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Legal Updates

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Legal Updates

1. China to Allow Foreign Control of Securities Firms: CSRC Officially Promulgates Measures for Administration of Foreign Investment in Securities Firms (Authors: TieCheng YANG, Yin GE, Ting ZHENG, Michael KAN)

On 28 April 2018, the China Securities Regulatory Commission ("**CSRC**") officially promulgated the *Measures for Administration of Foreign Investment in Securities Companies* (the "**Official Measures**")[1], following CSRC's issuance of a public comment draft of the same (the "**Draft Measures**")[2] on 28 March 2018. The Official Measures are widely considered a significant move to further open up China's domestic financial sector.

How will the Official Measures affect foreign investment in securities firms in China? This newsletter begins with a background of the previous foreign ownership limitations in China, interprets the key regulatory changes and impacts on foreign investment in securities firms as stipulated in the Official Measures, and briefly analyzes the regulatory trends for further implementing China's other commitments to ease restrictions on foreign investment in the financial sector.

Background

At present, there are 13 foreign-invested joint venture (JV) securities firms in China, including four JV securities firms approved under the Closer Economic Partnership Arrangement (CEPA). Global financial giants have until now mainly operated in China through minority-owned JV securities firms, among which most are limited to investment banking services due to the current regulatory constraints.

CSRC issued the Official Measures to replace the *Rules on the Establishment of Securities Companies with Foreign Equity Participation*[3], last amended by CSRC in 2012 (the "**2012 Rules**"). Under the 2012 Rules, the total proportion of shares, or of rights and interests, held directly or indirectly by foreign shareholders in a JV securities firm could not exceed 49%.

However, with the significant development and rapid changes in China's domestic securities markets,

[1] 《外商投资证券公司管理办法（正式稿）》 [Measures for Administration of Foreign Investment in Securities Companies (Official Version)] (China Securities Reg. Comm., Decree No. 140; promulgated and effective 28 Apr. 2018), *available at*: http://www.csrc.gov.cn/pub/zjhpublic/zjh/201804/t20180428_337509.htm (Chinese).

[2] 《外商投资证券公司管理办法（征求意见稿）》 [Measures for Administration of Foreign Investment in Securities Companies (Draft for Comment)] (China Securities Reg. Comm.; issued 9 Mar. 2018, for public comment until 8 Apr. 2018), *available at:* http://www.csrc.gov.cn/pub/zjhpublic/zjh/201803/P020180309603189338426.pdf (Chinese).

[3] 《外资参股证券公司设立规则（2012 年修订）》 [Rules on Establishment of Securities Companies with Foreign Equity Participation (Revised in 2012)] (China Securities Reg. Comm., Decree No. 86; promulgated and effective 11 Oct. 2012, annulled by the Official Measures on 28 Apr. 2018).

the 49% foreign ownership cap could no longer meet the need for the continuous development and opening up of the securities sector in China.

During U.S. President Donald Trump's visit to China in November 2017[4], China made the commitment to raise the cap on direct or indirect equity ownership by a single or multiple foreign investors in JV securities, fund management and futures companies to 51%, and there will be no equity cap limitation on such investments three years after the implementation of the proposed rules. Meanwhile, the strategic significance of further opening up the financial sector was also reiterated at other meetings, including the 19th National Party Congress and the National Finance Working Conference in 2017 as well as the meetings of the National People's Congress and the Chinese People's Political Consultative Conference held this March.

In this context, the Official Measures have been issued by CSRC as an effort to implement the strategic decision at the 19th National Party Congress to "significantly ease market access, further open the service sector…"[5] and to deliver the commitment of further opening up China's securities markets made at the high-level meeting between Xi Jinping and Donald Trump.

Key Changes in the Official Measures

The key changes in the Official Measures can be summarized in the five main areas as below:

a. Lifting shareholding cap for foreign shareholders

The first key regulatory change is lifting the cap on foreign shareholding in securities firms to 51% from the previous 49%. According to the Official Measures, the total proportion of the shares held directly and indirectly by foreign investors in a JV securities firm shall not exceed the 51% cap according to China's commitment to open up its securities sector. It is further expected that the 51% ceiling on foreign shareholding in securities firms will be eventually scrapped in 2021.

b. Broadening business scope for JV securities firms

JV securities firms will be allowed to engage in a wider range of services in incremental steps. Newly established JV securities firms are allowed to apply for securities business activities based on their specific circumstances. Specifically, according to the *Securities Law of the People's Republic of China (Revised in 2014)* and the *Interim Provisions on Examination and Approval of the Business Scope of Securities Companies (Revised in 2017)*[6], a newly established JV securities firm may apply

[4] 《新闻办就中美元首北京会晤经济成果相关情况举行吹风会》 [State Council Information Office Holds Briefing Regarding the Economic Results of the Meeting between the Heads of China and the U.S. in Beijing] (10 Nov. 2017), *available at*: http://www.gov.cn/xinwen/2017-11/10/content_5238617.htm#1 (Chinese).

[5] 《决胜全面建成小康社会，奋力夺取新时代中国特色社会主义伟大胜利》 [Secure a Decisive Victory in Building a Moderately Prosperous Society in All Respects and Strive for the Great Success of Socialism with Chinese Characteristics for the New Era] (delivered by Pres. Xi Jinping at the 19th National Congress of the Communist Party of China, 18 Oct. 2017), *available at:* http://www.xinhuanet.com/english/download/Xi_Jinping's_report_at_19th_CPC_National_Congress.pdf (English).

[6] 《证券公司业务范围审批暂行规定（2017 年修订）》 [Interim Provisions on Examination and Approval of the Business

to engage in four of the following services:

a) securities brokerage business;

b) securities investment advisory business;

c) financial advisory business related to securities trading and securities investment activities;

d) securities underwriting and sponsoring business;

e) securities business on its own account;

f) securities asset management; and

g) other securities business.

One year after regulatory approval and each year thereafter, the JV securities firm may apply to engage in two additional services as indicated above.

As a general requirement under the Official Measures, however, the initial business scope of a JV securities firm shall correspond to the relevant experiences of the controlling shareholder or the largest shareholder in conducting securities business.

c. Updating regulations on foreign holding of listed securities firms

CSRC has also raised the ceiling for shareholding of foreign investors of listed securities firms in China.

According to the Official Measures, the total proportion of shares held directly and indirectly by all foreign investors in a listed securities firm now corresponds to the updated cap for unlisted securities firms, which shall not exceed the current cap of 51% according to China's commitment to open up its securities sector. Similarly, the 51% ceiling on foreign shareholding in listed securities firms will be eventually scrapped in 2021. It is also notable that the previous 20% ceiling on the shareholding of a single foreign investor in a listed securities firm has been removed.

d. Clarifying regulations for a change of nationality by actual controllers of domestic shareholders

The Official Measures address a new occurrence which has arisen in recent regulatory practice where the actual controller of a shareholder in a domestic securities firm changes his or her nationality from Chinese to that of a foreign country. This change of nationality leads to the issue of indirect shareholding by a foreign investor in a domestic securities firm. The Official Measures provide that if the actual controller of a shareholder in a domestic securities firm is changed from a domestic investor to a foreign investor, the relevant foreign investor must comply with the relevant eligibility requirement and shareholding cap for foreign shareholders.

Scope of Securities Companies (Revised in 2017)], Art.7 (*as revised by* China Securities Reg. Comm.; promulgated and effective 7 Dec. 2017), *available at:* http://www.gov.cn:8080/gongbao/content/2018/content_5286376.htm (Chinese)

Where foreign investors do not meet the relevant criteria and requirements as specified in the Official Measures, they are required to complete the relevant rectification and remediation measures within three months.

e. Updating criteria and qualifications for shareholders

a) Raising the bar for foreign shareholders in JV securities firms

CSRC has expressed the intention to raise the bar for foreign investors planning access to China's domestic securities markets, by updating the criteria for foreign shareholders in a JV securities firm. According to the Official Measures, the foreign shareholders in a JV securities firm shall satisfy the following criteria:

i. their home country or region has a sound legal and regulatory system for securities business, and has concluded a memorandum of understanding on securities regulatory cooperation with CSRC or any institution recognized by CSRC and maintains constructive relations of regulatory cooperation with CSRC or any institution recognized by CSRC;

ii. they are lawfully established financial institutions in their home countries or regions, and all of their financial ratios have, for the last three years, conformed to the legal requirements applicable in their respective home countries or regions and to the requirements of their respective securities regulator;

iii. they have been operating securities business for no less than 5 years, and have not received any serious penalty from any securities regulator, administrative or judicial organ, or been investigated by any relevant authorities due to severe violation of any law or regulation in their respective home countries or regions within the last 3 years;

iv. they have sound internal control systems;

v. they have good international reputations and business performance records, with internationally leading track records in terms of business scale, revenue and profit, and high-level long-term credit within the last 3 years; and

vi. any other prudential criteria specified by CSRC.

As compared with the 2012 Rules, the Official Measures set higher requirements for foreign investors, requiring that they must be financial institutions with a sound international reputation, and good business and credit records over the past three years. This change reflects a higher standard from CSRC to attract high-quality foreign investors with good international reputations and leading management experience.

b) Updating the qualifications for PRC shareholders in JV securities firms

Another noteworthy change involves the qualification requirements for PRC shareholders in JV securities firms. According to Article 8 of the 2012 Rules, at least one of the PRC

shareholders in a JV securities firm had to be a domestic securities firm. There were only two exceptions to this rule, including: (i) where a foreign investor may have acquired some equity (previously less than 49%) in an existing domestic securities firm which was 100% owned by PRC corporates and thus converted the domestic securities firm into a JV securities firm; or (ii) where a qualified Hong Kong/Macao financial institution could have partnered with eligible PRC corporates to set up a JV securities firm in certain pilot zones under special CEPA arrangements.

The Official Measures relax this domestic securities firm shareholder requirement. CSRC has announced that the qualification requirements for PRC shareholders in a JV securities firm will be the same as those applicable to shareholders in a domestic securities firm. In both the Draft Measures and Official Measures, CSRC has also deleted the requirement that "in a JV securities firm, at least one of its PRC shareholders must be a domestic securities firm". This means that JV securities firms will no longer be required to have a domestic securities firm as its PRC shareholder. In other words, foreign investors will be allowed to partner with eligible PRC corporates to set up a JV securities firm.

c) Other key proposed requirements for shareholders' qualifications

We should also note that CSRC has issued the *Provisions on Administration of Equity of Securities Companies (Draft for Comment)*[7] on 30 March 2018 (the "**Draft Equity Provisions**"), to regulate the equity and shareholders of PRC securities firms (including JV securities firms), which may impose additional eligibility requirements on foreign and PRC shareholders. The Draft Equity Provisions propose to classify shareholders of PRC securities firms into the following four categories based on their level of shareholding and their influence on firm operations and management:

i. "controlling shareholders" refer to shareholders holding more than 50% equity in a securities firm, or shareholders holding less than 50% equity while their voting rights are sufficient to have significant influence on the resolutions of the (general) shareholders' meeting;

ii. "major shareholders" refer to shareholders holding more than 25% equity in a securities firm, or the largest shareholder holding more than 5% equity in securities firms;

iii. shareholders holding more than 5% equity in a securities firm; and

iv. shareholders holding less than 5% equity in a securities firm.

Each type of shareholder would be subject to different qualification requirements with respect to net assets, profitability, credit records, etc. These qualification requirements would also apply to

[7] 《证券公司股权管理规定（征求意见稿)》 [Provisions on Administration of Equity of Securities Companies (Draft for Comment)] (China Securities Reg. Comm.; issued 30 Mar. 2018, for public comment until 29 Apr. 2018), *available at:*http://www.csrc.gov.cn/pub/zjhpublic/zjh/201803/t20180330_336014.htm (Chinese).

domestic and foreign investors in terms of their equity investment in PRC securities firms (including JV securities firms). In particular, where a foreign investor seeks to have a controlling stake in a JV securities firm, it would need to satisfy additional qualification requirements applicable to controlling shareholders under the Draft Equity Provisions, including, among others, having net assets of no less than RMB100 billion (approximately US$15.9 billion), maintain profitability for the most recent 5 years and have business revenues of no less than RMB100 billion (approximately US$15.9 billion) for the most recent 3 years. Some foreign investors have expressed concerns over these proposed capital requirements, although the requirements as drafted would also apply to domestic investors. It is yet to be seen how these concerns may be addressed in the finalized rules.

Outlook

a. Increasing foreign investment in securities firms

In the past, the key issue with regard to foreign investors establishing JV securities firms has been whether the investors could have control over the JV securities firms. There are some precedents where foreign investors have had control over JV securities firms, but those precedents are exceptional and cannot be followed by other international investors. International investors will undoubtedly welcome China's move to permit foreign investors to take majority stakes in JV securities firms as stipulated in the Official Measures. For foreign investors who have invested in JV securities firms as minority shareholders in China, they may consider increasing their current shareholdings to become the controlling shareholders of the JV securities firms.

During CSRC's news briefing on the issuance of the Official Measures on 28 April 2018[8], CSRC officially announced that qualified foreign investors may submit applications for the change of the actual controller of existing JV securities firms or for the establishment of new JV securities firms, and CSRC will release updated operating guidelines in due course. CSRC also indicated that some international financial institutions in Europe and Asia have kicked off their initial communications with CSRC and plan to submit applications to CSRC based on the Official Measures. According to the latest media releases[9], UBS Securities Co., Ltd. ("**UBSS**") has submitted an application to change its actual controller to UBS AG by increasing the foreign shareholding percentage to 51% (previously UBS AG has had *de facto* control over UBSS through contractual arrangements). CSRC has accepted the UBSS application, and it is currently pending official review and approval by CSRC. Once the application is approved, UBSS may become the first JV securities firm with a foreign controlling shareholder in China.

b. Opening up of fund management and futures sectors

[8] 《证监会新闻发言人就〈外商投资证券公司管理办法〉答记者问》 [News Briefing by CSRC on the Release of *Measures for Administration of Foreign Investment in Securities Companies*] (28 Apr. 2018), *available at*: http://www.csrc.gov.cn/pub/newsite/zjhxwfb/xwdd/201804/t20180428_337508.html (Chinese).

[9] *UBS seeks regulatory nod for 51 pct controlling stake in China JV*, REUTERS (3 May 2018), *available at:* https://www.nasdaq.com/article/ubs-seeks-regulatory-nod-for-51-pct-controlling-stake-in-china-jv-20180503-00003 (English).

During the CSRC news briefing, CSRC also confirmed that it has allowed foreign investors to hold 51% stakes in fund management companies ("**FMCs**") in China, and the shareholding cap of 51% will be eventually removed in 2021. Qualified foreign investors may submit applications for the change of actual controllers of existing JV FMCs or for the establishment of new JV FMCs according to current FMC-related regulations and operating guidelines.

Following the news briefing, CSRC later issued the *Measures for Administration of Foreign Investment in Futures Companies (Draft for Comment)*[10] on 4 May 2018 for public comment until 4 June 2018, which provide clear guidance and specific requirements to be followed by foreign investors for their investment in futures companies on shareholders' qualifications, holding of equity stakes, and senior management personnel, etc. Similarly, the fundamental goal is to honor China's commitment to allow foreign controlling stake in the futures companies.

c. Other policy initiatives

In addition, the National Development and Reform Commission officially announced on 17 April 2018[11] that it is working jointly with other relevant departments to address the opening up of China's financial sector by updating the *Special Administrative Measures for Foreign Investment Access (Negative List for Foreign Investment Access)* in the *Catalog for the Guidance of Industries for Foreign Investment (Revised in 2017)*[12]. The 2017 negative list still classifies securities firms, FMCs and futures companies as restricted to foreign investment, thus requiring Chinese parties to hold a relative majority of shares. The new negative list for foreign investment access is expected to be officially promulgated by the first half of 2018.

All the policy initiatives discussed in this article have clearly shown the Chinese government's dedication to further open up its financial sector, which will offer broader business opportunities to those foreign investors interested in China's securities markets. We expect China will further open up its financial sector and that specific regulations will be released soon.

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[10] 《外商投资期货公司管理办法（征求意见稿）》 [Measures for Administration of Foreign Investment in Futures Companies (Draft for Comment)] (China Securities Reg. Comm.; issued 4 May 2018, for public comment until 4 Jun. 2018), *available at:* http://www.csrc.gov.cn/pub/zjhpublic/zjh/201805/t20180504_337678.htm (Chinese).

[11] 《国家发展改革委就制定新的外商投资负面清单及制造业开放问题答记者问》 [News Briefing by NDRC on Updating the *Negative List for Foreign Investment Access* and Opening up the Manufacturing Industry] (17 Apr. 2018), *available at*: http://www.gov.cn/xinwen/2018-04/17/content_5283379.htm (Chinese).

[12] 《外商投资产业指导目录（2017 年修订）》 [Catalog for the Guidance of Industries for Foreign Investment] (Nat'l Dev. Ref. Comm., Min. of Fin., Decree No. 4; promulgated Jun. 28, 2017, effective Jul. 28, 2017) 2017 ST. COUNCIL GAZ. 31, available at www.gov.cn/gongbao/content/2017/content_5237697.htm (Chinese).

2. A Big Step Forward - China May Enhance Drug Trial Data Protection (Authors: Kevin Duan, Lin Wang)

On April 26, 2018, the State Drug Administration issued for public comment the *Implementing Measures for the Protection of Drug Trial Data (for Interim Implementation) (Draft for Comment)* (the "**Implementing Measures**")[13]. Compared with the previous *Relevant Policies on Encouraging Innovation in Drug and Medical Equipment and Protecting the Rights and Interests of Innovators (Draft for Comment)* ("**Relevant Policies**") [14], and *Opinions on Deepening the Reform of the Evaluation and Approval System and Encouraging Innovations in Drugs and Medical Devices*[15], the Implementing Measures unprecedentedly expand the duration and scope of data protection for specialized drugs and, for the first time, implement data protection application, review, public notice of authorization, objection and revocation mechanisms.

I. High-standard drugs and drugs of the same variety may be granted 12 years of drug data protection

Compared with existing law and even recently promulgated opinions related to the protection of various types of drug data, the Implementing Measures further broaden the scope of data protection and extend the time of protection. These developments reflect the policy of promoting the research and development of innovative medicines and specialized drugs, while also setting out a high standard for drug trial data protection system. Comparisons between the Implementing Measures and current laws and the Relevant Policies are as shown in the below:

<table>
<tr><th colspan="2">Existing law[16]</th><th colspan="2">Relevant Policies (2017)</th><th colspan="2">Implementing Measures (2018)</th></tr>
<tr><td rowspan="2">Innovative drugs</td><td rowspan="2">6 years</td><td>Innovative drugs</td><td>6 years</td><td>Innovative drugs</td><td>6 years</td></tr>
<tr><td>Innovative therapeutic biological products</td><td>10years</td><td>Innovative therapeutic biological products</td><td>12 years</td></tr>
</table>

[13] *Implementing Measures for the Protection of Drug Trial Data (for Interim Implementation) (Draft for Comment)* (St. Drug Admin.; issued Apr. 26, 2018, for comment until May 31, 2018);

[14] *Relevant Policies on Encouraging Innovation in Drug and Medical Equipment and Protecting the Rights and Interests of Innovators (Draft for Comment)* (China Food and Drug Admin.; issued May 12, 2017, for comment until June 10, 2017)

[15] *Opinions on Deepening the Reform of the Evaluation and Approval System and Encouraging Innovation in Drugs and Medical Devices* (Gen. Office CCCPC, Gen. Office St. Council; promulgated Oct. 8, 2017) 2017 ST. COUNCIL GAZ. 29.

[16] According to Article 20 of Measures for Administration of Drug Registration (2007), "In accordance with the provisions of Article 34 of the Regulations for Implementation of the Drug Administration Law, for a period of 6 years from the date of approval of the original applicant, SFDA shall not approve a subsequent application that uses, without the consent of the original applicant, the undisclosed R&D data and other data generated by the original applicant approved to manufacture or market a drug containing new chemical ingredients unless the submitted data is generated by the subsequent applicant independently"

		Innovative orphan drugs	10years	Orphan drugs (Including indications)	12 years
		Improved new drugs for rare diseases	3 years		
		Innovative pediatric drugs	10 years	Pediatric drugs (Including indications)	6 years
		Improved new pediatric drugs	3 years		
		Generic drugs that have successfully challenged patents and been sold in offshore markets but are being sold as first generics in China	1.5 years	Drugs that successfully challenge patents	To be determined

According to the Implementing Measures, innovative biological products that are brought to market in the China are entitled to up to 12 years of data protection, a period equivalent to that granted under U.S. law[17], which is even greater than 10 years in the EU and 8 years in Japan and Canada[18]. In addition, compared with the Relevant Policies, the Implementing Measures reduce the innovation requirements for orphan drugs and pediatric drugs, by stipulating a general 6-year protection period for those two drug types. Furthermore, Article 7 of the Implementing Measures also provides an "independent operation" rule, which stipulates that where different data protection periods are granted to the same drug, each period will be determined from the respective application approval date for such protection period[19]. Thus, under the new data protection system, applicants will be able to receive additional data protections for orphan drugs and pediatric drugs.

It is notable that, in order to accelerate the internationalization of drug R&D in China and encourage the introduction of specialized drugs, the Implementing Measures further provide that drug registration applications in China submitted with data obtained from international multi-center clinical trials conducted in China can be granted data protection for a designated period that is applicable for the corresponding drug type. However, if the drug registration application in China is later than the drug registration application in other countries or regions, the data protection period that may be awarded will only range from one to five years, depending upon the circumstances, and no protection will be awarded if the drug registration application in China is later than six years following that in other countries or regions[20]. In addition, in order to support the upcoming "acceptance of data from

[17] See 42 U.S.C (United States Code) §262(7)(A): *"Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a)."*

[18] Lei Zhang and Wei Xia, *Study on the Data Protection Clauses for TPP Biopharmaceutical*, Intellectual Property, issue 5 of 2016, p.119.

[19] Implementing Measures at Art. 7: "Protection periods granted for the same drug shall be calculated respectively from the date of approval of the corresponding drug registration applications."

[20] Implementing Measures at Art. 5, paras. 1 and 2: "Innovative drugs approved to enter the domestic market will be entitled to a data protection period of six years, and this data protection period will be doubled to 12 years for innovative biological products for curative uses. For the drugs or biological products for curative uses under applications for entry into the domestic market or for synchronous entry into the domestic market and other

overseas clinical trials" system[21], and to strongly encourage applicants to carry out clinical trials on patients in China, the Implementing Measures also provide that a data protection period of only one fourth of the standard data protection period may be granted for drug registration applications in China solely based upon overseas trial data; a data protection period of one half of the standard may be granted where the underlying clinical trial data is supplemented by trials conducted in China[22].

II. Upon effectiveness, trial data protection applications to be submitted together with drug registration applications.

According to the Implementing Measures, trial data protection applications are required to be submitted together with drug registration applications and are subject to subsequent procedures, such as public notice of acceptance, technical reviews and public notice of authorization.

a. Application: drug registration applicants intending to obtain drug trial data protection should submit the trial data protection application together with the drug registration application, and provide a written statement to describe the reasons and term for trial data protection[23].

b. Acceptance: Upon acceptance of a drug registration application, the drug evaluation institution will publicize the trial data protection application submitted by the applicant for 30 days[24]. Publicizing of the application does not constitute an effective authorization of protection. During this period, the drug evaluation institution will normally review and approve the drug registration application of other applicants for the same-variety drug by use of data acquired on their own[25].

c. Review: the drug evaluation institution will review the applicant's data protection application at the same time when conducting a technological evaluation. If the data protection application

countries/regions by use of data of clinical trials conducted in China or data of international multi-center clinical trials conducted in China, a data protection period of 6 years or 12 years will be granted upon approval of their entry into market(s); for those data under applications for entry into the domestic market by use of data of international multi-center clinical trials conducted in China later than the applications for entry into other countries/regions, a data protection period of one to five years will be granted depending on circumstances, provided that no data protection period will be granted if the former applications are six years later than the latter ones."

[21] See Technical Requirements for Accepting Overseas Clinical Trial Data (Draft for Comment) promulgated by Center for Drug Evaluation, available at: http://news.163.com/17/1020/21/D17LIDSV000187VE.html.

[22] Implementing Measures at Art. 5, para. 3: "For the new drugs under applications for entry into the market by use of overseas data without clinical trial data for Chinese patients, a data protection period equivalent to one-fourth of the period calculated under the above method will be granted; if clinical trial data for Chinese patients are supplemented, a data protection period equivalent to one-second of the period calculated under the above method will be granted."

[23] Implementing Measures at Art. 9, para. 1: "A drug registration applicant, if attempting to apply to the state drug administration for data protection, shall file an application for the protection of trial data for the concerned drug, specifying the length of the data protection period and reasons, when applying for registration to obtain the drug marketing authorization."

[24] Implementing Measures at Art. 9, para. 2: "After a drug registration application is accepted, the drug evaluation department of the state drug administration shall publicize the applicant's application for protection of trial data for 30 days."

[25] Implementing Measures at Art. 13: "Before a drug has its trial data protected, other applicants' applications for the registration of the same-variety drug by use of data acquired on their own may be proceeded with according to the evaluation and approval procedures, and those meeting requirements shall be approved."

complies with the rules, the drug evaluation institution will issue examination findings that specify the reasons for data protection and the period of protection[26].

d. Authorization: drug trial data protection rights will be granted concurrently once the drug registration application is approved and publicized. The *Catalog of Marketed Drugs* will include and publicize the reasons for protection, both the starting and ending dates, and will timely delete information of drugs whose data protection period has expired so that third parties can determine when it is appropriate to submit generic drug applications[27].

III. Notification and objection, guarantee of data exclusivity

The Implementing Measures will also allow data owners to exercise their data exclusivity rights and related remedies.

It should be noted that the drug trial data protection period is not the same as a market exclusivity period. During the data protection period, the drug evaluation institution will not grant drug registration applications submitted based upon the trial data of data protection right holders, but will still examine and approve other drug registration applications submitted based upon independent data.

Relevant provisions of the Implementing Measures provide in that[28], during the data protection period, the data right holder must be notified within 30 days of when a drug registration applicant submits an application based on independent data for a drug that is of the same type as that of the holder. The data protection right holder can raise an objection within 30 days from the date of receipt of the

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[26] Implementing Measures at Art. 10: "When conducting a technological evaluation for the registration of a drug, the drug evaluation institution of the state drug administration shall concurrently evaluate the applicant's application for data protection; if the application is in compliance with the provisions, the drug evaluation institution shall specify reasons for protection and a protection period in an examination conclusion, and make an examination conclusion for the protection of trial data and marketing according to procedures."

[27] Implementing Measures at Art. 11: "The rights to protection of trial data of drugs shall become effective upon approval and publicity of the drug marketing and registration application, with data protection information and drug approval information publicized at the same time. The information on protection of trial data of drugs shall at least include reasons for protection of trial data of drugs, the starting and ending dates of the data protection period, and other information, and shall be set out and publicized in the Catalogue of Drugs for Marketing. Applicants applying for protection of trial data of drugs or any third parties may consult the Catalogue of Drugs for Marketing for protection status and protection period on their own. Upon expiration of the protection period for trial data of drugs, the relevant information shall be promptly deleted from the Catalogue of Drugs for Marketing."

[28] Implementing Measures at Art. 14: "Within the trial data protection period, if an application is filed for the registration of the same-variety drug by use of the trial data acquired independently or upon consent of the marketing authorization holder, in addition to the required corresponding registration application materials, a written statement of the independent acquisition of the relevant data or authorization shall be submitted.
The drug evaluation institution of the state drug administration shall, within 30 days upon acceptance of the above application, notify the data protection right holder, who may, within 30 days upon receipt of the notification, raise an objection with the institution designated by the state drug administration. If there is no objection or no objection has been raised within the time limit, it shall be deemed that the above-mentioned statement of independent acquisition of data is recognized.
Where the data protection right owner raises an objection to the authenticity of the above-mentioned data acquired independently, the drug evaluation department of the state drug administration shall organize and complete data verification within 90 days. If the data are found to be problematic or suspected of being fraudulent, the data shall be dealt with in accordance with the relevant provisions on drug registration administration and it shall be notified to the data protection right holder."

notification. The drug evaluation institution will issue a decision on whether to accept the objection within 90 days. If the decision is not satisfactory, either the generic drug applicant or trial data protection right holder may file for administrative reconsideration or administrative litigation.

The above provisions essentially provide a channel for data protection right holders to exercise their data exclusivity rights. During the data protection period, a data protection right holder can challenge the data of subsequent applicants by filing objections. Further, they may resort to remedies such as initiating administrative reconsiderations or administrative litigation, if the drug evaluation institution decides to support a subsequent applicant's application by finding that the relevant data were sourced independently.

The trial data protection system in the Implementing Measures differs somewhat from how things are handled in the United States. Under U.S. drug trial data exclusivity, if the data protection right holder believes that its data exclusivity rights have been infringed because the U.S. Food and Drug Administration ("**FDA**") has approved an abbreviated new drug application (ANDA) within the trial data exclusivity period, the holder may seek administrative or judicial relief against the FDA's decision[29]. By contrast, the Implementing Measures may enable the data protection right holder to become aware of the possibility that a subsequent applicant may submit a drug registration application by relying on data from other sources at an earlier stage, which would provide more protection to the holder.

IV. Prohibit abuse of rights, requirements on data disclosure, and cancellation of protection period

To prevent abuse of the trial data protection system, the Implementing Measures provide for a data disclosure system and a data exclusivity cancellation mechanism if no drug sales are made for a period of one year.

Regarding the disclosure system, the Implementing Measures stipulate that data protection right holders are required to disclose data under protection from the date of obtaining the data protection authorization[30]. This measure will not only prevent data fraud by subjecting the relevant data to public oversight, but will also help avoid duplicative experiments which may lead to wasted resources. However, it remains to be seen how this system will be specifically implemented, considering that the relevant data may include data right holders' trade secrets or the sensitive personal information of data subjects.

The Implementing Measures also provide for a data exclusivity cancellation mechanism if no drug sales are made for a period of one year. That is, if a drug that has obtained data protection has not

[29] Tong Chu, *Study on Protection of Drug Trial Data under TRIPS Agreement* (First Edition), Intellectual Property Publishing House, January 2015, p. 112.

[30] Implementing Measures at Art. 17, para. 1: "Data protection right holders shall voluntarily disclose their data under protection as of the date when the right is acquired."

been sold on the market for any reason for one year following the date of approval for sale, an interested party may file an application for cancellation of protection with the State Drug Administration[31], which, once verified, will cause the data protection period to be cancelled. After cancellation, other applicants can again submit drug registration and data protection applications for drugs of the same type[32]. The purpose of this mechanism is mainly to encourage the introduction of new drugs as early as possible for the benefit of the public. Therefore, drug R&D enterprises developing the same types of drugs should pay close attention to the sales status of approved drugs, and may again apply for data protection rights if the approved drugs have "no sales for one year." It should be noted that according to Article 4 of the Implementing Measures, if other applicants again submit drug registration and data protection applications, the applications must be entirely based on data acquired independently without reliance on the trial data of others or publicly released research results[33]. Such applications cannot be based upon trial data that have been previously published by the data protection right holder.

V. Patent challenge system not expressly provided, remains to be supplemented with a drug patent linkage system

Compared to the Relevant Policies, the Implementing Measures in their current form do not restrict data protection only to first generics once a successful patent challenge has been made. However, we tend to believe that the protection of "drugs that successfully challenge patents" will be further restricted based upon similar policies in the United States[34] and in consideration of the optimal distribution of pharmaceutical production resources. In addition, it is worth noting that the Implementing Measures fail to specify the definition of "successful patent challenge" and the corresponding protection period[35]. By referring to the 180-day market exclusivity period for new

[31] Implementing Measures at Art. 17, para. 2: "Where a drug under data protection has not been sold on the market within one year from the date of approval for marketing for its own reason, the relevant stakeholder may file an application for revoking the protection period with the state drug administration; if the situation is true upon verification, data protection shall be revoked."

[32] Implementing Measures at Art. 18: "Where the trial data protection of a drug is revoked, the state drug administration may, as of the date when the revocation decision is made, approve other applicants' applications for marketing and registration of the same variety; if an applicant files an application for the protection of drug data at the same time, the data meeting requirements shall be given the corresponding protection period in accordance with provisions."

[33] Implementing Measures at Art. 4: " For the purpose of the Measures, "trial data" refer to the non-clinical and clinical trial data contained in the data package of drug marketing and registration application documents submitted by a drug marketing applicant in accordance with requirements, which are related to the effectiveness of drugs but are not related to drug safety, and which shall meet the following requirements:
1. the data are required to be provided in the drug registration application materials submitted for obtaining the marketing authorization of drugs;
2. the data have not been publicly disclosed before a drug registration application is filed; and
3. the data are acquired independently without reliance on others' trial data or publicly released research results."

[34] Taoxi Lin, Na Yu and Lu Huang, *Research on the first generic drug system and patent challenge strategy of USA*, Chinese Journal of New Drugs, issue 19, Vol. 25, 2016, p. 2171.

[35] Implementing Measures at Art 3, para. 5: "The protection of trial data of drugs refers to the system under which the state drug administration shall, according to legal procedures, grant a certain data protection period to the following drugs for which applicants have obtained marketing authorization based on the test data acquired on their own:…(5) drugs that successfully challenge patents".

drugs under the U.S. *Drug Price Competition and Patent Term Restoration Act*[36], and the drug patent linkage system found in so-called "paragraph IV" certifications[37], we understand that "successful patent challenge" may imply a scenario where a generic drug applicant submits an application for registration together with a statement that potentially triggers litigation under the patent linkage system. The applicant certifies that it can prove through litigations that the patent for the branded drug is invalid, or prove that the applicant's generic drug, including its commercial manufacture, use, and sale, does not constitute patent infringement[38].

The Implementing Measures in their current form leave these relevant provisions blank because the drug patent linkage system is still at a preliminary stage in China. Aspects of the drug patent linkage system remain to be clarified, such as the specific declaration system for patent challenges, patent litigation linkage rules and the stay period[39]. Overall, the patent challenge system, after being promulgated, will be an effective tool to strike a balance between generic drugs and innovative drugs, and will provide a channel for generic drug applicants to seek data exclusivity protection by initiating patent litigations.

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[36] See 21 U.S.C (United States Code) §355(j)(5)(B)(iv): *"…Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant."*

[37] See 21 U.S.C (United States Code) §355(b)(2)(A): "*An application submitted under paragraph (1)…shall also include— a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)— (i) that such patent information has not been filed, (ii) that such patent has expired, (iii) of the date on which such patent will expire, or (iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted…*"

[38] See 21 U.S.C (United States Code) §355(j)(2)(A)(iv): *"An abbreviated application for a new drug shall contain…a certification…(IV)that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted..."*

[39] Lin Wang, Rui Luo, *China May Establish a "Drug Patent Linkage System," How Should Companies Respond?* (Chinese), Han Kun Law Offices, May 27, 2017.

Important Announcement

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