



Newsletter

Update

February 12th, 2019

- [China Announces New Initiatives to Generic Drugs Industry](#)
- [NMPA Regulates Overseas Inspections of Drugs and Medical Devices](#)
- [CSRC Approves Additional Three Commodity Options Trading](#)
- [China Intends to Ease Foreign Shareholding Limit in Education and Health Care Sectors](#)
- [CSRC Promulgated Measures for the Information Technology Management of Securities and Public Funds Operators](#)

Article(s)

- [Expanded QFLP Policies Presents New Opportunities for Foreign VC and PE](#)

Update

China Announces New Initiatives to Generic Drugs Industry

The National Medical Products Administration ("NMPA") issued a new announcement relating to the evaluation of consistent quality and efficacy of generic drugs on December 28, 2018. The announcement outlines a series of measures to carry out the Reform of "Streamlining Administration, Delegating Power and Strengthening Regulation and Improving Services" in China.

NMPA adjusts and loosens the requirement of time limit with the new announcement: (1) Dynamic adjustment mechanism of consistence evaluation will prevail; (2) Based on the old rules, the consistency evaluation of the oral solid preparations on the National Essential Medicine List shall be completed by the end of 2018 except for special cases. However, as the new management system related to the National Essential Medicine List was launched in November 2018, the time limit requirement will no longer apply. (3) the "3-year" time limit for other generic drugs to complete the consistence evaluation can be extended as the case maybe.

NMPA Regulates Overseas Inspections of Drugs and Medical Devices

The National Medical Products Administration ("NMPA") has enacted and issued the Administrative Measures for Overseas Inspections of Drugs and Medical Devices (the "Provisions"), immediately effective from December 26, 2018.

The Provisions clearly state that, overseas inspections, targeting drugs and medical devices that have been or will be sold in the Chinese market, are not limited to on-the-spot inspections carried out in the production facility, but are expanded to cover inspections conducted at places of overseas research and development and production. The Provisions also provide

that inspection results will be responded differently through risk control measures and through case establishment and investigations. In the event that grave quality risks are found in such inspections, immediate measures must be taken to bring the risks under control.

CSRC Approves Additional Three Commodity Options Trading

The China Securities Regulatory Commission (“CSRC”) announced on January 4, 2019 that it has approved three categories of commodity options trading, which includes the tradings of (i) natural rubber options on Shanghai Futures Exchange; (ii) cotton options on Zhengzhou Commodity Exchange; (iii) corn options on Dalian Commodity Exchange. The specific listing time of the option contracts is January 28, 2019.

China Intends to Ease Foreign Shareholding Limit in Education and Health Care Sectors

In the last regular press conference of MOFCOM held on December 28, 2018, the speaker indicated that MOFCOM would further relax market access to foreign investors and accelerate the process of opening up in telecommunications, education, medical care, culture, and other sectors. It was particularly mentioned that China would ease the foreign shareholding limit in the areas such as education and health care.

CSRC Promulgated Measures for the Information Technology Management of Securities and Public Funds Operators

The China Securities Regulatory Commission (“CSRC”) has recently issued the Measures for the Information Technology Management of Securities and Public Funds Operators (the “Measures”), which will become effective on June 1, 2019.

The Measures mainly discuss the following aspects: (1) the Measures will be applicable to various types of institutions, such as securities institutions, public fund management companies (collectively “Operators”), and information technology service providers for securities and public fund operation. (2) The Operators shall be required to formulate clear regulatory arrangements for information technologies, set up Information Technology Management Committee and appoint Chief Information Officer (“CIO”). (3) The Operators shall be required to allocate appropriate resources to compliance departments and risk-control departments for information technology management. (4) The Operators shall regularly carry out auditing for information technology management and promoting the integration of information technology and business, risk control and compliance management. (5) The Operators shall continuously upgrade the emergency plans and organize emergency exercise on regular basis for key personnel in accordance with the updated emergency plans. (6) The Operators shall be allowed to set up its subsidiaries specialized in information technologies for technology support. (7) The Measures clearly specify the responsibilities and liabilities of responsible persons.

Article(s)

Expanded QFLP Policies Presents New Opportunities for Foreign VC and PE

by *Echo Liu*

The *Interim Measures for Implementing the Pilot Program for Foreign-funded Equity Investment Enterprises in Zhuhai* became effective on January 20, 2019, which means Zhuhai QFLP had been officially launched. QFLP, is short for Qualified Foreign Limited Partner, which refers to a foreign institutional investor who converts foreign capital into RMB funds and invest in the domestic PE and VC markets after the examination and approval of qualification and the regulatory procedures of its foreign exchange funds. Shanghai Financial Office, when the director was Xinghai Fang who now is the vice chairman of the CSRC, issued the *Measures for Implementing the Pilot Program for Foreign-funded Equity Investment Enterprises in Shanghai* On December 24, 2010, which is marked as the beginning of the pilot program of the QFLP in Shanghai. As of January 2019, the pilot programs of the QFLP are carried out in one province and eight cities nationwide. Zhuhai QFLP holds over the main core terms of the QFLP policies in most province and cities, but also made some provisions of its own characteristics. We have compared some of the main core policies among Shanghai, Shenzhen and

Zhuhai.

Province/ Municipality	The Date of Issue	The Date of Effectiveness	Name of the Regulations
Shanghai	2010.12.24	2011.1.24	Measures for Implementing the Pilot Program for Foreign-funded Equity Investment Enterprises in Shanghai
Beijing	2011.2.28	2011.2.28	Interim Measures for Implementing the Pilot Program for Foreign-funded Equity Investment Funds and Relevant Management Enterprises in Beijing
Chongqing	2011.5.16	2011.5.16	Operating Procedures for Implementing the Pilot Program for Foreign-funded Equity Investment Enterprises in Chongqing (For Trial Implementation)
Tianjin	2011.10.14	2011.10.14	Interim Measures for Implementing the Pilot Program for Foreign-funded Equity Investment Enterprises and the Management Agencies in Tianjin
			Rules for Implementation of Interim Measures for Implementing the Pilot Program for Foreign-funded Equity Investment Enterprises and the Management Agencies in Tianjin
Shenzhen	2012.11.26	2012.11.26	Interim Measures for Implementing the Pilot Program for Foreign-funded Equity Investment Enterprises in Shenzhen (invalid)
	2013.2.6	2013.2.6	Operating Procedures for Implementing the Pilot Program for Foreign-funded Equity Investment Enterprises in Shenzhen (invalid)
	2017.9.22	2017.9.27	Measures on the Pilot Program for Foreign-funded Equity Investment Enterprises in Shenzhen
Qingdao	2015.2.9	2015.3.11	Interim Measures for Implementing the Pilot Program of Qualified Foreign Limited Partner in Qingdao
Guizhou Province	2017.10.25	2017.10.25	Interim Measures for Implementing the Pilot Program for Foreign-funded Equity Investment Enterprises in Guizhou Province
			Operating Procedures for Implementing the Pilot Program for Foreign-funded Equity Investment Enterprises in Guizhou Province
Pingtian	2018.3.27	2018.3.27	Implementing Measures for the Pilot Foreign-funded Equity Investment Enterprises in Pingtan Comprehensive Experimental Area (For Trial Implementation)
Zhuhai	2018.12.21	2019.1.20	Interim Measures for Implementing the Pilot Program for Foreign-funded Equity Investment Enterprises in Zhuhai

In our opinion, there are two prominent characteristics of Shanghai QFLP as the cornerstone of the pilot program of the QFLP. First, the funds obtained the QFLP qualification shall be eligible for national treatment in the equity investment; second, the pilot program of the QFLP in Shanghai broke through the restrictions on the foreign exchange settlement.

Regarding the national treatment, the regulation stipulates that *the foreign-funded equity investment management*

enterprises that have been approved for piloting may use the foreign exchange capital to invest in the equity investment enterprises initiated by itself and the amount shall not exceed 5% of the total amount of the funds raised, which shall not affect the nature of the equity investment enterprises it invests, which was a breakthrough regulation on the problem whether the managers with QFLP qualification as the GP of the QFLP fund would cause any changes of the nature of the fund. However, the National Development and Reform Commission (NDRC) sent *the Reply from the General Office of the State Development and Reform Commission on Issues Relevant to Foreign Equity Investment Enterprises* to the Shanghai Development and Reform Commission, which clarified that the limited partnership equity investment enterprises, of which Shanghai Blackstone Equity Investment Partnership Enterprise and such General Partners (GP) are foreign capital and limited partners (LP) which are domestic capital, should be managed in accordance with foreign investment policies and regulations and their investment projects are applied to the *Guiding Catalogue of Foreign Investment Industries*. That reply directly denied the national treatment in the pilot program of Shanghai QFLP, which led to the most cautious and low-key pilot in Shanghai, although pilot program of QFLP was launched in Shanghai at the earliest.

Nevertheless, the pilot programs of the QFLP are issued by Shenzhen, Qingdao, Guizhou respectively after the NDRC issued the reply, which show the confidence in QFLP policies through practical actions. Among which, the pilot program of Shenzhen QFLP gained the experiences from the pilot in Shanghai and clearly stipulates that *foreign-funded equity investment enterprises should be directly invested in the industry under the guidance of Guiding Catalogue of Foreign Investment Industries* in the Article 16. Therefore, it can be clarified that if the foreign-funded equity investment enterprises who conduct the domestic reinvestment should be regarded as foreign investors and the relevant policies on the foreign investment industry and relevant regulations should be applied.

As the national treatment has been denied in the pilot program of the QFLP, the reason that the provinces and the cities are still launching the QFLP pilots is to resolve the biggest obstacle for foreign-funded managers and foreign funds to carry out PE and VC investments in China, which is the foreign exchange capital settlement issues. Regarding the foreign capital settlement issues, SAFE has constantly adjusted its policy orientation with a series of regulations. *Notices on the Relevant Operating Issues concerning the Improvement of the Administration of Payment and Settlement of Foreign Currency Capital of Foreign-funded Enterprises* (invalid, hereinafter referred to as “Regulation No.142”) issued in 2008, which clearly stipulates that *the RMB funds acquired from foreign exchange capital settlement of foreign-funded enterprises shall be used within the business scope approved by the government approval department and shall not be used for the domestic equity investment unless otherwise stipulated*. The enterprises under the pilot program in Shanghai have breached the Regulation No.142 at the time of launching within the scope of pilot enterprises. On July 4, 2014, SAFE issued the *Notice of Issues Concerning the Pilot Program of Reforming the Administrative Modes for the Settlement of Foreign Exchange Capital of Foreign-Funded Enterprises in Certain Regions* (invalid, hereinafter referred to as “Regulation No.36”), stipulated that *the foreign exchange capital settlement of the foreign-funded investment enterprises in the pilot areas shall temporarily not be applicable to Regulation No.142*. SAFE issued the *Notice of the State Administration of Foreign Exchange on Reforming the Mode of Management of Settlement of Foreign Exchange Capital of Foreign-Funded Enterprises* (hereinafter referred to as “Regulation No.19”) on March 30, 2015, which extends the pilot area determined in Regulation No.36 to the nationwide and further clarifies the use and supervision of foreign exchange settlement funds, and implements a new capital settlement policy in 16 pilot areas named the dispositional exchange settlement. SAFE issued the *Notice on Reforming and Regulating the Policies for the Administration of Foreign Exchange Settlement under the Capital Account* on June 9, 2016. (hereinafter referred to as “Regulation No.16”) Synthesizing the provisions of the Regulation No.19 and Regulation No.16 still in force currently, firstly, foreign-funded investment enterprises are allowed to apply to the dispositional exchange settlement, which theoretically foreign currency capital with the confirmation of contribution interests by the local SAFE in the foreign exchange capital account of the foreign-funded investment enterprises shall be

under the exchange settlement in the bank according to the actual business needs of the enterprises; secondly, the foreign currency capital shall be applicable to the dispositional exchange settlement and the ratio of the dispositional exchange settlement is tentatively 100%; thirdly, the foreign-funded investment enterprises with investment as the main business (including foreign-funded enterprises with the main business of investing, foreign-funded venture capital enterprises and foreign-funded equity investment enterprises) shall directly handle the exchange settlement or transfer the RMB funds in the unpaid exchange settlement account to the account of the invested enterprises according to the actual investment scale on the premise that the domestic investment projects are true and compliant.

However, according to our understanding, the foreign-funded investment enterprises, as the subject of the dispositional exchange settlement, which are generally recognized as the pilot equity investment enterprises obtained the QFLP qualification by the local SAFE and banks in practice. So, it is not hard to understand why local governments are still launching QFLP policies even foreign-funded equity investment enterprises across the country are allowed to conduct a full exchange settlement and use the foreign funds freely by regulations literally.

We believe that QFLP policies have achieved some pilot significance in the past ten years from the initial launch to the present, but there is still a huge gap between the provisions of the QFLP policies and the substantial impact on the development of foreign PE managers and foreign PE funds in China. In view of the current international situation and economic situation, the introduction of QFLP policies nationwide as early as possible will be more beneficial to play the role of foreign-funded managers and foreign funds in impulsing the development of PRC fund market and providing the demonstration effect of advanced management experience and models, which making private equity funds an important tool to promote the development of PRC economy.

Contact Us

Grandway Law Offices (Shanghai)

www.grandwaylaw.com

23F, S2 Building, Bund Financial Center, 600

Zhongshan No. 2 Road (E), Shanghai, 200010, China