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Newsletter

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Legal Updates

1. Legal Analysis of Illegal Pharmaceutical and Medical Device Advertising under the New Advertising Law (Authors: Min ZHU, Chao WANG)

The pharmaceutical, medical device, and food (including health food) industries have always been particularly prone to illegal advertising. Since September 1st, 2015 when the new *Advertising Law* formally entered into force, the food and drug administrations and administrations for industry and commerce ("FDA" and "AIC," respectively) have made greater efforts in the fight against illegal pharmaceutical and medical device advertising. As indicated by the disclosed monitoring information regarding illegal pharmaceutical and medical device advertising, some noteworthy changes have emerged with respect to the illegal advertising activity in the pharmaceutical and health fields, and there also exist some general and common problems.

New Provisions Concerning Pharmaceuticals and Medical Devices in the New *Advertising Law*

The new *Advertising Law* adds many new provisions regarding pharmaceuticals and medical devices, and certain provisions have been updated ranging from the scope of pharmaceuticals for which advertising is prohibited, notices in advertisements, forms of advertising, endorsements, protection of minors, and penalty rules, including in detail the following:

a. Article 15: in addition to "narcotics, psychotropic pharmaceuticals, toxic pharmaceuticals, and radioactive pharmaceuticals," for which advertising was prohibited under original provisions, "pharmaceutical precursor chemicals, as well as pharmaceuticals, medical devices, and treatment methods for drug addiction treatment" have been added to the scope of prohibited advertisements.

b. Paragraph 1 of Article 16: this clause creates a new provision which, in part, prohibits the use of spokespersons for endorsements or testimonials in any advertising for medical treatment, pharmaceuticals, medical devices, or health foods.

c. Paragraphs 2 and 3 of Article 16: it has been newly added that the content of pharmaceutical advertising must be consistent with that indicated in the instructions approved by the drug administration authorities. Contraindications and adverse reactions must be marked conspicuously, and if any registered certificate of a medical device product contains any contraindication or precaution, the product advertisement must display conspicuously the words "see instructions for details about contraindications or precautions."

d. Article 19: in order to prevent "advertorials" that evade advertising examination and supervision, it has been newly regulated that broadcasting stations, television stations, newspapers,

periodicals, audio and video publishing entities, and internet information service providers cannot publish advertisements for medical treatment, pharmaceuticals, medical devices or health foods in a disguised manner through the introduction of health or health maintenance knowledge.

e. Article 40: a provision has been added to prohibit mass media advertising which targets minors for medical treatments, pharmaceuticals, health foods, medical devices, cosmetics, alcohol or beauty products, or advertising for online games unfavorable to the physical and mental health of minors.

f. Articles 55, 57, 58, 59, and 62: the provisions concerning penalties raise the standards for fines, add the penalties of revoking business licenses, cancelling advertisement approvals, and refusing to accept advertisement examination applications by the breaching parties for a period of one year, and newly establishing legal liabilities for advertising spokespersons.

Changes in Illegal Pharmaceutical and Medical Device Advertising

a. Overall Growth in Illegal Pharmaceutical and Medical Device Advertising

According to supervisory reports disclosed by some provinces, the rate of illegal advertising has clearly risen both overall and in the areas of pharmaceuticals and medical devices. To a certain degree, this is because, compared with the original law, the new *Advertising Law* has made many changes to the specific content of legal provisions and criteria for determining illegal advertising, which has resulted in broader legislation and enforcement, stricter determining criteria, and more severe punishment.

Additionally, among various forms of illegal advertising, the amount of illegal advertising activity in the areas of pharmaceuticals and medical devices is strikingly high. As shown by the statistics from Beijing with respect to areas in which illegal advertising is concentrated, the amount of illegal pharmaceutical and medical device advertising ranks first or second among advertising categories which include internet, automobile sales, medical and clinic services, insurance, tourist services, and other types of household advertising.

b. Clear Significance of the Handling of Illegal Celebrity Endorsements

Paragraph 1 of Article 16 of the new *Advertising Law* adds the provision that any advertisement for medical treatments, pharmaceuticals, medical devices, or health foods cannot use spokespersons to make endorsements or testimonials. The Article 2 definition, together with this paragraph, introduces the concept of “advertising spokesperson,” which not only includes professional organizations, specialists, or ordinary persons such as “medical research institutes, academic institutions, medical authorities or experts, doctors, or patients,” as stated in the original provision, but has now been broadened to include the much criticized “celebrity spokesperson.”

In reality, celebrity endorsements do not account for a substantial amount of pharmaceutical and medical device advertising. However, due to the social effects produced by celebrity, even a single illegal celebrity-endorsed advertisement for pharmaceuticals or medical devices can spread widely, which is reflected in the penalty imposed on Hongmao Medical Liquor for an advertisement endorsed by Chen Baoguo in Shanghai shortly after the new law was implemented. It is to be inferred from the subsequent celebrity news reports and statements that celebrities have become more cautious and conservative when handling endorsements. Thus, it is quite remarkable the deterrent effect that the handling of illegal endorsement cases has had in managing the chaotic celebrity endorsement market with minimal enforcement costs.

Additionally, with regard to celebrity endorsements, some have argued that provisions related to advertising spokespersons can be circumvented by distinguishing between endorsements and performances. We disagree with this notion, however, because pursuant to the basic consensus reached in a seminar recently held by the China Advertising Association, although the identity of a highly popular subject may not be stated in the advertisement, the subject's presence should be deemed to be popular to the audience of the product or service being advertised. The subject's presence should also be regarded as using "its own image" if the subject's identity can be recognized by its image.

c. Emergence of New Media

As a new form of media, the internet has been the increasingly preferred means for a variety of advertising. Under such a background, Articles 19, 43, 44, 45, 63, and 64 of the new *Advertising Law* specifically regulate advertising on the internet and provide for legal liability. The China Food and Drug Administration ("**CFDA**") has strengthened website inspection and punishment for publishing false information on websites, and will disclose information regarding its handling of websites that publish illegal pharmaceutical or medical device advertisements in two batches after the new *Advertising Law* has been implemented (Notice No. 67 and Notice No. 84 of 2015).

As a newer form of mobile internet advertising, WeChat advertisements for pharmaceuticals and medical devices possess more advantages than traditional forms, such as precise consumer targeting, interactivity, low cost, and so on. However, WeChat advertisements for pharmaceuticals and medical devices do not appear to have aroused sufficient attention of administrative authorities yet, and no enforcement cases can be found in publicly disclosed information. In other words, there is a legal enforcement vacuum for such types of advertising, whether it is in the AIC's supervision of internet advertising or in the FDA supervision of pharmaceuticals and medical devices. To a certain degree, WeChat interactive information in various forms, especially the push notifications with information which are "advertorial" in nature, such as health knowledge sharing, user interaction, and notifications of promotional information, etc., constitute pharmaceutical advertising which should be subject to yet escapes FDA examination or approval. Strictly speaking, there is no obstacle for the relevant provisions in the new *Advertising Law* to apply to the advertising

of pharmaceuticals and medical devices on WeChat. Therefore, this enforcement vacuum is caused by the attitudes of regulatory authorities regarding enforcement instead of being a legislative gap.

Analysis of Common Issues Concerning Illegal Pharmaceutical and Medical Device Advertising

a. Highly Consistent Causes of Illegality

Through studying publicly available cases regarding illegal pharmaceutical and medical device advertising disclosed after the new *Advertising Law* entered into force, it has been found that, in practice, most illegal pharmaceutical and medical device advertisements were in violation of Article 16 of the new *Advertising Law* and mainly involved the following three circumstances in which the advertising:

i) Contained absolute affirmations or guarantees as to efficacy and safety;

ii) Exaggerated the cure or effectiveness rate;

iii) Used the titles or images of advertising spokespersons such as academic institutions, medical experts, doctors or patients with recommendations and testimonials.

Many illegal pharmaceutical and medical device advertisements may involve two or three of these illegal activities. These illegal activities are not newly added regulated conduct, and when the original *Advertising Law* was implemented those activities already faced strict supervision and punishment. After the new *Advertising Law* entered into effect, there has continued to be a high frequency of illegal advertising violations, which means that there is much to do with respect to improving compliance with the law for pharmaceuticals and medical devices.

Other common illegal pharmaceutical and medical device advertisements cited in the disclosed information also included:

i) Failing to acquire an advertisement approval in accordance with law;

ii) Tampering with the content of approved advertisements;

iii) Failing to indicate in a conspicuous manner the contraindications and adverse reactions;

iv) Failing to indicate in prominent manner that “this advertisement is for reading by medical and pharmaceutical professionals only” for prescription drugs advertisements; failing to indicate in prominent manner that “please purchase and use in accordance with the drug instructions or under the guidance of pharmacists” for advertisements of over-the-counter drugs.

b. Strengthened Administrative Penalties

As stipulated in the new *Advertising Law*, the AIC is permitted to impose the following penalties on

advertisers for violations of the three most common violations cited above: suspension of advertisements, fines, revocation of business licenses, cancellation of advertising approvals, refusal to accept advertising examination applications. Among these forms of punishment, the last three measures are newly added administrative penalties under the new *Advertising Law* with respect to illegal pharmaceutical and medical device advertisements. According to the publicly disclosed information, regarding punishment imposed by regulatory authorities, the most common forms of punishment included suspension of advertisements, fines, and cancellation of advertising approvals. More severe forms of punishment do not yet appear to have been imposed, such as revocation of business licenses and refusal to accept advertising examination applications.

Moreover, pursuant to the *CFDA Notification Concerning Further Implementation Cessation of Sales of Pharmaceuticals, Medical Devices, and Health Food Involved in Severely Illegal Advertisements* (Guo.Shi.Yao.Jian.Ji. [2013 No.45]), FDAs may take administrative measures against the products involved as follows:

i) Adverse publicity;

ii) Suspension of sales during a rectification period;

iii) Order suspension of business for rectification in case of failure to implement.

In October 2015, the Shandong Food and Drug Administration gave notice to impose a suspension of sales on 19 products pursuant to the notice guidelines above. However, from a legislative perspective, these three administrative measures are not administrative penalties or administrative mandatory measures provided for by laws and regulations. Thus, it may be reasoned that such FDA-imposed administrative measures may be challenged as a matter of law.

c. Domestic Small- and Medium-sized Enterprises are the Main Subjects of Violations

The advertisers subject to penalties for publishing illegal pharmaceutical and medical device advertisements are generally small- and medium-sized domestic enterprises, while offshore, joint-venture and large domestic pharmaceutical and medical device enterprises are seldom engaged in such violations. In the disclosed cases, we have not yet found a case in which the illegal advertising activities were committed by such offshore or larger enterprises. This phenomenon reflects, to a certain extent, the competitive market environment for pharmaceuticals and medical devices: pharmaceutical and medical device enterprises with relative advantages may take greater care to ensure compliance and choose not to take unreasonable or risky actions. In contrast, pharmaceutical and medical device enterprises which are under pressure with fewer advantages may choose to achieve sales targets by using all methods, and even risk using illegal advertising or adopting some seemingly compliant advertising techniques to create grey propaganda.

At the current stage, pharmaceutical and medical device enterprises are seen as relatively small and dispersed, as the overall market concentration in the pharmaceutical and medical device industries is low. Furthermore, under the background of medical reform, the existence and

business environment for pharmaceutical and medical device enterprises is influenced by the reform of public hospitals, centralized procurement and the pricing system for pharmaceuticals and medical devices, as well as reform of the review and approval system for pharmaceuticals and medical devices, which leads to added pressure for small- and medium-sized pharmaceutical and medical device enterprises. Consequently, the promulgation of the new *Advertising Law* does not necessarily mean that illegal pharmaceutical and medical device advertisements will be completely eliminated rapidly and effectively, and that it will be a systematic and protracted battle for the regulatory authorities and market participants to cleanse the pharmaceutical and medical device advertising market.

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2. The Tax Man Cometh: A Large Wave of Income Tax Incentives is Coming - Not Only the 70% Deduction for Corporate Partners of Limited Partnerships (Authors: Bing XUE, Yizi XIE)

In the process of constructing and developing a multi-level capital market, market participants have always been looking forward to more stable and transparent tax rules. Along with improvements to the capital market-related tax regime, we are also looking forward to more systematic and well-reasoned income tax incentives which may be the icing on the cake of an increasingly liberal investment environment.

Near the end of this year, the Ministry of Finance ("**MOF**") and State Administration of Taxation ("**SAT**") released a series of tax incentive policies which extend nationally the four tax incentives that have been implemented in the National Innovation Demonstration Zone ("**NIDZ**").

Four NIDZ Pilot Tax Incentives to be Rolled out Nationwide

On October 23, 2015, MOF and SAT jointly released the *Circular on Promoting the Pilot Tax Policies in NIDZ Nationwide* (Cai Shui [2015] No.116, "**Circular 116**"), rolling out the four income tax incentives nationwide.

- Enterprise income tax ("**EIT**") policy for corporate partners of limited partnership venture capital enterprises
- EIT policy for income from transfers of technology
- Individual income tax ("**IIT**") policy for reserve-converted shares
- IIT policy for equity incentives

We summarize below our insights on the four tax rules for your reference.

a. EIT Policy for Corporate Partners of Limited Partnership Venture Capital Enterprises

Despite the lengthy title, this preferential policy is worthy of applause by corporate partners. SAT released the *Announcement on Issues Concerning EIT on Corporate Partners of Limited Partnership Venture Capital Enterprises*, dated November 16, 2015 (SAT Announcement 2015 No.81, "**Announcement 81"**), which further clarified the implementation of the preferential EIT policy for corporate partners.

	Tax Policy	**Han Kun Notes**
Implementation Date	From October 1, 2015	
Applicable to	**Corporate partners** of limited partnership venture capital enterprises nationwide	➢ Limited partnership venture capital enterprises refer to limited partnerships which specialize in venture capital and are established in accordance with the *Partnership Enterprise Law of the People's Republic of China*, *Interim Administrative Measures on Venture Capital Enterprises* and *Administrative Provisions on Foreign-invested Venture Capital Enterprises*. ➢ The partnership enterprise itself is not subject to EIT. Instead, the principle of "distribution before taxation" applies, and each partner is itself a taxpayer ("**First Distribute, Then Pay Tax**"). This preferential tax policy only applies to corporate partners that are resident enterprises subject to audit-based taxation.
Form of Investment	Equity investment	
Target Enterprise	Non-listed **small or medium-sized high-tech enterprises**	

	Tax Policy	Han Kun Notes
Investment Term	Greater than 2 years (24 months)	Greater than 2 years means that, as of October 1, 2015, the limited partnership venture capital enterprise shall have fully contributed capital to a non-listed small or medium-sized high-tech enterprise for a period exceeding 2 years, while at the same time, the corporate partner shall have fully contributed capital to the limited partnership venture capital enterprise for a period exceeding 2 years.
Tax Incentives	Corporate partners may take a deduction of 70% of the amount invested in the non-listed small or medium-sized high-tech enterprise from its taxable income distributed from the limited partnership venture capital enterprise for the current year, and if its taxable income for the current year is less than 70% of the investment amount, the deduction may be carried forward to the following tax year(s).	➢ If a corporate partner invests in more than one qualified limited partnership venture capital enterprise, the deductible investment amount and taxable income attributable to the corporate partner may be calculated on a consolidated basis. ➢ It is noteworthy that, pursuant to Circular 116 and Announcement 81, this tax incentive may only be applicable to the following direct structure: corporate partners - limited partnership venture capital enterprise - non-listed small or medium-sized high-tech enterprise ➢ As the tax incentives of Circular 116 and Announcement 81 have been implemented nationally, investors may have more flexibility in selecting the location of the enterprise when designing the investment structure

Salient Issues to be Resolved

Limited liability partnerships have been widely used since the new *Partnership Enterprise Law* came into force in 2007. The *Circular on Issues Concerning EIT on Partners of Partnership Enterprises* (Cai Shui [2008] No.159), issued by MOF and SAT in 2008, specifies the principle of "First Distribute, Then Tax." Unfortunately, although the new *Partnership Enterprise Law* has been amended for nearly ten years, partnership-related income tax collection continues to follow rules which have been in place for more than fifteen years, and which may not be current with the development of the market. For instance, principle matters such as whether the equity investment gains of a corporate partner from investment in a target enterprise through a limited partnership can be considered exempt income remains to be further defined.

b. EIT Policy for Income Derived from Transfers of Technology

SAT released the *Announcement on Issues concerning EIT on Income from Transfers of Technology* (SAT Announcement 2015 No.82, "**Announcement 82"**), which specifies the EIT tax incentives for income from transfers of technology. We briefly summarize the provisions of Circular 116 and Announcement 82 as follows:

	Tax Policy	**Han Kun Notes**
Implementation Date	From October 1, 2015	
Applicable to	Income from transfers of technology derived by resident enterprises from the transfer of non-exclusive technology licenses with terms of more than five years.	
Scope of Technology	Patents (including national defense patents), computer software copyrights, exclusive rights to integrated circuit layout designs, rights to new plant varieties, new biological medicinal products and other technologies as determined by MOF and SAT.	Technology shall be limited to proprietary technology.
Tax Incentives	The portion of annual income derived from transfers of technology of less than RMB 5 million are tax-exempt, and the portion in excess of RMB 5	

	Tax Policy	Han Kun Notes
	million is subject to a 50% reduction in EIT.	

c. IIT Policy for Reserve-converted Shares

i) Salient Issues Concerning Tax Policies for Reserve-converted Shares

The IIT related to using undistributed profits and surplus reserves to increase share capital in the current tax collection regime is relatively clear. However, there is more controversy moving from theory to practice for the taxation of capital reserves which are used to increase share capital. Actually, this controversy derives from the following two SAT tax collection documents:

- Article One of the *Circular on the Exemption of IIT on Increase of Share Capital and Bonus Share Distribution of Joint-Stock Enterprises* (Guo Shui Fa [1997] No.198, "**Circular 198**") stipulates that when a joint-stock enterprise converts its capital reserves into share capital, it shall not be defined as distribution of dividends or other distribution of similar nature, and the amount of the share capital acquired by the individual shall not be treated as taxable income.
- Article Two of *Reply on Taxable IIT on Income from Individual Shares Added Value in Process of Former Urban Credit Cooperatives Transforming into Urban Cooperative Banks* (Guo Shui Han [1998] No.289, "**Reply 289**") points out that the "Capital Reserve" in Circular 198 shall mean the capital reserve derived from income of a joint-stock enterprise when issuing shares at a premium ("**Additional Paid-in Capital**"). Individual income from Additional Paid-in Capital shall not be subject to IIT, while individual income from capital reserves other than Additional Paid-in Capital shall be subject to IIT.

Reply 289 specifies that only the income from Additional Paid-in Capital of a joint-stock enterprise is not be subject to IIT when converting capital reserves into share capital. In the practice of investment and financing, discrepancies arise as to whether individuals recognize income when converting capital reserves derived from Additional Paid-in Capital of a limited liability company into share capital and when converting capital reserves which are derived from the conversion of a limited liability company into a joint-stock enterprise into share capital.

ii) Further Clarification of Tax Incentives for Reserve-converted Shares

Although the aforementioned controversy on the taxability of converting capital reserves into share capital has not been fundamentally resolved, *Announcement on Issues Concerning the Collection and Administration of IIT on Incentive Shares and Increased Shares from Distributions,* released by SAT and dated November 16, 2015 (SAT Announcement 2015 No.80, "**Announcement 80**"), has

provided a positive signal to the market regarding preferential IIT policies for reserve amounts which are converted into shares distributable to shareholders.

	Tax Policy	**Han Kun Notes**
Implementation Date	From January 1, 2016	
Applicable to	Small or medium-sized high-tech enterprises nationwide using undistributed profits, surplus reserve or capital reserve to increase the shareholdings of individual shareholders	➢ Small or medium-sized high-tech enterprises refer to certified enterprises registered in China and subject to audit-based taxation, with both annual sales and total assets of not more than RMB 200 million and with not more than 500 employees. ➢ Where the listed small and medium-sized high-tech enterprises or the small and medium-sized high-tech enterprises listed on the National Equities Exchange and Quotations use undistributed profits or reserves to increase the shareholdings of individual shareholders, the individual shareholders shall continue to pay IIT in accordance with the existing differentiated IIT policies on dividends, while the preferential policy on installment tax payments shall not apply.
Tax Incentives	Where such individual shareholders have difficulty in paying the IIT in a lump sum, they may develop installment plans by themselves according their actual circumstances and pay taxes in installments within five calendar years, and report the relevant materials to the competent tax	➢ The increased shares distributed to individual shareholders shall be subject to IIT at the rate of 20% under the item of “income from interest, dividends and bonuses”. ➢ Where any of the aforesaid shareholders transfer the distributed shares and thus obtain cash income, the cash income shall first be used to

	Tax Policy	Han Kun Notes
	authorities for filing.	pay the outstanding taxes. ➢ In case that the relevant enterprise declares bankruptcy before any of the aforesaid shareholders transfer the distributed shares, and such shareholder obtains no income or income less than the initial investment amount after disposing of the relevant rights and interests, the competent tax authorities may exempt such shareholder from payment of the outstanding IIT.

d. IIT Policy for Equity Incentives

According to Circular 116 and Announcement 80, individuals acquiring equity incentives from high-tech enterprises subject to audit-based taxation may enjoy relevant IIT preferential policies.

	Tax Policy	Han Kun Notes
Implementation Date	From January 1, 2016	
Applicable to	Equity incentives granted to relevant technicians of high-tech enterprises nationwide in return for their technological achievements	➢ Relevant technicians refer to employees who are granted equity incentives approved by resolutions of the board of directors and shareholders' meeting of the enterprise, including technicians who have made outstanding contributions to the research, development and industrialization of technological achievements of the enterprise and managers who have made outstanding contributions to enterprise development. ➢ The equity incentives for all staff of an enterprise shall not be subject to the tax incentives specified in Circular 116 and

	Tax Policy	Han Kun Notes
		Announcement 80.
Tax Incentives	Where such individuals have difficulty in paying the IIT in a lump sum, they may develop installment plans by themselves according to their actual circumstances and pay taxes in installments within five calendar years, and report the relevant materials to the competent tax authorities for filing.	➢ The tax payable by an individual receiving equity incentives shall be determined by referring to the income tax calculation for stock options. ➢ If any of the aforesaid technicians transfer the equity awards (including the bonus stock derived from the equity award) and thus obtain cash income, the cash income shall first be used to pay the outstanding taxes.

Han Kun Viewpoint:

Extending the four NIDZ tax incentives nationally will play a positive role in stimulating entrepreneurship and innovation in the market and in creating a fair tax environment. We recommend that market participants pay attention to the applicable scope and filing requirements specified in the relevant policies, so as to control the risk of tax compliance in investment and financing transactions.

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3. Pros and Cons of Drug Price Renegotiation (Authors: Chen MA, David TANG, Yan WANG, Will HUANG, Min ZHU)

The issue of second-round drug price negotiations following centralized procurement ("**Price Renegotiation**") was bound to be controversial from the start.

From its opponents' point of view, Price Renegotiation has no merit: it reduces the credibility of provincial bid invitations, violates the *Law of the People's Republic of China on Tenders and Bids* ("***Bidding Law***"), breeds corruption and unhealthy practices within medical institutions, adds to sales costs and expenses, and reduces profit margins for drug manufacturers, gives rise to inconsistent regional purchase prices, creates disorderly market competition, and results in a decreased quality of drugs.

Supporters of Price Renegotiation believe that its advantages far outweigh any drawbacks: it helps to widely decrease drug prices, restores balance to the bargaining power between hospitals and pharmaceutical companies, brings transparency to drug purchase discounts offered to medical institutions, reduces the opportunity for doctors to collect kickbacks, efficiently solves the chronic problem of commercial bribery, lightens financial burdens of local governments, and promotes the reform of centralized drug procurement ("Centralized Procurement").

Centralized Procurement Has Led to Price Renegotiation

From 1993 to around 2000, Henan, Liaoning, Sichuan, Zhejiang, Shandong, Fujian and other provinces carried out independent exploratory work regarding Centralized Procurement. On November 12, 2001, the promulgation of Working Procedures on Centralized Bidding and Procurement of Drugs by Medical Institutions (Trial Implementation) [No. 308] marked the formation of Centralized Procurement at the national level. On September 23, 2004, six ministerial level governmental departments promulgated the Certain Provisions on Further Regularizing the Centralized Bidding and Procurement of Drugs by Medical Institutions [No. 320], which improved the organizational units in charge of Centralized Procurement at the provincial level. On January 17, 2009, six ministerial level governmental departments jointly issued the Opinions on Further Regularizing Centralized Procurement of Drugs by Medical Institutions, and the system design using provincial online Centralized Procurement as a model came into effect. On February 9, 2015, the General Office of the State Council issued Guidance on Improving Centralized Procurement of Drugs by Public Hospitals [No. 7], which presented the model under which Centralized Procurement would take place both at the provincial level and in certain pilot cities undergoing medical system reforms.

The policy aims of Centralized Procurement are to "consolidate the orderly distribution of drugs, standardize drug prices, redress unhealthy tendencies found in medical procurement and sales, and lighten the burden of public medical expenses," and of these, the primary aim is to decrease drug prices. However, Centralized Procurement at the national level inevitably weakened the independent drug procurement rights of regional governments and hospitals, which gave rise to the issue of Price Renegotiation.

On April 14, 2012, the General Office of the State Council issued the Circular on Major Arrangements in Deepening Health Care System Reform in 2012, which stated that the reform of public hospitals would result in the cancellation of drug price markups. Prohibiting drug price markups reduced the income streams for public hospitals from three to two, namely service charges and government subsidies. The remaining income streams for public hospitals have not been enough to offset the loss of income derived from drug price markups since service charges have not keep pace with expenses and government subsidies have been insufficient. As public hospital income decreased, the issue of Price Renegotiation became even more severe.

Attitudes of Ministries Vary, Local Authorities Lack Coordination

Price Renegotiation involves multiple government authorities, including the State Council's Office for Rectifying Malpractice (supervisory authority), the National Health and Family Planning Commission ("NHFPC"), the Development and Reform Commission (the Administration of Commodity Prices), the Administration for Industry and Commerce, the Food and Drug Administration, and the Administration of Finance, among others.

At the ministerial level, the NHFPC is the most adamant opponent of Price Renegotiation. Since 2004, the NHFPC has repeatedly stated its opposition to Price Renegotiation in a series of regulatory documents and notices. The attitude of the National Development and Reform Commission ("NDRC"), however, has been relatively vague. On November 21, 2013, the NDRC declared its support for Price Renegotiation in a symposium about drug prices. However, it is noteworthy that the NDRC is also a co-signer of several documents prohibiting Price Renegotiation issued by multiple ministries from 2004 to 2010.

Government attitudes towards Price Renegotiation differ widely at the subnational level. According to rough estimates, approximately 16 provinces prohibit Price Renegotiation in written documents while 3 provinces permit it. Other provinces have not issued any specific opinions. However, even in the provinces that expressly prohibit Price Renegotiation, there exist some flexible approaches at the municipal level, and many local governments give tacit approval to Price Renegotiation from a financial perspective.

Pharmaceutical companies are most disadvantaged by Price Renegotiation and are always in opposition to it. Price Renegotiation not only increases the burden on pharmaceutical companies, reduces profit margins, disrupts sales strategies, but also subjects companies to possible administrative punishment. By contrast, public hospitals generally seek to initiate various forms of Price Renegotiation in order to realize profits under the existing procurement system while facing pressure from the NHFPC.

Legal Application Issues of Price Renegotiation

Public hospitals and pharmaceutical companies are most concerned about regulatory prohibitions on Price Renegotiation and the potential administrative penalty risks that apply to engaging in such transactions. Price Renegotiation is prohibited by a series of regulatory documents promulgated by the General Office of the State Council, the NHFPC and other ministries, and local government regulations promulgated by different provinces. However, according to relevant provisions of the Legislation Law and the Administrative Punishment Law, these regulatory documents and local government regulations cannot not give rise to any administrative penalties without legal or State Council regulatory authorization. Therefore, Price Renegotiation prohibition penalties could only be found in higher-level legislation.

The main laws and regulations relating to Price Renegotiation include the Bidding Law, the Government Procurement Law and their implementing regulations, the Anti-unfair Competition Law, the Price Law, the Drug Administration Law, and the Administrative Punishment Law. Currently, it remains controversial whether the Bidding Law is applicable to Centralized Procurement and Price Renegotiation. The reason for this controversy is that it is ultimately the medical institutions which act as the final signatories and purchasers under Centralized Procurement, although the provincial and municipal Centralized Procurement centers and other platforms engage in the bidding and procurement process. Therefore, this case does not involve a conventional bidding arrangement since the tenderee and the purchaser are not the same party. In addition, another controversy has arisen as to whether the Government Procurement Law is applicable to the Centralized Procurement of drugs following the case of Shenyang Aojina Pharmaceutical Co., Ltd. v. Shandong Finance Bureau, which was heard by the Shandong Jinan Intermediate People's Court in March, 2015.

Another law which cannot be ignored is the Anti-monopoly Law. The language of the Anti-monopoly Law might be adopted to challenge certain ministerial regulations, and local government normative documents which prohibit Price Renegotiation. Some have argued that a prohibition of all Price Renegotiation enables administrative monopolies in violation of the Anti-monopoly Law. Additionally, in practice, the local NHFPC and/or the medical groups organize public hospitals within a particular region, and the hospitals can use their collective market position to force pharmaceutical companies to conduct Price Renegotiation after the companies win bids through Centralized Procurement. Such activity may constitute an abuse of market dominance in violation of the Anti-monopoly Law.

Possible Legal Risks

Based on the cases collected so far, no pharmaceutical company has been punished as a result of engaging in Price Renegotiation. In most circumstances, it was the medical institutions which were punished because they were involved in compliance issues related to commercial bribery or other anti-unfair competition activity during Price Renegotiation. In other words, the medical institutions received administrative punishment for unrelated matters when engaging in Price Renegotiation and were not punished by the NHFPC, despite the NHFPC's express opposition to Price Renegotiation.

In terms of legal risk, pharmaceutical companies cannot be entirely exempted from liability in the context of commercial bribery. In practice, precedent shows that both parties found to be engaging in commercial bribery will be subject to administrative punishment. In addition, we cannot completely discount the risk of criminal prosecution. In commercial bribery cases, it is relatively difficult for pharmaceutical companies to prove that such bribery was not aimed at obtaining illegal benefits or competitive advantage.

The NHFPC, however, cannot directly create any administrative penalties without legal or State

Council regulatory authorization. Therefore, the NHFPC's administrative penalties for engaging in Price Renegotiation require a legal basis from laws such as the Government Procurement Law, the Price Law or the Anti-unfair Competition Law. In addition, it should be noted that the NHFPC is in charge of directly regulating medical institutions under the functional division of government agencies. Therefore, NHFPC regulations are seen as only applying to medical institutions rather than pharmaceutical companies.

Furthermore, if the Government Procurement Law is applicable to Centralized Procurement, medical institutions and pharmaceutical companies have to consider the potential risks posed by the Government Procurement Law and the Administrative Measures on Tenders and Invitations to Bid in Government Procurement of Goods and Services in the case that purchasers and suppliers substantively change the bidding results.

Strategies for Pharmaceutical Companies

In this article, we have discussed the issues that pharmaceutical companies should pay attention to during Price Renegotiation and the strategies that they may take in response. We welcome pharmaceutical companies with specific Price Renegotiation issues to discuss those issues with us for a more targeted case analysis and discussion. We also recommend pharmaceutical companies to re-examine their existing contracts and business methods from the following aspects:

a. Be clear about the policy environment and regulatory attitudes in different provinces. The Centralized Procurement of drugs is the responsibility of local governments, and it is therefore crucial for pharmaceutical companies to clarify local policy orientations and regulatory attitudes. We recommend pharmaceutical companies to consult local government authorities and refer to relevant laws and regulations in order to better understand local policies and regulatory attitudes, and to evaluate potential risks. Meanwhile, we recommend pharmaceutical companies to pay special attention to informal methods of Price Renegotiation and to evaluate different levels of potential risk.

b. Optimize business models and processes. For instance, when doing business with distributors, pharmaceutical companies should engage in risk prevention and conduct a review of business practices such as processing documents, communication methods, issuing invoices, and distributors' codes of conduct.

c. Implement internal checks and recordkeeping. For transactions involving Price Renegotiation, we recommend that pharmaceutical companies establish an internal check and recordkeeping system to record the transaction process which can be used as a basis of evidence or defense in any possible subsequent investigation.

d. Legal defenses based upon anti-monopoly legal analysis. As pharmaceutical companies are faced with more and more pressure to engage in Price Renegotiation, it is worth noting that

Price Renegotiation may be involved with administrative monopoly or abuse of market dominance. It is of interest to the pharmaceutical industry to discuss how the Anti-monopoly Law can be used as a tool to protect the rights of pharmaceutical companies.

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 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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