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Legal Updates

Legal Updates

1. Overview of the New Regulations for Private Schools (Authors: Yaohua HU, Laixiang LI)

On January 18, 2017, the State Council officially promulgated the *Several Opinions of the State Council on Encouraging Non-governmental Sectors to Run Schools and Promoting the Healthy Development of Non-governmental Education* (Guo Fa [2016] No. 81) (the "**Opinions**"). On the same day, the Ministry of Education published two regulations regarding private schools on its official website, namely the *Notice of the Ministry of Education and other Four Departments on the Issuance of Detailed Rules for the Implementation of Private Schools Classification Registration* (Jiao Fa [2016] No. 19) (the "**Registration Rules**") and the *Notice of the Ministry of Education, the Ministry of Human Resources and Social Security and the State Administration for Industry and Commerce on the Issuance of Detailed Rules for the Implementation of the Supervision and Management of For-Profit Private Schools* (Jiao Fa [2016] No. 20) (the "**Management Rules**", which, together with the Opinions and the Registration Rules, are referred to as the "**Regulations**"). The Regulations mentioned above are regarded as key rules in the private education industry and supplement the *Private Education Promotion Law of the PRC* (revised in 2016)[1] (the "**Promotion Law**"), as amended on November 7, 2016. The Regulations will help to promote private school classification administration reforms and facilitate the implementation of related preferential policies. This article will provide a brief overview of the Regulations based upon relevant provisions of the Promotion Law.

Approval and Registration

a. Approvals / School Licenses

Based on the Promotion Law, the Registration Rules further clarify that school licenses mustbe obtained to set up both non-profit and for-profit private schools. The Management Rules further specify that establishing for-profit private education institutions is subject to the same requirements applicable to establishing for-profit private schools. We understand this to mean that for-profit private educational institutions also need to obtain school licenses in order to be established. If this is the case, for-profit private educational institutions that have registered with AIC as companies will be required apply to obtain school licenses. We will monitor the latest regulatory developments with respect to this issue.

b. Classification Registration

The Registration Rules set forth different rules for the registration of newly established non-profit

[1] The Promotion Law will become effective from September 1, 2017. For comments on the Promotion Law, please refer to a previous newsletter entitled Comments on the Revisions to the Private Education Promotion Law (Chinese).
（http://www.hankunlaw.com/downloadfile/newsAndInsights/5d6ea3265feb360cd30ab4426cdb5481.pdf）

private schools and for-profit private schools, respectively.

i. Non-profit private schools: Non-profit private schools are to be registered as private non-enterprise units in accordance with the *Interim Regulations on the Registration and Administration of Non-governmental Non-enterprise Units* (the "**Interim Regulations**") or registered as public institutions in accordance with the *Interim Rules on the Registration and Administration of Public Institutions* (the "**Interim Rules**"). The Interim Regulations will be replaced by the *Regulations on the Registration and Administration of Social Services Institutions* (the "**Administration Regulations**"), which has been issued for public comment by the Ministry of Civil Affairs. After the Administration Regulations come into effect, private non-enterprise units will be regarded as "social service institutions."[2] According to the Interim Rules, "public institutions" refer to social service organizations that are organized by state organs or other organizations by using state assets. They are founded for social welfare purposes and mainly carry out education, science and technology, culture and public health activities, etc. According to Article 2 of the Promotion Law[3], public institution-type private schools refer to educational institutions set up by non-state institutions that utilize state assets (excluding state fiscal funds). Thus, the difference between public institution-type private schools and the private non-enterprise unit private schools is that the latter are funded from non-state assets[4].

   With respect to the level of the registration authority, non-profit private universities that provide education at the undergraduate level or above are required to be registered with the relevant departments at the provincial level, while non-profit private schools that provide education at the junior college level or below below should be registered with the relevant department at the county level or above as determined by the provincial government.

ii. For-profit private schools: The Registration Rules only provide that for-profit private schools that have obtained formal approval for establishment should carry out registration with competent AIC in accordance with the laws, but they do not explicitly provide whether such schools must register solely as companies (limited liability companies or limited liability companies), or may be registered as another type of commercial entity. We understand the general practice in this area to be that such schools should be registered as companies.

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[2] http://www.mca.gov.cn/article/zwgk/tzl/201605/20160500000664.shtml

[3] According to Article 2 of the Promotion Law, this law shall be applicable to activities conducted by public organizations or individuals, other than state organs, to establish and run schools and other educational institutions with non-governmental financial funds which are geared towards the needs of society. In cases in which no provisions of this Law are applicable, the provisions in the Education Law and other laws concerning education shall apply.

[4] According to Article 2 of the Interim Regulations, publicly-run non-enterprise units referred to herein mean social organizations founded by enterprise institutions, social groups and other social forces and individual citizens with non-state-owned assets that engage non-profit social services.

According to Article 5 of the Interim Regulations, the publicly-run non-enterprise units must have legitimate properties matching with its business operations, of which the percentage of the non-state-owned assets cannot be less than two-thirds. The start-up capital of the units must meet the minimum standards applicable to the industry.

With respect to the classified registration of existing private schools, the Registration Rules only reiterate the principles provided by the *Decision of National People's Congress Standing Committee on the Amendment of the Private Education Promotion Law of PRC*. That is, where existing private schools choose to register as non-profit private schools, they should revise the school's articles of association and re-register with the government to continue operating. Where the existing private schools choose to register as for-profit private schools, they should carry out financial settlement, apply to the relevant departments below the provincial level to ascertain the ownership of land, school buildings, profits and other school property and pay related taxes, apply for a new school license and re-register with the government to continue operating. In addition, the government at provincial level should formulate the rules related to the amendment of private school registration types in accordance with relevant state rules and based upon actual local conditions.

Support Policies

One highlight of the Opinions the clarification of the support policies for private schools. The support policies mainly include:

a. Financial support

The government's financial support for private education is required to be included in its budget. Local governments at all levels are to establish and improve the government subsidies system and specify projects, targets, standards and purposes of the subsidies. The government will improve the standards and procedures for services procurement, establish performance evaluation systems, and formulate specific policies and measures related to the purchase of degree courses, curriculum materials, scientific research achievements, vocational training courses and policy consultation services from private schools. The local governments may establish private education development foundations in reference to state rules applicable to foundation management, support to establish corresponding foundations and organize various types of activities that will help to develop private education.

Han Kun Comments: The above policies provide a basis for governments at all levels to extend financial support to private schools in which they have no ownership interest.

b. Tax preferences

Real property and land that enterprises use to operate all types of schools and kindergartens are exempt from property tax and urban land use tax. Enterprise donations to support education is eligible for an income tax deduction of up to 12% of total annual profits. Individual donations for education may also be deducted when calculating the individual's taxable income. Non-profit private schools are subject to tax treatment equal to that of public schools. This means that, following tax-exempt certification, non-profit private schools can operate as tax-exempt entities in accordance with the tax laws, and their non-profit income will be exempt from enterprise income

taxes. In addition, private schools will be subject to the same electricity, water, gas and heat price as public schools.

Han Kun Comments: Relevant tax matters under the above policies still need to be further clarified. For example, when private schools make charitable donations, can they be considered as charitable organizations in accordance with the Charity Law? As for non-profit private schools, can they be directly regarded as non-profit organizations as defined in Article 26 of the Enterprise Income Tax Law?

c. Land policy

Land for constructing private schools is managed as science and education-use land. Non-profit private schools will enjoy the same policy as that applicable to public schools and can acquire land by way of assignment. Land will be transferred to for-profit private schools according to corresponding state policy. Where there is only one purchaser bidding for a land parcel, the land may be assigned to the purchaser in accordance with an agreement. Afterwards, if the purchaser changes the use purpose of all or part of the land, the government will reclaim the purpose-changed land and re-sell the land to a purchaser at a new market price according to law.

Han Kun Comments: In addition to acquiring land through bid invitation, auctioning and listing, for-profit private schools may also acquire land pursuant to an agreement. This provides an opportunity for for-profit private schools to acquire land at a below-market prices. However, if the land user subsequently changes the purpose of the land purchased at a lower price, there is a risk of the government reclaiming such land.

d. Broadening financing channels

Financial institutions are encouraged to develop financial products suitable for private schools to the extent the risks are controllable. Financial institutions should explore business methods of providing loans to private schools as pledged by the schools' operating income and intellectual property and aim to provide the schools with diversified financial services including bank loans, trusts and financial leases. Various societal forces are encouraged to make donations to non-profit private schools.

Han Kun Comments: It is noteworthy that, according to the Management Rules, for-profit private schools are prohibited from mortgaging their teaching facilities for loans or guarantees. The profits of the business operations of the schools are to be allocated after annual financial settlement.

e. Equal Student Subsidy Policy

Private school students will enjoy the same student subsidy policies as those applicable to public schools, such as policies regarding student loans and scholarships. Governments at all levels should establish and improve the support system for private school student loans business and increase the proportion of financially-disadvantaged students that are qualified to receive financial assistance in private schools. Private schools should establish a sound scholarship assessment

and grant program, and should extract no less than 5% from the tuition revenues to reward and fund students. The government should implement preferential policies for education-related donations and encourage and guide enterprises and public institutions, social organizations and individuals to provide scholarships to private schools.

Han Kun Comments: Private schools should extract no less than 5% from the tuition revenue to provide scholarships, which will be deducted from allocable school profits.

Corporate Governance of Schools

According to Article 16 of the Management Rules, for-profit private schools are to set up six internal organizations, which are the board of directors, supervisors (or board of supervisors), administrative department, party organization, faculty congress and trade unions. The following highlights should be noted with respect to these organizations:

a. Board of Directors

According to Article 16 of the Management Rules, for-profit private schools are to establish a board of directors. Therefore, we understand that the Company Law provision that allows a company to have an executive director rather than a board of directors does not apply in the case of for-profit private schools. Also, pursuant to Article 44 of the Promotion Law, the quorum of a private school board of directors can be no fewer than five persons, while the board quorum of a limited liability Company under the Company Law must be at least three members.

In line with Article 22 of the Promotion Law, the Management Rules specify that the board, rather than the shareholders' meeting or investors, is the highest decision-making body of for-profit private schools. If a for-profit private school intends to carry out a division, merger, termination or other major changes, it should initially seek the approval of its board before submitting an application to the examination and approval authority for review and approval. However, according to the Company Law, the decision-making body with similar roles in a company is the board of shareholders (or shareholders' meeting) of the company. Therefore, in case of the occurrence of any of the above events, we recommend incorporated for-profit private schools to seek approval of both the board of directors and the board of shareholders (or shareholders' meeting).

b. Supervisors (Board of Supervisors)

The Promotion Law has no provisions regarding supervisors (board of supervisors). However, the Management Rules provide detailed rules with respect to the supervisors (board of supervisors). According to the Management Rules, faculty representatives must make up at least 1/3 of the board of supervisors of for-profit private schools, and the board of supervisors should have party leadership organization members. However, the Management Rules do not provide that, if a school only

appoints one or two supervisors[5] but does not establish a board of supervisors, whether the supervisors should be faculty representatives, party leadership organization members or other specified persons.

The Management Rules also set forth that a natural person cannot serve as a member on the board of directors and the board of supervisors of a for-profit private school at the same time. In addition, in accordance with Article 51 of the Company Law, a senior officer of a company cannot simultaneously serve as a supervisor (this includes the manager, deputy manager, chief financial officer, board secretary in case of a listed company and other persons designated by the articles of association of the company). This provision applies to for-profit private schools established in corporate form.

c. Principals

The Promotion Law provides that the principal of a private school is in charge of teaching activities and school administration, and is appointed by the school's council or board of directors. The Opinions further clarify that private school principals should be familiar with the education industry and related laws and regulations, have five years or more of school management experience, and have good personal credit.

The Opinions also provide for nepotism avoidance measures for key school management positions. However, the Opinions fail to explain how these measures apply between private school founders / investors and key management personnel or between the key management positions.

Standardizing school operations

The Management Rules provides detailed rules with respect to the organizational structure, teaching activities, financial assets and information disclosure of for-profit private schools and specifies punishment for violations. The Management Rules also provide for the "school founder blacklist" system. According to Article 48 of the Management Rules, under any of the following circumstances, the founder of for-profit private schools shall be put onto the blacklist and shall be prohibited from establishing or participating in the establishment of other for-profit private schools:

i. The corporate property rights of the school are not fully protected.

ii. The for-profit private school was put onto the list of enterprises with abnormal operations or the list of enterprises with serious legal violations or dishonest conduct.

iii. School operating conditions are not up to standard.

iv. Failed in the annual review in the most recent two years.

[5] According to Article 51 of the Company Law, A large-scale limited liability company shall have a board of supervisors, which shall be composed of not fewer than 3 members. A small-scale limited liability company with only a few shareholders may have one or two executive directors without establishing a board of directors.

v. Other circumstances prescribed by laws and regulations.

It is believed that the "school founder blacklist" system will restrict the subsequent investment activities of those that have been placed on the list.

Strengthening Party Leadership

In addition to specifying the establishment and functions of the general decision-making and management organizations of private schools, the Regulations also require the strengthening of the party in private schools. According to the Regulations, the party organization is the "political core ... which should be responsible for directing, guaranteeing and supervising decision-making on matters with respect to the aim of the school operations and the major interests of teachers and students."

i. All schools should have party organization coverage[6]. When applying to establish private schools, in addition to the materials required by the Promotion Law and other laws and regulations, the applicant should also submit school party building-related materials[7].

ii. In private universities, government commissioned-supervisors must be the person in charge of the party organization[8]. According to Article 25 of *Several Provisions on the Administration of Non-publicly Funded Universities*, a commissioned supervisor refers to the person delegated by the provincial education department to the private universities in accordance with the relevant state provisions, whose responsibilities are to supervise the universities' implementation of relevant laws, regulations and policies. However, it is awaiting to be further clarified whether the person-in-charge of the party organization in private universities must be the commissioned supervisor, or whether the school will initially appoint the person-in-charge of the party organization and propose to the provincial education department for him to be designated as a commissioned supervisor. If it is the former case, it would be difficult for the founder/shareholders' committee representative of the private university to appoint the person-in-charge of the university party organization.

iii. Actively promoting the system of "cross appointment of party members between school and party organizations," means that party organization members[9] may simultaneously hold posts in decision-making and administrative bodies. Principals and deputy principals who are party members can also have seats in the party leadership organization pursuant to relevant party articles. The board of supervisors should have party leadership organization members[10].

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[6] Article 3 of the Opinions.

[7] Article 5 of the Registration Rules.

[8] Article 3 of the Opinions.

[9] Article 20 of the Management Rules further clarify that "the secretary of the party organization shall be appointed to the board of directors or administrative organs through legal procedures".

[10] Article 19 of the Opinions.

iv. Local governments are required to consider school party organization building and the party's leadership as important factors in the annual inspection of private schools[11].

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2. Shanghai Further Optimizes Local Policies to Promote the Establishment of Regional Headquarters of Multinational Corporations (Authors: David TANG, Jun LI, Serina WEI)

Shanghai, as the leader of further opening up and attracting foreign investment in China, has recently promulgated the revised *Regulations of Shanghai Municipality on Encouraging Multinational Corporations to Establish Regional Headquarters* ("**2017 Regulations**") on February 14, 2017, which further optimizes the investment, economic development and governmental service environments, in order to spur multinational corporations ("**MNC**") to consider Shanghai as their first choice for establishing regional headquarters.

In 2002, Shanghai promulgated the first interim regulations in China to encourage multinationals to establish regional headquarters ("**Regional Headquarters**").[12] These regulations were revised twice in 2008 and 2011[13], and implemented as the *Regulations of Shanghai Municipality on Encouraging Multinational Corporations to Establish Regional Headquarters* (Hu Fu Fa [2011] No. 98) ("**2011 Regulations**"). Under these regulations, Shanghai developed a basic set of preferential policies to promote MNC to move their regional headquarters to Shanghai, including financial support and awards, convenience in managing funds and centralized management of foreign exchange, convenience in exit-entry formalities and employment permits, and other preferential policies such as talent introduction and more convenient customs clearances and so on.

The 2017 Regulations mainly concentrate on revising the following:

Broadening the scope of Regional Headquarters

a. Introducing Quasi-Headquarters Entities

One of the highlights of the current revision is the official introduction of "Quasi-Headquarters Entities". Quasi-Headquarters Entities refer to wholly foreign-owned enterprises (including branches) that, despite not meeting the standards for a multinational corporate regional headquarters, effectively provide multiple support service functions, including management decision-making, fund

[11] Article 3 of the Opinions.

[12] *Interim Regulations on Encouraging Multinational Corporations to Establish Regional Headquarters* (Hu Fu Fa [2002] No. 24), which promulgated on July 20, 2002.

[13] The regulations were revised successively on July 7, 2008 and December 19, 2011, and the immediate predecessor to this revision is *Regulations of Shanghai Municipality on Encouraging Multinational Corporations to Establish Regional Headquarters* (Hu Fu Fa [2011] No. 98).

management, procurement, sales, logistics, settlement, research and development, and training, for the Multinationals in a region that includes more than one country. By introducing Quasi-Headquarters Entities, Shanghai has expanded the scope of enterprises entitled to preferential incentives granted to the Regional Headquarters of MNC. If the Shanghai Municipal Commission of Commerce ("**SMCC**") recognizes a wholly foreign-owned enterprise as a Quasi-Headquarters Entity, the enterprise will enjoy the same advantages as a Regional Headquarters.

The standards and preferential policies for Quasi-Headquarters Entities were first seen in the *Supplementary Provisions on the Implementing Opinions on the "Provisions of Shanghai Municipality on Encouraging the Establishment of Regional Headquarters by Multinational Companies,"* which was jointly promulgated in 2014 by 4 local Shanghai authorities, including the SMCC. The 2017 Regulations integrate the regulations in these supplementary provisions with respect to Quasi-Headquarters Entities. Meanwhile, the 2017 Regulations further adjust the recognition requirements for Quasi-Headquarters Entities (described in the following paragraph), so that the recognition of such entities and preferential policies will be implemented consistently.

b. Cancelling enterprise type and business scope requirements for Regional Headquarters

Before this revision, an enterprise recognized as a Regional Headquarters could only be established as either an investment company or a management company. The 2017 Regulations remove this limitation and allow a wholly foreign-owned enterprise that satisfies all of the requirements to be recognized as a Regional Headquarters, regardless of entity type (the identification requirements are described in the following paragraph). Furthermore, the limitation on business scope description is excluded from the 2017 Regulations, thereby allowing enterprises to enjoy more discretion with respect to business scope.

c. Adjustment of recognition requirements

Investment companies and management companies were previously subject to different standards in order to be recognized as Regional Headquarters. Investment companies could be directly recognized by SMCC as Regional Headquarters and thereafter enjoy policy benefits regardless of the assets of its parent company and the capital contributions of its parent company that had been paid in China. By contrast, management companies were required to satisfy certain requirements before applying to SMCC for recognition. The 2017 Regulations explicitly set out that certain requirements which must be satisfied for both investment companies and management companies (Article 5 of the 2017 Regulations).

The recognition standards specified in the former regulations and in 2017 Regulations are set out below:

Type of Regional Headquarters	**Regulations before the revisions**	**2017 Regulations**
Investment	Can be directly recognized as	

Company	Regional Headquarters	
Management Company	1. The minimum total assets of the parent company is USD 0.4 billion; 2. a) The total accumulative registered capital for the parent company's investment that has been paid in China cannot be less than USD 10 million, and the number of enterprises that the management company is authorized to manage in and outside of China by the parent company cannot be fewer than three; or b) the number of enterprises that the management company is authorized to manage in and outside of China by the parent company is not fewer than six. 3. the registered capital of the company cannot be less than USD 2 million	1. Wholly foreign owned enterprises which are independent legal person status; 2. The minimum total assets of the parent company is USD 0.4 billion. Considering the asset light approach of the service industry, the minimum amount of total assets of the parent company enterprise engaging in a service industry is permitted to be USD 0.3 billion; 3. a) The total accumulative registered capital for the parent company's investment that has been paid in China cannot be less than USD 10 million, and the number of enterprises that the company is authorized to manage in and outside of China cannot be fewer than three; or b) the number of enterprises that the company is authorized to manage in and outside of China by the parent company is not fewer than six. 4. The registered capital of the company cannot be less than USD 2 million.
Quasi-Headquarters Entities	Not specified in the 2011 Regulations. *Implementing Opinions on the "Provisions of Shanghai Municipality on Encouraging the Establishment of Regional Headquarters by Multinational Companies"* in 2014: 1. The total assets of the multinational corporation can be no less than USD 200 million, and it	1. Wholly foreign owned enterprises or their branches which have independent legal person status; 2. The total assets of the parent company can be no less than USD 200 million, and it has established and invested in at least 2 foreign-invested

	has established and invested in at least 3 foreign-invested enterprises within Mainland China, with at least 1 of them registered in Shanghai; 2. The chief person in charge of the regional business and the senior management personnel are based in Shanghai for work on a long-term basis; and 3. The Quasi-Headquarters Entity occupies an operating space of 500 square meters or more, and has 50 or more employees performing the functions of headquarters operations and management.	enterprises within Mainland China, with at least 1 of them registered in Shanghai; 3. The registered capital cannot be less than USD 2 million; as for branches, the operating funds allocated to them by the head office cannot be less than USD 2 million.

d. Adjustments to application document requirements

The revisions delete the requirements for capital verification reports and authorization documents, as well as the personal identification of the legal representative of the Regional Headquarters. The revisions now require an auditor's report for the parent company for the preceding year. This adjustment keeps the required documents consistent with the conditions for recognition, and also coincides with the reforms of the registered capital subscription system. Further, the involving of the parent company's audit report reflects the SMCC's practical attitude towards the recognition of Regional Headquarters, and shows that the authority is more concerned about the overall condition of the multinational corporation.

More policy conveniences

a. Shortening of time to receive recognition

After the revisions, the statutory time limit for the SMCC to recognize a Regional Headquarters will be shortened from 10 business days to 8 business days.

b. Clarifying the scope of fund management business that Regional Headquarters can participate in

The 2017 Regulations specify that Regional Headquarters and Quasi-Headquarters Entities can participate in the centralized management of foreign exchange funds as prescribed in the

Regulations on the Centralized Operation and Management of Foreign Exchange Fund of Multinational Corporations, and encourage Regional Headquarters and Quasi-Headquarters Entities to participate in cross-border RMB business. Regional Headquarters and Quasi-Headquarters Entities based in the Shanghai Free Trade Zone can also open free trade accounts. These changes further simplify the procedures for foreign exchange fund management and cross-border payments within multinational corporations, and improve the efficiency of fund utilization.

Follow-on support policies from district governments

This Revision authorizes and encourages district governments in Shanghai to develop their respective implementing policies that fit in their practical conditions to establish a favorable environment for the development of Regional Headquarters. This will act to further refine the provisions of 2017 Regulations.

Conclusion

Compared to the policies of other cities, the revised 2017 Regulations relax the recognition requirements, simplify documentation requirements, shorten the approval time, and further specify the preferential policies that include fund management, exit-entry formalities and talent introduction, which undoubtedly will increase Shanghai's competitiveness as the first choice for multinationals to establish Regional Headquarters. Moreover, given the revision repeals the *Implementation Opinions of Shanghai Municipality on Encouraging Multinational Corporations to Establish Regional Headquarters (Hu Fu Ban Fa [2012] No. 52)*, including the financial support and reward policies found in the implementing opinions, we expect new implementing provisions to be issued soon to address these financial support and reward policies, and we expect more detailed policies to be promulgated by the SMCC and district governments in this area.

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3. Legal Analysis of CMO Contracts (Authors: Min ZHU, Effy SUN)

On May 26, 2016, the State Council promulgated the Pilot Program for the Drug Marketing Authorization Holder System, announcing implementation of the marketing authorization holder ("**MAH**") program in 10 pilot provinces and cities. Within the pilot areas, drug MAHs may entrust qualified contract manufacturing organizations to manufacture market-authorized drugs, regardless of whether the MAH possesses production capacity. Before this, MAHs were only allowed to use contract manufacturers in the case of insufficient production capacity.

Contract manufacturing can effectively integrate the production capacity of pharmaceutical

companies, promote the development of high-quality pharmaceutical enterprises and facilitate the rational allocation of industry resources. Regulators are also vigorously promoting contract manufacturing. Whether the contract manufacturing is MAH-related or general in nature, contract manufacturing organization contracts ("**CMO Contracts**") lay a foundation for cooperation between principals and contract manufacturers, and play a key role in protecting all parties' interests and guaranteeing drug production quality. Based on our experience in helping clients to handle contract manufacturing matters, and our extensive study of various litigation cases and agreements, we consider the following CMO Contract terms to significantly impact the rights, obligations and responsibilities of contracting parties, and therefore require special attention when negotiating and concluding such contracts:

Quality Agreements

Drug quality agreements are an indispensable supplemental document to CMO Contracts, which may be signed separately or included as an annex. The contents of these two documents are obviously different. CMO Contracts mainly deal with procedural matters, such as production cooperation methods, rights and obligations of the parties, production plans, packaging and shipping, production transfers and contract termination conditions. Quality agreements mainly address matters related to quality control and management, such as product quality and safety obligations, production process change management, quality control and clearances, and liability for damages from product defects. CMO Contracts and drug quality agreements complement and are indispensable to each other in a manner similar to the relationship between GMP operating procedures and process specifications.

Quality agreements are, unfortunately, often missing from domestic CMO transactions. Since domestic pharmaceutical companies fail to fully understand the importance of quality agreements, they rarely sign a separate quality agreement. The quality standards and quality control management and control provisions included in CMO Contracts also tend to be very simple and far from sufficient. This causes trouble if disputes subsequently arise between the parties.

Intellectual Property Rights

Intellectual property rights provisions mainly provide for the licensing and use of technical secrets, patents and trademarks of contract manufactured drugs. The following issues should be clearly stipulated in these provisions.

Ownership of Contract/Cooperative Research Products: Some CMO Contracts not only provide for contract manufacturing, but also contain provisions relating to contract or collaborative research. The parties should expressly agree upon the ownership of the products from the research. Absent such an agreement, the products of contract research belong to the developer, and the products of collaborative research are jointly owned among all parties to the cooperative research. Furthermore,

if a party refuses to apply for a patent related to a research product, other parties cannot apply for that patent. However, if a party waives its right to apply for a patent related to a research product, other parties can apply for the patent and the waiving party may implement the patent free of charge.

Technical Improvement Rights and Ownership of Those Rights: Contract manufacturers implement and use the principal's technical secrets and may create new intellectual property rights during drug manufacturing. Considering drug patents or technical secrets lie at the core of a pharmaceutical company's competitiveness, the parties should clearly agree upon whether the contract manufacturer has the right to amend and improve/develop the patents, technical secrets and other project information provided by the principal. If the contract manufacturer is granted a right to make improvements, the parties should further agree on the ownership and handling of such improvements, including but not limited to the right to apply for patents, whether the improvement can be protected as a trade secret, and whether the improvement can be disclosed or licensed to any third party.

Intellectual Property Infringement: Principals must ensure that formulas, technical and quality documents, trademarks and packaging that it provides do not infringe on the rights of a third party, including intellectual property rights. Unless otherwise agreed by the parties, the principal will be held fully liable for damages if a contract manufacturer is sued for infringement of a third party's legitimate rights and interests due to its use in the production process of a patent, technical secrets or trademarks in accordance with the contract. If the contract manufacturer also provides any intellectual property for purposes of performing the contract, it should make the same representations and warranties as above.

It practice, however, we often see that intellectual property terms are still missing from domestic CMO Contracts, despite being of great concern to foreign pharmaceutical companies.

Confidentiality Provisions

CMO Contracts may involve various type of confidential information. In order to avoid disputes arising between the parties with respect to determining which technical drug content and intellectual property rights are subject to confidentiality provisions and to better protect the interests of both parties, CMO Contracts should define the scope of confidential information as clearly as possible, either by providing a definition that includes several express examples or itemizing all information that is deemed confidential in an annex attached to the CMO Contract. Many technical secrets, including but not limited to drug formulas, ingredient descriptions, production processes and procedures, quality standards and inspection records may be regarded as confidential information related to the CMO Contract, which will be subject to the approval of the parties based upon actual circumstances.

In addition, technical drug information is generally considered a trade secret unless a patent has been applied for with respect to that information. In judicial practice, in deciding whether certain

information is to be protected as a trade secret, the court will consider several factors including whether such information is "unknown to the public," whether it "has economic benefits and practicability" and whether "the information owner has taken protective measures." In particular, the third factor is most important judgement criteria, and is also the focus of disputes. There was a case in which the judge denied certain information as confidential trade secret information on grounds that the information owner failed to take protective measures with respect to such information. We recommend that relevant provisions be drafted carefully by referring to the Supreme People's Court's judicial interpretations on unfair competition civil cases and based upon the actual circumstances of the project.

In China, domestic pharmaceutical companies have not paid enough attention to the protection of confidential information. Even confidentiality provisions contained in CMO Contracts tend to be poorly drafted, and are sometimes simply a standard boilerplate term reading as "any party shall not disclose the content of this contract and any information including the technical information related to the drug hereunder to any third party." This is far from enough in practice for CMO transactions, which are complex and often involve substantial technical secrets.

Rescission

CMO Contracts may be terminated by operation of law or through the maturity of any agreed terms. In both cases, the conditions for termination should be clearly provided in the contract. With respect to termination by the operation of law, in order to avoid misunderstandings and to mitigate the burden of proof in litigation, we recommend that CMO Contracts restate the statutory causes for termination as provided in the Contract Law and specify those actions that are regarded as committing a "delay in performing significant obligations" or "other breaches of contract." Although CMO Contracts generally stipulate that the contract manufacturer should have a Drug Production License and a GMP certificate to become a qualified contract manufacturer, there have been cases where judges held that the absence of such a license or certificate does not necessarily constitute a legal cause for termination of a CMO Contract.

However, the burden of proof for statutory contractual termination is relatively high. Furthermore, in the process of contract manufacturing, either party may undergo commercial adjustments, production transfers or become unqualified to engage in contract manufacturing due to administrative punishment. In such cases, a party may wish to terminate the CMO Contract and seek new partners to ensure the continuation of normal business operations. To ensure the right to exit, we recommend CMO Contracting parties to obtain as many rights to terminate as possible. Causes that can result in the termination of CMO Contracts include but are not limited to personnel requirements and staffing, compliance and regulatory control, document management systems, GMP supplier quality assurance programs, environmental requirements, raw material controls, test controls, unqualified products (defects) and the investigations thereof, product manufacturing and release, product complaints and packaging and shipping.

Contract Amendments

In most cases, the MAH and the contract manufacturer would prefer to form and maintain a long-term cooperative relationship, because the termination of a CMO Contract requires significant manpower, material and financial resources to transfer production. Provided the circumstances related to the contract manufacturing have not undergone any significant changes and the contracting parties are willing to continue performing the contract, the parties may agree to allow for amending the CMO Contract, including the terms and methods for making amendments. In fact, amendment clauses are as important as termination clauses, which together constitute a complete mechanism to protect the parties' rights and interests.

In practice, many CMO Contract items may need to be changed in various ways, such as product formulas, manufacturing processes, quality standards and requirements, manufacturing process quality control and quality operation systems (such as key quality personnel are subject to administrative penalties due to bad management, etc.). In addition, since the healthcare law and policy are undergoing significant reforms, the performance of CMO Contracts may also be impacted by many unpredictable macro-environmental factors. In light of this, we recommend the parties to reasonably anticipate such changes and agree upon the relevant means of handling them in the CMO Contract, provided the overall cooperation framework and core interests of the contracting parties are not harmed. In practice, it is a test of the drafter's ability to properly align the termination and amendment provisions in CMO Contracts.

Default Liability Provisions

For a CMO Contract, the importance of default liability provisions can never be overemphasized. Since common and stable business practices have yet to be established in the CMO industry in China, and the macro-environment of the pharmaceutical industry in China is undergoing rapid and dynamic change, CMO Contracts must include certain penalty and control mechanisms to protect the contracting parties' legitimate rights and interest. Based upon actual circumstances, the parties may agree upon default provisions with respect to the following matters: contract assignment, delayed delivery, unqualified products, insufficient order quantities, intellectual property rights, confidentiality liability, non-competition, price payment, self-dealing, maintenance of quality systems and contract manufacturing plans that are affected by administrative penalties, etc.

Correspondingly, CMO Contracts should further provide reasonable relief entitled to non-defaulting parties in the event of a default. Remedies for default mainly include penalty and liquidated damages, which will be decided by the parties based upon the actual circumstances of the project. If a penalty is provided as a remedy for breach, when a default arises, the non-defaulting party may directly claim against the defaulting party for payment of the penalty. The challenge for the drafter is how to determine a reasonable amount for the penalty beforehand. However, if liquidated damages are chosen as a remedy, the non-defaulting party will be obliged prove that its losses were

suffered due to the default. This means that the non-defaulting party will be subject to a greater burden of proof in litigation.

Generally, for some unquantifiable acts of default, such as changes that occur to the quality systems and delayed return of articles or materials, the parties may agree on a fixed penalty amount. Penalties for quantifiable acts of default may be determined based upon the value of the products involved, such as delays in product delivery and unauthorized sales or unauthorized contract assignments.

Production Transfers

A party may wish to transfer drug production to a new contract manufacturer or relocate the project to a new location because of the termination of a CMO Contract due to substantial breach of contract, or because of the adjustment to a party's strategic or business plans. Therefore, CMO Contracts should clearly provide for the transfer of production, in particular with respect to the following matters:

a) Assistance obligations. The contract manufacturer should be required to designate an appropriate person who is responsible for answering questions from the principal or the new contract manufacturer selected by the principal. In addition, the contract manufacturer should provide all written documents in its possession that are necessary for manufacturing qualified products, such as test records, government approval documents, audit and inspection information, technical parameters and product standards.

b) Term setting. The process of transferring production is long and complex, and may involve a significant handover work. In order to ensure a smooth and orderly transfer process, CMO Contracts should provide a sufficient transition period, normally 12-24 months, based upon actual project circumstances. In addition, CMO Contracts should also stipulate for a continuous supply of products during the transition period.

Transferring production is very different in China's overall industry environment compared to other countries. For example, domestic CMO Contracts often fail to clearly stipulate with respect to the allocation of transfer costs if the production transfer is necessary due to reasons attributable to the contract manufacturer. In other countries, the CMO business model is relatively mature and the principal and contract manufacturer have equal footing in their cooperation. In the case of transferring production, the transfer costs would be allocated between the parties according to their degree of fault. However, in China, as MAH has been recently launched and is still in an early stage, the contract manufacturer is often in a strong position. By contrast, the principal is in a relatively weaker position in the arrangement. This requires the principal to fight even harder to protect its rights when drafting CMO Contracts.

Purchases of Insurance

Currently, an insurance policy is a necessary document to apply for a MAH certificate. Therefore, whether required by a CMO Contract or not, the principal must purchase the relevant insurance as a MAH. However, there is no clear stipulation with respect to whether contract manufacturers need to purchase insurance. The CMO Contract should clearly set forth whether the contract manufacturer needs to purchase comprehensive liability insurance or property damage insurance related to its own production facilities and equipment, or is obliged to purchase the clinical trial liability insurance, drug quality and safety liability insurance or additional drug recall cost insurance related to the contracted drugs. The premium is determined by considering various factors, including but not limited to the amount of cover, expected sales, variety and destination of the contracted drugs.

In other countries, both the principal and contract manufacturer are required to purchase the relevant insurance, and the CMO Contracts clearly stipulate the minimum limit of liability for the occurrence of a single insured event, as well as the aggregate liability limitation for all insured events.

Summary

Generally speaking, both CMO Contracts and quality agreements are complicated transaction documents that cover wide range of issues. CMO Contracts concluded by foreign pharmaceutical enterprises and experienced domestic pharmaceutical companies always come in the form of several dozen pages, which is in stark contrast with the leaner contracts prepared by some domestic enterprises. This article is too brief to fully address all legal issues related to CMO Contracts. In practice, many legal issues should be analyzed on case by case basis based upon the actual progress of the project. Nonetheless, we recommend that parties reach CMO Contracts that are as detailed and clear as possible before the project commences.

Important Announcement

This Newsletter has been prepared for clients and professional associates of Han Kun Law Offices. Whilst every effort has been made to ensure accuracy, no responsibility can be accepted for errors and This Newsletter has been prepared for clients and professional associates of Han Kun Law Offices. Whilst every effort has been made to ensure accuracy, no responsibility can be accepted for errors and omissions, however caused. The information contained in this publication should not be relied on as legal advice and should not be regarded as a substitute for detailed advice in individual cases.

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