Legal Commentary

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# 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*

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