



漢坤律師事務所  
HAN KUN LAW OFFICES

# Han Kun Newsletter

Issue 149 (9th edition of 2019)

## **Legal Updates**

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## 1. A New Era for the Regulation of Online Education

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On September 5, 2019, the Ministry of Education promulgated the first comprehensive national-level regulatory document on mobile education apps—the *Opinions of the Ministry of Education and Seven Other Departments on Guiding and Regulating the Sound and Orderly Development of Education Mobile Internet Applications* [Jiao Ji Han (2019) No. 55] (“**Circular 55**”). On the same day, officials from the Ministry of Education announced, during a press conference, that the preliminary draft of record-filing measures for education mobile Internet apps is planned to be issued for further public comments by the end of September<sup>1</sup>. It has been only little more than one month since the Ministry of Education promulgated its first regulatory document specially targeting online extracurricular training institutions, the *Implementing Opinions on Regulating Online Extracurricular Training Institutions* (“**Circular 8**”). The promulgation of Circular 8 and Circular 55 indicates that the long-awaited policies on online education in the education industry are soon arriving, and that online education is welcoming a new regulatory era.

This article will briefly review the recently issued online education regulatory policies and briefly analyze the compliance trends of online education enterprises in the new regulatory environment.

### Retrospective: overview of online education-related policies

Since the NPC Standing Committee published the amendments on the *Law on the Promotion of Privately-run Schools* on November 7, 2016, the relevant national departments have promulgated the following primary regulatory documents pertaining to online education:

Date of Issue	Document Name	Subject of Regulation	Main Content Concerning Online Education
2018/08/06	Opinions of the General Office of the State Council on Regulating the Development of Extracurricular Training Institutions [Guo Ban Fa (2018) No. 80]	Non-degree educational training provided by extracurricular training institutions for primary and middle school students (mainly for offline training institutions)	<ul style="list-style-type: none"> <li>■ Cyberspace, culture, industry and information technology, radio and television departments are to cooperate with education departments to fulfill online education supervision within their respective areas of responsibility</li> </ul>
2018/08/10	Regulations for the Implementation of the Law on the Promotion of	Privately-run schools (including privately-run education and training institutions)	<ul style="list-style-type: none"> <li>■ (i) Privately-run schools that engage in academic education online by using Internet technology <b>shall obtain a school-running license and relevant Internet operation license</b>; (ii) <b>the relevant Internet operation licenses shall be obtained</b> to carry out online training</li> </ul>

<sup>1</sup> Ministry of Education press conference explains the Opinions of the Ministry of Education and Seven Other Departments on Guiding and Regulating the Sound and Orderly Development of Education Mobile Internet Applications, available at [http://www.gov.cn/xinwen/2019-09/05/content\\_5427621.htm](http://www.gov.cn/xinwen/2019-09/05/content_5427621.htm) (Chinese).

Date of Issue	Document Name	Subject of Regulation	Main Content Concerning Online Education
	Privately-run Schools <sup>2</sup> (Revision Draft) (for Review) (“ <b>Draft Regulations</b> ”)		and education activities, vocational qualification or skills training by using Internet technology, or providing services for engaging in the foregoing activities online by using Internet technology, <b>but education and training activities requiring a school-running license must not be carried out</b>
2018/11/20	Circular on Improving Several Working Mechanisms for Special Regulation and Rectification of Extracurricular Training Institutions [Jiao Ji Ting (2018) No. 10] (“ <b>Circular 10</b> ”)	Extracurricular training institutions (mainly for offline training institutions)	<ul style="list-style-type: none"> <li>■ Education administrative departments at the provincial level shall <b>fulfill record-filing work for training and education activities conducted online</b> using Internet technology for primary and middle school students</li> <li>■ <b>Regulate online education and training institutions in line with offline training institution administrative policies</b>, and conduct <b>record-filing of relevant information of subject-based training courses provided by online training institutions and relevant information of teachers</b></li> <li>■ Education administrative departments at the provincial level shall join with industry and information technology, cyberspace and other departments to strengthen supervision of online training content</li> </ul>
2018/12/25	Circular on Prohibiting Harmful Applications Entering Primary and Middle Schools [Jiao Ji Ting Han (2018) No. 102] (“ <b>Circular 102</b> ”)	On-campus learning apps (“ <b>On-campus Apps</b> ”)	<ul style="list-style-type: none"> <li>■ Carry out the “<b>double review</b>” <b>responsibility system for On-campus Apps</b>, and schools shall select the On-campus Apps and report to the higher-level competent department for approval</li> <li>■ Conduct comprehensive investigations of On-campus Apps</li> <li>■ Strengthen the daily supervision of On-campus Apps; Non-record-filed On-campus Apps shall not be organized or recommended for use, and timely handling shall be undertaken of apps containing harmful content, commercial advertisements or which increase student burdens</li> </ul>
2019/07/12	Implementing Opinions on Regulating Online Extracurricular Training Institutions [Jiao Ji Han (2019) No. 8]	Online extracurricular training activities for primary and middle school students via Internet technology	<ul style="list-style-type: none"> <li>■ Implement a <b>record-filing and review system for extracurricular online training institutions, training content and training personnel</b></li> <li>■ Conduct audit and rectification work for online extracurricular training activities applying for record-filings (including soundness of content, appropriate length of time, teacher qualifications, information security, operation requirements, etc.)</li> <li>■ Establish a black and white list system, those who violate relevant regulations shall be listed in the gray list and ordered to rectify with a time limit, those who refuse to rectify or delay in completing the rectification shall be blacklisted and severely dealt with</li> </ul>
2019/08/10	Opinions on Guiding and	Mobile Education apps (“ <b>Education</b> ”)	<ul style="list-style-type: none"> <li>■ <b>Implement a record-filing system for Education App providers.</b> The Education Apps provider <b>shall make</b></li> </ul>

<sup>2</sup> Revisions have not yet been officially promulgated for the Regulations for the Implementation of the Law of the People’s Republic of China on the Promotion of Privately-run Schools.

Date of Issue	Document Name	Subject of Regulation	Main Content Concerning Online Education
	Regulating the Orderly and Healthy Development of Mobile Education Applications [Jiao Ji Han (2019) No. 55]	Apps”) and their providers	<p><b>education business record-filings</b> with the provincial education administrative department of the place of incorporation <b>and update relevant information before launching new apps</b></p> <ul style="list-style-type: none"> <li>■ Standardize on-campus cooperation, and formulate requirements regarding the content, fees, and exclusive cooperation with schools for different types of Education Apps</li> <li>■ Require strengthening of the construction of Education Apps content, standardize data and personal privacy collection management, and establish a network security review and certification system</li> <li>■ Establish a recommendation mechanism to evaluate the Education Apps and develop a list of recommendations; establish a “double review” system for Education APPs, which means approval of education department and decision-making bodies of school is required for selecting Education APPs, and the selected apps must be filed with the education department</li> </ul>

A review of the regulatory history of online education reveals that the supervision of online education has gradually expanded from offline to online and from on-campus apps and online subject-based training to online education activities of various stages and varieties. After promulgation of Circular 10, education departments have primarily focused on extracurricular offline training institutions, and the regulatory policy for online training institutions has primarily been enforced by referencing to offline education. However, online education is welcoming a new regulatory era with the promulgation of Circular 102, Circular 8, Circular 55 and related forthcoming regulatory rules, further implementation of an online education record-filing system, and also the commencement of online education compliance audits.

### **Clarity: requirements for online education enterprise operation licenses and record-filing**

The Draft Regulations serve as the starting point for Circular 102, Circular 8 and Circular 55 to put forth the record-filing and review requirements for online education enterprises and their app products. Besides, online education ordinarily involves industries such as telecommunications, broadcasting and publishing, and Circular 55 calls for the establishment of a joint supervisory mechanism which will conduct coordinated supervision of the online education industry, headed by the education departments and including the departments of cyberspace, telecommunications, public security, press and publication, civil affairs, and market supervision administration, among others.

The increasingly strict regulatory environment underscores the importance for online education enterprises to fully obtain qualification certificates, complete record-filing requirements and operate in compliance with laws and regulations. In addition to record-filing required by Circular 102, Circular 8 and Circular 55, the operation of online education enterprises and the products they developed typically involve qualification and licensing requirements in telecommunications, broadcasting, publishing and other fields. According

to current Chinese laws, regulations and relevant policies, we briefly summarize the primary operational qualification certificates and record-filings required for online education enterprises based on their business content:

#	Business Content <sup>3</sup>	License/Record-filing	Handling Department	Notes
1	Education app operations (for all enterprises operating education apps)	Education business record-filing	The <b>provincial education administrative department</b> where the app provider is registered (record-filings for existing education apps to be completed by the end of 2019; education app providers that have completed record-filings to update the filings before new apps are launched).	<ul style="list-style-type: none"> <li>As expanded, the scope of education apps that can be covered is broad, involving learning apps, training apps and even other on-campus service apps for different subjects and education levels, meaning that all enterprises which provide education-related apps may need to record-file in accordance with Circular 55</li> </ul>
2	Platforms providing subject-based online extracurricular training	Online extracurricular training institution record-filing, Subject-based training content record-filing; Subject-based training personnel record-filing	The <b>provincial education administrative department</b> of the institution's place of domicile (institutions which conduct extracurricular training shall submit relevant materials before October 31, 2019, and newly established online extracurricular training institutions shall submit relevant materials according to the record-filing requirements).	<ul style="list-style-type: none"> <li>The record-filing is against subject-based online extracurricular training activities for primary and middle school students. Trainings that are not subject-based or not for primary and middle school students are excluded</li> <li>In addition to its own record-filing, online training institutions are required to record-file for their courses and personnel. Circular 8 also requires training personnel to obtain teacher qualification certificates and prohibits the employment of primary and middle school teachers</li> </ul>
3	On-campus learning apps	School selection, record-filing by the competent education department	The record-filing department is generally <b>the education department of each district or county</b> , but practices may vary from place to place (for example, in Guangdong province, app providers directly apply to the provincial education administrative department for record-filing).	<ul style="list-style-type: none"> <li>The record-filing is mainly for learning apps that are organized or recommended for use on campus by education administration and schools</li> <li>However, since the record-filing is mainly implemented by the provinces based on actual circumstances, the provinces have different interpretations of the scope of apps. For example, Guangdong province regards apps with teaching or homework functions for primary and middle school students as on-campus apps, including on-campus learning and subject-based training apps, whether or not they are organized or recommended on campus</li> </ul>
4	Information services offered	Internet Content Provision License, i.e., Business	If it is a purely domestic enterprise, the approval department is the	<ul style="list-style-type: none"> <li>Common forms of Internet information services in the online education field include providing educational e-books, training</li> </ul>

<sup>3</sup> The record-filing listed in item 1 of this table is for all education app operating enterprises; items 2 through 8 relate to one or more qualification certificates or record-filings relating to online education enterprises or their products, depending on the content of their business.

#	Business Content <sup>3</sup>	License/Record -filing	Handling Department	Notes
	within online education products	scope includes value-added telecommunications services (only Internet information services)"	telecommunications department where the enterprise is domiciled;  If there exist foreign investors in the company's upper-tier ownership structure, the approval authority is the Ministry of Industry and Information Technology	courses, videos, audio and other information provided by third parties to users for fees on online education platforms  ■ If the enterprise intending to apply for an ICP license has foreign investors in its upper-tier ownership structure on a look-through basis, the foreign investors' collective shareholding shall not exceed 50% in accordance with the <i>Provisions on Administration of Foreign-invested Telecommunications Enterprises</i>
5	Audio-visual programs offered within online education products	Information Network Audio-visual Program Transmission License	Radio and television administrative departments at the provincial level conduct an initial review, and the State Administration of Press, Publication, Radio, Film and Television approves.	<ul style="list-style-type: none"> <li>■ Common forms of online audio-visual programming in online education include recording and broadcasting audio and video lessons</li> <li>■ The applicant for the license must not have any foreign capital and must be a wholly-state-owned or state-controlled entity</li> <li>■ In practice, different understandings of "audio-visual programs" in different regions lead to various extents of law enforcement as to whether the recording and broadcasting audio -visual lessons shall be regarded as audio-visual programs</li> </ul>
6	Network publications offered within online education products	Online Publication Services License	Press and publication administrative departments at the provincial level conduct an initial review, and State Administration of Press, Publication, Radio, Film and Television approves.	<ul style="list-style-type: none"> <li>■ Common forms of Internet publishing services include providing public the digital versions of offline publications(such as educational books, audio-visual products, etc.) through Internet, and providing digital textbooks, supplementary materials, educational recording-broadcasting audios and videos with publication features like editing, producing and processing</li> <li>■ Online publication service belongs to the foreign investment prohibited industries</li> </ul>
7	Production of radio and television programs for online education	Radio and Television Program Production and Operation License	Radio and television administrative departments at the provincial level	<ul style="list-style-type: none"> <li>■ Video programs other than pure advertisements may be considered as radio and television programs. Therefore, the production of online education videos involves the production of radio and television programs, which requires obtaining this license. In practice, whether the license need to be obtained depends on the specific requirements of the local regulatory authorities, which differs due to different understandings of the relevant provisions</li> </ul>
8	Engaging in publishing within online	Publication Business Operating License	Press and Publication departments at the district and county level	<ul style="list-style-type: none"> <li>■ The common form of online publication business is to sell publications through online educational products (such as</li> </ul>

#	Business Content <sup>3</sup>	License/Record -filing	Handling Department	Notes
	education products			educational books, audio-visual products, etc.)

## Outlook: compliance trends under the proposed regulatory rules

With the promulgation of Circular 102, Circular 8 and Circular 55, three levels of record-filing and review are on the agenda in the online education industry, for (i) on-campus apps, (ii) online subject-based training enterprises and product content, and (iii) education app providers. Recently, we have observed the state of implementation of these regulatory documents based on feedback from our consultations with the relevant competent education authorities in Beijing, Shanghai, Guangdong, Jiangsu, Zhejiang, Shandong, Hubei, Hunan, Shanxi and other locations:

- The record-filing requirements of Circular 102 have been implemented to various extents in most provinces, and a few provinces remain in the process of studying and formulating corresponding implementing measures. Since Circular 102 only stipulates that the competent authorities of primary and middle schools conduct record-filing for on-campus apps, there are different implementation plans among provinces and even in their districts and counties. For example, a few provinces require on-campus app sponsors to go directly to the provincial education administrative department to submit documents for record-filing, while most other regions require schools to submit documents to the relevant district/county education departments, or require on-campus app operators to cooperate with schools to provide such documents to complete record-filings.
- The Ministry of Education plans to launch a unified platform for online extracurricular training institutions to fulfill the Circular 8 record-filing requirement before the end of 2019. The provinces propose to publish record-filing detailed rules before or after the platform is launched and, concurrently, to commence the compliance audit and rectification work for online subject-based training institutions.
- Due to the relatively short time since promulgation of Circular 55, the provinces are still waiting for further policies to be introduced, and the relevant matters will be clarified once the Ministry of Education further issues record-filing administrative measures.

Until now, Circular 8 and Circular 55 have provided only relatively principled provisions on the record-filing and review of online subject-based training institutions, product content and education app providers. Some particular issues still need to be clarified through the issuance of detailed rules, both by the Ministry of Education and at the provincial level. Based on our initial observations, the specific provisions of these detailed rules will further affect compliance trends in the online education industry:

### I. The scope of education apps and review obligations of mobile app distribution platform providers

Circular 55 requires mobile app distribution platforms to strengthen the review and management of education app offerings, establish an information registration system for the true identities of developers, conduct security reviews on education apps, timely handle apps in violation of laws and

regulations, and make education business record-filings an important condition for displaying on app stores. Since mobile app distribution platforms are the main distribution channel for education apps, an app that is defined as an education app under Circular 55 may have its app product listings affected by not completing education business record-filings or amendment filings with the competent education departments at the provincial level.

Based on the provisions of Circular 55 and the interpretation of Ministry of Education officials at the press conference, education apps under Circular 55 are defined broadly. In theory, the definition can cover learning apps and online training courses for different subjects and educational levels, online training apps and other campus service apps. However, due to the different contents of app products, the rules on how the education departments and mobile app distribution platforms determine whether an app is an education app during actual implementation and thus apply the relevant record-filing and review rules need to be clarified by the detailed regulatory rules.

## **II. Scope of education apps which may collect fees from parents**

Circular 102 clearly requires that on-campus apps not collect fees from students or require payment of related expenses. In current practice, competent education departments in most provinces and cities require that on-campus app products not include a fee collection function at the time of Circular 102 record-filing. However, the parent end can retain a fee collection function, which parents can choose to utilize. Circular 55 further establishes the principle that “education apps that are mandatory to use must not charge fees, the apps that charge fees must not be mandatory”, and regulates that education app which is a “teaching and management tool requiring uniform use” must not charge to students and parents, nor include commercial advertisements and games. Meanwhile, “recommended use” education apps must in principle be optional and not be tied to teaching and management activities.

In the context of “Internet plus education,” in order to facilitate the correction of homework, reviewing tests, grade management and analysis, local primary and middle schools in many regions will introduce high-quality education app products for teaching, in-school testing or uniform use. These products may open value-added services for students and parents, for which parents pay fees. In this case, the charging of fees to parents end and the business model for these types of app products will be influenced by how the competent education departments define whether an education app constitutes a “teaching and management tool requiring uniform use” or a “recommended use” product.

## **III. Boundary between “subject-based” and “quality-based” training**

The Draft Regulations divide the content of private education and training into three categories: subject-based training, quality-based training and adult training, within which “language skills” for primary and middle school students falls within the scope of quality-based training. However, English language proficiency may also be classified as subject-based training due to its connection with school cultural curricula, further study and review. According to the literal definition in Circular 8, “quality-based” training enterprises and the content of their products, other than subject-based training, are not subject to the Circular 8 record-filing system. Despite this, there is no clear guidance on the division of subject-based and quality-based categories for language training in primary and middle schools.

In practice, more than a few online training institutions use English training as a primary or important component of their trainings. The courses offered by these institutions may also specifically include those for English academic examinations in primary and middle schools. Therefore, for such institutions, distinguishing between “subject-based” and “quality-based” training standards will determine whether it is necessary to perform the corresponding record-filing and review procedures and whether it is necessary to make adjustments to comply with the relevant rules.

#### **IV. Do online extracurricular training institutions need to obtain a school-running license after completing the record-filing?**

In view of whether extracurricular training institutions must obtain a “private school-running license” (“**school license**”), the Draft Regulations propose the principle of “classification and certification.” Pursuant to this principle, training institutions must obtain a school license to engage in youth and child cultural education, while quality-based and adult training institutions are not required to obtain a school license. At the same time, however, the Draft Regulations restrict online education and training activities to those which do not require a school license. Despite this, the subsequent online education and training-related documents have not mentioned school license requirements for online training institutions.

The Ministry of Education indicated in a press conference at the time Circular 8 was promulgated that online and offline training will be treated differently due to their different characteristics<sup>4</sup>: offline training will be subject to county-level review and pre-certification, while online training will be subject to a record-filing and review system. When Circular 55 emphasizes the establishment of a joint supervisory mechanism, it refers to the civil affairs departments focusing on fulfilling registration administration work for private non-enterprise education units, while the market supervision administration departments will focus on fulfilling registration administration for online for-profit education institutions, which will treat the two types of education institutions differently. Since there are no clear provisions at the regulatory and policy levels, it remains to be seen whether the requirements for school licenses apply to online extracurricular training institutions.

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<sup>4</sup> Persons-in-charge of the Basic Education Department of the Ministry of Education brief the press on *Implementing Opinions of the Ministry of Education and Five Other Departments on Regulating Online Extracurricular Training Institutions*, [http://www.moe.gov.cn/jyb\\_xwfb/s271/201907/t20190715\\_390634.html](http://www.moe.gov.cn/jyb_xwfb/s271/201907/t20190715_390634.html) (Chinese); Ministry of Education holds a press conference to explain the *Implementing Opinions on Regulating Online Extracurricular Training Institutions*, [http://www.gov.cn/xinwen/2019-07/15/content\\_5409824.htm](http://www.gov.cn/xinwen/2019-07/15/content_5409824.htm) (Chinese).

## 2. Along the Path of Regulatory Reform: A Brief Review of the Revised Drug Control Law

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On August 26, 2019, the *Drug Control Law of the People's Republic of China* (the “**Law**”) was revised at the Twelfth Meeting of the Standing Committee of the 13th National People's Congress following three rounds of review and deliberation. The Law, as revised, will take effect on December 1, 2019. Generally speaking, the Law is a phased summary of the drug regulatory reforms following the issuance of “Circular 44” in 2015, such as the marketing authorization holder (**MAH**) system and drug review and approval system. The Law also lays a solid foundation for the future development of drug reforms. For example, the Law provides new provisions on online sales of prescription drugs and building a drug traceability system, among others.

### All mature reform efforts included

One of the main ideas of the revised Law is to consolidate and enter into law the results of reforms and practices in the pharmaceutical industry which have proven to be effective. Thus, the Law contains many provisions which may be familiar to those who closely watch supervision reforms in the pharmaceutical industry, and may involve issues that have been discussed at length in the past few years or have been repeatedly validated in industry practice. Relatively important provisions, issues and topics include the following:

#### I. Affirmation of the MAH system

The MAH system has been an important step in drug supervision system reforms in recent years since its launch in November 2015 in ten pilot provinces and cities. The MAH system emphasizes quality and safety supervision throughout the entire drug lifecycle, specifies persons responsible and risk distribution rules in drug supervision, and has become the core of the new drug supervision system. As revised, the Law provides a special chapter on the MAH system which emphasizes the responsibility of MAHs for drug quality and safety during the entire drug lifecycle, strengthening the comprehensive supervision and regulation, and implementing an enterprise accountability system.

The Law affirms the legal status of MAH, which not only applies the scope of the system from ten pilot provinces and cities to the whole country, but also extends the mature systems and practices formed during the pilot period. However, there are still many issues remaining to be further clarified, including compatibility between the MAH system and the “two-invoice system”, issues related to centralized procurement tender and bidding and financial and tax treatments.

#### II. Simplified review and approval process

The long clinical trial, review and approval process not only wastes time and financial resources of enterprises and exhausts governmental supervision resources, but also delays the availability of good drugs to the public. The Law enters into law many mature practices related to the optimization of clinical trial management and the reform of the new drug review and approval system, which mainly

include:

1. Clinical trial applications are approved by default upon expiry of the review and approval period, record-filing administration for bioequivalence tests and clinical trial institutions;
2. Establish communication and exchange, expert advisory and other systems. Based on previous experiences, the current situation is “communication is the rule, non-communication is the exception”, which fully promotes efficient drug approvals;
3. Open a green channel to prioritize the review and approval of urgently needed drugs, drugs for major infectious diseases, rare diseases and pediatric drugs;
4. Establish a conditional market-launch approval system (similar to the FDA Accelerated Approval Program in the United States).

### III. Cancellation of GxP certifications

GMP and GSP certifications, which originally existed as independent administrative licensing measures, have come to increase the burden on enterprises due to the duplication of drug manufacturing and trading licensing regulations, and run counter to the new regulatory approaches of ex-ante and ex-post supervision by the government. The two certifications have therefore increasingly come to be seen as being of little utility. The Law cancels the two certifications, taking advantage of longstanding industry calls for their cancellation and the positive statements in this regard by regulatory authorities. Going forward, GxP certificates will disappear from the field of drug supervision, and GMP and GSP certificates (GLP and GCP themselves do not issue certificates) will pass into history.

Of course, cancellation of GxP certifications does not mean the weakening of supervision. In fact, GxP supervision will only be strengthened in the future, because relevant documents, including *Guidance for Good XX Practice for Drugs* are still in place, a team of professional specialized drug inspectors will be constituted and various methods will be employed for on-site compliance inspections.

### IV. Say goodbye to “counterfeit” drugs

“Counterfeit” drugs are an issue in the industry that has come to the public’s attention, beginning with the “Acrivastine” incident which occurred in a hospital in Shanghai in 2011, and followed by the impact of the Jiangsu Lu Yong case, Shandong Liaocheng case, and the a women’s outpatient department case in Shanghai and the influence of the well-received movie, “Dying to Survive”. The Law provides appropriate responses. First, the basic position of lawmakers is that operators are prohibited from producing and importing drugs without obtaining an approval certificate, according to Article 98, para. 4. Second, Article 124, para. 3 gives rise to heated debate by stipulating that punishments imposed may be reduced or exempted for offenders who import without approval small quantities of drugs which have been legitimately launched in overseas markets. Third, according to Article 65, small quantities of imported drugs are to be regulated pursuant to relevant national provisions where they are urgently needed by medical institutions for clinical purposes or are brought into China by individuals for personal use.

However, these provisions of the Law leave more than a little room for interpretation, such as the connection between administrative and criminal penalties. In short, removal of these drugs out of the scope of counterfeit drugs does not mean removal of supervision of these drugs. We will further discuss relevant issues in the future.

In respect of this issue, the Law redefines the scope of counterfeit and substandard drugs based upon their efficacy, and no longer retains the concept of “drugs deemed as either counterfeit or substandard”. The Law adjusts counterfeit drugs into four types from the original eight: (i) the ingredients in the drug are different from those specified by national drug standards; (ii) a non-drug substance is simulated as a drug or one drug is simulated as another; (iii) it is deteriorated; or (iv) the indications or functions indicated are beyond the specified scope. Substandard drugs include seven types: (i) drugs with content not conforming to national drug standards; (ii) contaminated drugs; (iii) drugs for which the date of expiry is not indicated or is altered; (iv) drugs for which the batch number is not indicated or is altered; (v) drugs which are beyond the date of expiry; (vi) drugs with unauthorized added preservatives or excipients; or (vii) other cases in which drugs do not conform to drug standards.

## **V. Serious punishment for violations**

18 years have passed since the 2001 revision of the Law. Penalties for legal violations under the earlier versions of the Law have long been out of date, and rules related to food and medical device supervision promulgated by the former China Food and Drug Administration have also been substantially revised, including the means and scope of punishment for violations. Therefore, it was imperative to adjust the Law in relation to legal liability for violations.

The Law stipulates various penalties for legal violations, including financial penalties (substantially increasing the amount of fines, RMB 1.5 million at a minimum), cancellation of qualifications, detention and criminal liability, among which the following are highlights:

1. Persons responsible for counterfeit and substandard drug violations will subject to permanent industry bans, which is increased compared to the previous period of ten years;
2. Punishment of individuals includes legal representatives and key persons-in-charge, who are exposed to greater risk;
3. Civil liabilities include joint liability, first liability system, punitive damages and other compensation mechanisms, which will apply based on differing circumstances.

## **Next steps stipulated in the Law**

As mentioned above, the Law incorporates many recent important reform achievements and mature practices, and also leaves many issues to be further explored and discussed. However, the basic regulatory trends and ideas in these areas have been clarified and merely await the promulgation of detailed rules.

### **I. Online sales of prescription drugs**

The Law finally elevates to the level of laws the issue of online sales of drugs, following the

promulgation of a series of documents, including *Measures for Supervision and Administration of Online Marketing of Foods and Drugs (Draft for Comment)* issued by the former China Food and Drug Administration in May 2014, *Measures for Supervision of Online Marketing of Foods* promulgated in 2015, *Measures for Supervision of Online Marketing of Medical Devices and Drugs* promulgated in 2017, and *Measures for Administration of Online Medical Diagnosis* promulgated in 2018.

In particular, the issue of online sales of prescription drugs has been discussed for many years without the promulgation of specialized rules. The Law clarifies this issue eventually. Rather than prohibiting all online prescription drug sales, the Law only prohibits the online sale of prescription drugs subject to special administration stipulated by the State, such as vaccines, blood products, anesthesia and psychiatric drugs, medical-use poisons, radiative drugs, pharmaceutical precursor chemicals, etc. “All is permissible unless prohibited” and given statements made by the regulatory authorities at several press conferences, we can expect a promising future in the implementation of the policy on online prescription drug sales considering this principle.

## II. Drug traceability system

Although the Law proposes the drug traceability system at the level of laws for the first time, building of the drug traceability system has already been explored for years both conceptually and in practice; one example of this is the implementation of the controversial “drug electronic supervision code” system. The former China Food and Drug Administration formulated the *Opinions on Promoting Food and Drug Producers and Operators to Improve the Traceability System* in 2016, and promulgated *Guiding Opinions on Building of the Drug Informatization Traceability System* in November 2018, both exhibited the determination and efforts of the regulatory authorities to realize source traceability and destination tracking for all drug varieties throughout the entire drug lifecycle.

According to the requirements of the Law, the National Medical Products Administration (the “NMPA”) will build a joint traceability platform and a traceability supervision platform, and issue a series of technical traceability standards. At present, the NMPA has issued the *Guidelines for the Building of the Drug Informatization Traceability System and Encoding Requirements for Drug Traceability Codes*. Today, we also see three other documents promulgated, including *Basic Technical Requirements for Drug Traceability Data Exchange*, *Basic Dataset for Vaccine Traceability* and *Basic Technical Requirements for Vaccine Traceability Data Exchange*. In addition, NMPA will also actively promote the building of collaborative service platforms and supervision platforms. With the joint endeavors of the government and enterprises, it is also worth observing how all parties use information technology to ensure the quality and safety of drug operations to achieve the control of counterfeit and substandard drugs and to recall drugs with precision.

## III. Ensure availability of drugs in short supply

The Law provides a special chapter, “Drug Reserves and Supply”, which addresses shortages of commonly used drugs and urgent (rush) rescue drugs. This chapter ensures the availability of drugs in short supply through the following major aspects:

1. The State implements a list management system for drugs in short supply, with the specific

management measures to be jointly formulated by the National Health Commission and NMPA;

2. Reporting system for production stoppages of drugs in short supply;
3. Prioritize review and approval of drugs in short supply;
4. Prohibit export of drugs in short supply;
5. Monitoring system for drugs in short supply: the State will establish a drug supply and demand monitoring system, collect and aggregate information on supply and demand of drugs in short supply in a timely manner, and propose response measures.

#### **IV. Other new supporting provisions**

In addition to the major changes mentioned above, the Law also assigns tasks to regulatory authorities and market players. Therefore, it is certain that there will be a large number of supporting provisions to be promulgated in the future, including:

1. Pharmacovigilance system;
2. Drug retail sales chain incentive policy;
3. Pediatric drug development and innovation incentive policy;
4. Uniform publication system for drug safety information, etc.

#### **Reforms still have a long way to go**

The Law not only provides a phased summary of past experiences, but also marks a new starting point for drug regulatory reforms. Many drug supervision systems and policies with which we are familiar are not reflected in the Law, including the definition of new drugs, the list of marketed drugs (Chinese Medicine Orange Book), the patent linkage system for drugs, the patent term compensation system for drugs and the drug experimental data protection system. We understand that drug supervision is a complex undertaking which is impossible to be accomplished solely with the Law. We are looking forward to the promulgation of *Regulations for Implementation of the Drug Control Law*, *Measures for Administration of Drug Registration* and other supporting departmental rules and regulatory documents, as well as the improvement of related provisions, including the Patent Law and its supporting regulations. Rome was not built in a day—while they may have a long way to go, we can look toward the future of drug reforms with optimism.

## ***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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