information; and (iii) how to file or report a complaint. Networks must have security incident plans in place, and if there is a possibility of, serious consequences arising from the breach, the network operator must immediately report the breach to competent authorities and notify the affected children and their guardians by email, letter, telephone or push notification. The Provisions also demand the network operator restrict internal access to children's personal information.
- Clarifies commissioned processing requirements. To the extent a network has a third-party data processor processing the children's personal information, the network operators must have a data processing agreement in place with and undertake a security assessment of the third party to ensure sufficient information security. The third-party processor must have procedures in place to delete and promptly notify the network operator in the event of a child's personal information being compromised, and the third-party processor is not permitted to use sub-processors to process children's personal information.

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Dispute Resolution

Supreme People's Court Issues Summary of Trial Work for Civil and Commercial Courts

最高人民法院印发《全国法院民商事审判工作会议纪要》

On Nov. 8, 2019, three months after the Civil Trial Division of China's Supreme People's Court collected comments from the public in August 2019, the China's Supreme People's Court issued the *Summary of the National Conference for the Work of Courts in the Trial of Civil and Commercial Cases* (*Summary*). The *Summary* declares itself only a reference for courts to analyze the reasons for application of law, particularly in "the court holds that" section for the judgment of courts. The *Summary* should not be relied upon by courts for their own judicial interpretations or as a legal basis to render their judgments.

The *Summary's* 12 sections relate to legal transition for the application of the *General Rules of the Civil Law*, trial of cases respectively involving corporate disputes, contractual disputes, guarantee disputes, disputes over the protection of financial consumers' rights and interests, securities disputes, business trust disputes, property insurance contract disputes, bill disputes, bankruptcy disputes, relief of a person not a party involved in a case, and the procedure for the handling of cases involving both civil and criminal liabilities. The *Summary* provides detailed guidelines of more than 44,000 words, for courts across the nation to organize a relatively standard reasoning mechanism for both civil and commercial trials.

Mainland China and Hong Kong On Interim Measures in Aid of Arbitration Took Effect on Oct. 1, 2019

内地最高人民法院与香港特别行政区律政司签署的《关于内地与香港特别行政区法院就仲裁程序相互协助保全的安排》已正式生效

On Sept. 26, 2019, the Supreme People's Court of the People's Republic of China announced that a previously signed (on April 2, 2019) arrangement between Mainland China and Hong Kong the *Interim Measures in Aid of Arbitral Proceedings by the Courts of the Mainland and of the Hong Kong Special Administrative Region concerning Mutual Assistance* (the *Arrangement*) would take effect Oct. 1, 2019. Prior to the *Arrangement*, Mainland China courts did not grant interim measures in aid of arbitration unless the arbitration was seated in Mainland China. Now, with the *Arrangement*, the Mainland courts are empowered to grant interim measures (property preservation, evidence preservation, and conduct preservation) in aid of Hong Kong-seated arbitrations administered by qualified institutions. Six institutions are listed as qualified: the Hong Kong International Arbitration Centre, the International Court of Arbitration of the International Chamber of Commerce – Asia Office, the Hong Kong Maritime Arbitration Group, China International Economic and Trade Arbitration Commission Hong Kong Arbitration Center, South China International Arbitration Centre (Hong Kong), and eBRAM International Online Dispute Resolution Centre. The list may be updated with further applications for qualifying institutions.

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Although the *Arrangement* is labeled "mutual assistance," the real change brought by implementation of the *Arrangement* is that the Mainland courts are obliged to order interim measures in aid of Hong Kong arbitral proceedings. The reciprocal undertaking by Hong Kong has been long granted, because the Hong Kong Arbitration Ordinance has empowered the Hong Kong courts to grant interim measures in relation to any arbitral proceedings commenced in or outside Hong Kong, including in Mainland China.

To apply for interim measures, applicants will need to submit an application to the relevant arbitral institution. The arbitral institution is responsible for forwarding the application to the appropriate Mainland court. Such Mainland court should be the Intermediate People's Court in connection with the respondent's residence or where the property or evidence is situated. Because the referral from the Hong Kong arbitral institution to the Mainland court may cause delay in practice, the *Arrangement* allows the applicant to submit the application directly to the relevant Mainland court with certain conditions. If the applicant's identity material is formed outside the Mainland China, then the relevant certificates should be provided.

The Shanghai Maritime Court issued the first order on Oct. 8, 2019, granted under the *Arrangement*.

* *This GT Newsletter is limited to non-U.S. matters and law.*

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