Legal Commentary

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Highlights on New Draft Rules of Drug Administration

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On May 9, 2022, National Medical Products Administration (NMPA) issued for public comments a draft revision (the "**Draft Revision**") to the *Regulations for the Implementation of the Drug Administration Law of the People's Republic of China* (the "**Regulations**"). The public comment period ends on June 6, 2022.

The Regulations were last revised and became effective in March 2019. However, the Drug Administration Law of the PRC (the "**Drug Administration Law**") was substantially revised about six months later in August 2019, officially adopting the marketing authorization holder ("**MAH**") system that had been piloted for many years in certain provinces and cities. The revised Drug Administration Law has come into effect for more than two years, and the public is eagerly looking forward to the revision of the corresponding implementing regulations. Since the implementation of the MAH system, the NMPA and other authorities have formulated and updated numerous supplementary rules in addition to the Drug Administration Law. These rules are scattered in various separate regulations, notices, announcements, and guiding principles. Per its content, the Draft Revision would add a considerable number of provisions that have not been explained or clarified in the Drug Administration Law and also integrate the scattered rules and principles found in various normative documents of different levels.

Here are our summary and commentary on the key contents of the Draft Revision.

DRUG DEVELOPMENT

I. Requirements for Domestic and Foreign Research and Development Activities

The Draft Revision stipulates that drug research and development activities for the purpose of marketing drugs in China, whether undertaken inside or outside China, must comply with the requirements of Chinese laws, regulations, rules, standards, and norms. This article would apply the Regulations to research and development activities undertaken overseas, which reflects an important method for the NMPA to ensure drug safety and strengthen supervision since drug development, manufacture, and distribution activities have become more and more globalized.

II. Establishment of Technical Specification System

China joined the International Council for Harmonization of Technology for Registration of Pharmaceuticals for Human Use (ICH) in 2017 and became a member of its management committee in 2018. China has since gradually transformed and implemented international advanced technical standards and guidelines and has actively participated in rulemaking. The Draft Revision once again specifies that China will further adapt to international rules. The NMPA will formulate relevant technical specifications and guiding principles for drug development in China and with reference to internationally accepted technical requirements.

III. Non-clinical Research

In 2007, the predecessor to the NMPA promulgated the *Measures for Administration of the Certification of Quality Management Standards for Drug Nonclinical Research*, which has not since been updated. The Regulations do not currently mention this certification, but only require research institutions to comply with the corresponding quality management practices for non-clinical drug research (GLP). The Draft Revision expressly includes the GLP certification requirements for the first time and clarifies that certifications are valid for five years. The requirement on GLP certification would therefore be upgraded to be included in the Draft Revision, a State Council administrative regulation, which demonstrates that the authorities attach great importance to GLP certification and relevant supervision activities.

IV. Change of Sponsor

The Draft Revision clarifies that a sponsor can change during drug clinical trials and stipulates that the change should be approved by the NMPA (if necessary, the NMPA will re-issue the drug clinical trial approval notice). The sponsor is equivalent to the status of the MAH in the clinical trial stage, and accordingly, the changed sponsor assumes the corresponding obligations and responsibilities for the drug clinical trials. This also confirms the practice of changing sponsors in the current administrative guidelines and guidelines at the level of the NMPA Center for Drug Evaluation (CDE).

APPLICATION FOR DRUG MARKETING AUTHORIZATION

I. Drug Marketing Authorization Application (New Drug Application)

The Draft Revision clarifies for the first time in administrative regulations that a drug marketing authorization applicant (an "**NDA applicant**") and a drug clinical trial sponsor (an "**IND sponsor**") can be different entities. The NDA applicant assumes the obligations and responsibilities related to the marketing authorization application.

The transferability of research results and marketing rights is the core of the MAH system. In addition to determining who is responsible for the entire life cycle of drugs, another primary purpose of the MAH system is to provide liquidity for drug-related rights and interests, thereby providing flexibility for business arrangements for enterprises and enhancing the value of such rights as assets. To a certain extent, this also provides new approaches for business arrangements for companies who have established VIEs for business activities within negative list.

Notably, the Draft Revision stipulates that at the drug registration application stage, the applicant and trial drug manufacture site should both be in China or overseas. However, it does not expressly prohibit the transfer of the applicant's location and that of the drug trial manufacture from overseas to China or vice versa.

II. Encourage Innovation

The Draft Revision supports clinical value-oriented drug innovation. In November 2021, CDE released the *Guidelines for Value-oriented Clinical Research and Development of Anticancer Drugs*, which indicate that the development of new drugs should take providing patients with better treatment options as its ultimate goal (more effective, safer or more convenient). Encouraging first-in-class or best-in-class research, meanwhile, this document is seen as a powerful squeeze on the cluttered R&D "bubble". As a result, the developing prospects for numbers related companies were no longer clear and the financing and marketing plans of some were affected. Although the influences of this policy was controversial among the industry, it indicated the CDE's purpose to alleviate the homogenized competition in drug research and development and also showed CDE's determination and means. Judging from the inclusion of phrase "clinical value-oriented" in the Draft Revision, authorities may continue to, by adopting guiding principles or through other means in the future, encourage and promote higher standard innovation in the field of innovative drugs (not limited to anti-tumor drugs), emphasize avoiding the development of drugs with limited clinical value ("me worse"), and to guide companies to prudently choose R&D targets.

In addition, the Draft Revision also clearly provides that drug innovation should be supported in terms of scientific and technological project establishment, financing, credit, bidding procurement, price payment, and medical insurance. In view of the significant regulatory reforms and market fluctuations experienced by the pharmaceutical industry in recent years, there is a certain gap between the industry's expectations and the reality of the overall investment and financing environment, capital market performance, centralized procurement bidding, and national negotiations. By reaffirming this supportive position, the Draft Revision also provides a brighter perspective for the effective implementation of follow-up supporting rules to provide practical and powerful legislative and policy support for drug innovation.

III. Accelerating Marketing Channels

The Draft Revision references systems stipulated in the Drug Administration Law for encouraging drug R&D innovation and shortening the process of drug R&D and review, including those for breakthrough therapeutic drugs, conditional approval for marketing, priority review and approval, and special approvals. The Draft Revision does not provide for extensive details on these matters because the *Measures for Administration of Drug Registration,* promulgated in 2020, already provides sufficient rules and are accompanied by relevant implementation guidelines to support related policies concerning accelerated marketing channels.

IV. Dispute Resolution Mechanism

The Draft Revision proposes that the NMPA would establish a drug registration objection resolution

mechanism to properly handle applicants' objections to the technical review conclusions in the registration. This is not the first reference to such a system. In August 2020, the NMPA issued the *Procedures for Resolving Objections to Drug Registration Review Conclusions (for Trial Implementation)*. Pursuant to these procedures, objection resolution refers to "where, upon completion of the comprehensive review and the conclusion is not to approve, following the CDE informing the applicant, the applicant raises an objection and the CDE organizes a comprehensive assessment or expert advisory committee demonstration to form the final technical review conclusion."

V. R&D of Chemical Generic Drugs

The Draft Revision specifies that the NMPA is to select and publish the catalogue of generic drug reference preparations; that the R&D of chemical generic drugs refers to relevant technical guidelines to select reference preparations or reference drugs; and the NMPA is to establish a drug patent information registration platform. The drug registration applicant and the MAH would register the relevant drug patent information according to the regulations and explain the relevant drug patents involved and their ownership status.

This catalogue of generic drug reference preparation and drug patent information registration platform are combined together as a counterpart to the Orange Book in the United States. The Orange Book is not only the basis for chemical generic drug applicants to provide a patent ownership status statement, but also the patent drug MAH's reliance for its intellectual property and regulatory rights protection.

China's Orange Book is not new. The *Catalogue of Marketed Drugs in China* was formulated as early as the end of 2017. The Draft Revision merely reconfirms this system and links it with other drug regulatory laws and regulations. It is believed that if this part of the Draft Revision is adopted, the Orange Book system will continue to develop and mature in the future.

DATA EXCLUSIVITY / MARKETING EXCLUSIVITY

As early as 2018, the NMPA issued the *Implementation Measures for Drug Trial Data Protection (for Interim Implementation) (Draft for Comment)*, but it has not been formally promulgated. The Draft Revision directly specifies the relevant data exclusivity rules in the absence of the draft measures. To compare, the draft measures provide data exclusivity periods for drugs approved for marketing in China: a six-year data protection period for innovative drugs, orphan drugs, and pediatric drugs; and a 12-year period for innovative therapeutic biological products.

By contrast, the Draft Revision does not distinguish between innovative chemical drugs or innovative therapeutic biological products and would uniformly grant all applicable drugs a data exclusivity period of six years from the date when an MAH obtains the drug registration certificate. Orphan drugs, pediatric drugs and first-approved generic drugs would be given marketing exclusivity periods of 7 years, 12 months, and 12 months respectively (which all differ from the draft measures).

INTELLECTUAL PROPERTY PROTECTION OF MEDICINES

I. Patent Linkage System

Although the Drug Administration Law (2019) does not address the drug patent linkage system, China has gradually adopted a series of related provisions firstly since the Patent Law update in 2020, such as the *Implementation Measures for Early Resolution Mechanism of Drug Patent Disputes (for Trial Implementation)*, the *Measures for Administrative Adjudication of Drug Patent Disputes under the Early Resolution Mechanism*, *Provisions of the Supreme People's Court on Several Issues concerning the Application of Law in the Trial of Civil Cases of Patent Disputes Related to Drugs Applied for Registration*, etc. The Draft Revision also specifies patent linkage principles so that a comprehensive and holistic "China Patent Linkage System" may be established, in conjunction with the Patent Law and relevant judicial interpretations.

In practice, the first administrative and judicial decisions on the drug patent linkage system are also recently open to public-channel access. As part of the reform of innovative drug regulation, we look forward to more "drug patent linkage" practices in the industry in the future.

II. Compulsory License of Drug Patents

Compared to the Patent Law, the Draft Revision puts forward more specific requirements for compulsory license of drug patents. For instance, out of public health purposes or during a national emergency, the National Health Commission can purpose a compulsory patent license according to the needs of disease diagnosis and treatment. Enterprises that meet the corresponding conditions could take the initiative to apply to the China Intellectual Property Office then obtain and implement the compulsory license of the corresponding patents in accordance with the Patent Law. At the same time, the Draft Revision provides that drugs granted compulsory patent licenses will be given priority review and approval according to the regulations.

DRUG MARKETING AUTHORIZATION HOLDERS (MAH)

I. All lifecycle Quality Assurance System

Per the MAH system established in the revised Drug Administration Law, MAHs are responsible for the safety, efficacy, and quality of their products throughout the product lifecycle, including non-clinical research, clinical trials, manufacture and distribution, and post-marketing monitoring. Correspondingly, the Draft Revision stipulates that not only MAHs (including vaccine MAHs) should establish a comprehensive quality assurance system covering all steps of drug development, clinical trials, manufacture, distribution, and use. In addition to MAHs, certain other parties involved in drug activities, including clinical trial sponsors, medical institutions, and drug manufacturers, also need to establish a quality management assurance system.

II. MAH's Manufacturing License Requirements

The Draft Revision again clarifies the specific qualification requirements for MAHs for drug manufacturing licenses mentioned in the *Measures for the Supervision and Administration of Drug*

Manufacturing. That is, when an MAH entrusts the manufacture of drugs, it must also obtain a drug manufacturing license, but it can exempt some qualification requirements for actual contract manufacturing enterprises, such as site and facilities and equipment.

III. Appointment and Change of Domestic Agent

The Draft Revision proposes two potential schemes for regulating overseas MAHs appointing domestic agents. Under the second scheme, overseas MAHs can appoint a domestic agent while drug marketing authorization is approved. That is, it may be possible to change the domestic agent right before marketing. This would give the MAH more flexibility in picking an onshore agent. At the same time, such domestic agent would also need to establish a quality assurance system for all lifecycle of the products and be equipped with corresponding management department and professional and technical personnel.

IV. Post-Marketing MAH Obligations

The Draft Revision emphasizes that MAHs must undertake the obligations for drug traceability, pharmacovigilance, management responsibility for entrusted activities, risk management plans and post-marketing research, and management of filing and reporting matters after the drug is marketed. Each of the obligations is aimed at clarifying that MAHs are responsible for the safety, efficacy, and quality of their drugs post-marketing and continuously fulfill their responsibilities for post-marketing evaluation. According to the results of post-marketing evaluation, MAHs would be required to take measures such as revising drug inserts, improving quality standards, improving process prescriptions, suspending manufacturing and sales, recalling drugs, and canceling drug approval documents.

V. Transfer of Marketing Authorization for Multi-Specific Drugs

The Draft Revision stipulates that when transferring the marketing authorization of a multi-specification drug, a change to the same variety with different specifications needs to be completed once and the manufacture site, prescription, manufacture process, and quality standards of the drug need to be changed at the same time.

Drug Manufacturing

Most of the Draft Revision related to the issue of drug manufacturing has been stipulated in the *Measures for the Supervision and Administration of Drug Manufacturing*, which will not be mentioned in this article. However, the Draft Revision also answers many questions that are not clear in practice.

I. Commercial-Scale Batch Drug Sales

The Draft Revision clarifies that, after obtaining the drug registration certificate, commercial-scale batches of drugs whose quality standards and manufacture processes are consistent with the registration certificate can also be marketed if they meet the product release requirements. This kind of arrangement has not been clearly stipulated in the previous laws and regulations and can only to be permitted by negotiating with the regulatory authorities in current practice. Such clarification in the Draft Revision is a definite regulatory development, which not only effectively solves the problem of

setting reasonable distinction between manufacturing release and marketing release in terms of regulatory logic, but also eliminates concerns on the unclear regulatory rules when pharmaceutical companies making specific commercial arrangements for drug manufacturing and marketing.

II. Overseas Manufacturing Sites

The *Measures for the Supervision and Administration of Drug Manufacturing* (2020) for the first time specified that they apply to the manufacturing, supervision and management of all drugs marketed in China. The Draft Revision would further specify that if the drug manufacturing site is overseas, its manufacturing activities must comply with the relevant requirements of Chinese laws, regulations, rules, standards, and norms. With the upgrade of China's drug R&D level, many more drugs registered in China will extend the supply chain overseas in the future. This provision indicates that the NMPA may further strengthen the supervision and inspection of overseas manufacture activities in the future.

III. Contract Vaccine Manufacturing

The Draft Revision specifies circumstances regarding the contract manufacturing of vaccines. The Vaccine Administration Law stipulates that vaccine MAHs should have the vaccine manufacturing capacity and they must obtain NMPA approval if it becomes necessary to entrust third parties to manufacture the vaccines due to lack of capacity. The Draft Revision details the specific circumstances in which contract manufacturing can be approved. At the same time, it emphasizes once again that, in addition to the corresponding responsibilities of the entrusting party as the MAH, contract vaccine manufacturers must comply with relevant regulations to ensure the quality of vaccines.

IV. Staged Manufacturing

For the first time, the Draft Revision stipulates the content of drug manufacturing stages, emphasizing that MAHs should establish a unified quality assurance system for the entire drug manufacturing process and all manufacture locations. The Draft Revision also clarifies that the conditions for applying staged manufacturing are limited to: innovative drugs that have special requirements for manufacturing technology, facilities and equipment, or drugs that are urgently needed in clinical practice, and need to be approved by NMPA.

DRUG DISTRIBUTION

I. MAH Network Sales Management

The Draft Revision stipulates that the subjects engaged in online drug sales activities include MAHs and drug distributors. Drugs to be sold online must either belong to the MAH or within the scope of drugs allowed to be distributed by the distributor. The Drug Administration Law stipulates that an MAH who engages in drug retail activities must obtain a drug distribution license. In view of hierarchy of laws and regulations, the Draft Revision cannot contravene provisions of the Drug Administration Law. Therefore, MAHs engaged in online drug retail would still need to obtain a drug distribution license and online sales activities that can be carried out without obtaining a drug distribution license are limited to drug wholesale. However, as explained above, it appears that the NMPA does not emphasize that MAHs may engage in online drug wholesale without the drug distribution license, so

the NMPA needs to further explain this issue. At the same time, the Draft Revision clarifies that drug retail enterprises can sell prescription drugs through the Internet, but it is also notable that China imposes drugs under special administration or with high risk are not allowed to retail online. Corresponding catalogues will be formulated.

II. Emergency Management Requirements

Possibly due to actual needs against the Covid-19 pandemic, the Draft Revision contains emergency measures for drug retailers. Emergency management includes measures such as removing products from shelves and suspending sales, etc. Circumstances where emergency management is applicable include public health emergencies and other emergencies that seriously threaten public health.

III. Prohibition on Drug Distribution Outside Manufacturing and Business Premises

Notably, the Draft Revision clearly prohibits MAHs and drug distributors from selling drugs in exhibitions, expositions, trade fairs, order fairs, promotion conferences, etc. outside manufacturing and business premises; this prohibition does not distinguish between prescription and over-the-counter drugs.

IV. Individuals Carrying a Small Quantities of Drugs for Personal Use

The Drug Administration Law removes the manufacture and import of unapproved drugs from the definition of counterfeit drugs. When importing a small quantity of drugs that have been legally marketed overseas, the regulatory authorities can impose lighter or mitigated penalties or exempt the penalties. The Draft Revision further loosens the requirements, frankly stipulating that individuals who carry or deliver a small quantity of drugs for personal use into China should declare in accordance with the Customs' administrative regulations. This article can be understood as an acknowledgement of the legality of individuals carrying a small quantities of unapproved drugs for their own use. At the same time, the Draft Revision also emphasizes that drugs must not be sold in China after entering the country (including disguised sales).

PHARMACY MANAGEMENT IN MEDICAL INSTITUTIONS

The Draft Revision would provide a separate chapter for the pharmaceutical management of medical institutions, indicating the NMPA intends to raise the supervision of medical institutions to a new level. The following four aspects are worth noting:

I. Pharmaceutical Quality Management System and Requirements for Medical Institutions

The Draft Revision would require that medical institutions establish and improve the drug quality management system; improve the quality management system for the purchase, acceptance, storage, maintenance, and use of drugs; clarify the position responsibilities of personnel in each aspect; and set up special departments or designated personnel to be responsible for drug quality management. The standalone proposal for "Medical Institutions Drug Quality Management System and Requirements" not only to fills in the vague provision ("…shall strengthen drug management in accordance with drug management laws and regulations") in the *Regulations on Administration of*

Medical Institutions, but also to addresses the widespread issue of drug quality in medical institutions. It is likely that medical institutions would be given responsibilities similar to MAHs.

II. Pharmacovigilance System of Medical Institutions

The Draft Revision proposes a "Pharmacovigilance System for Medical Institutions", which aims to improve and supplement the *Pharmacovigilance Quality Management Standards* because the latter only regulates MAH and IND sponsors, leaving a gap in the system. Pharmacovigilance in medical institutions has a wide range of applications and is not limited to specific activity stages. Medical institutions should report and communicate as long as they find adverse drug reactions and other harmful drug use-related reactions in the entire drug use process. Given that medical institutions have the function of diagnosis and treatment, when they discover a cluster of adverse drug reactions, they need to take emergency measures such as actively treating patients, conducting clinical investigations, and suspending drug use.

III. Compassionate Use

Compared with the revised Drug Administration Law regarding "compassionate drug use", the Draft Revision adds the principle of "voluntary request by patients". Therefore, the principle requires that "the physician believes that the benefits may outweigh the risks based on the medical analysis of the patient's condition and the patient cannot participate in the clinical trial of the drug" and "make a recommendation (the patient decides on his own)." At the same time, the requirements for physicians have also been further improved, requiring physicians to have experience or be trained in using experimental drugs, which further mitigates unnecessary risks in compassionate medication.

IV. Emergency Drug Use

The Draft Revision contains new provisions on the emergency drug use, which refers to where no effective treatment exists in the event of a major public health emergency or other emergency that seriously threatens public health, the National Health Commission will propose an emergency according to the needs of medical treatment. The NMPA would then organize and demonstrate, with the approval of the State Council, the drugs under clinical trials that can be used urgently within a certain scope and within a certain period of time, or the use of drugs that are not specified in the drug instructions can be used for treatment. As the most significant public health event all over the world, the Covid-19 Pandemic has also profoundly affected the development of the medical legal system. However, it can still be seen that the procedures stipulated in this article are relatively strict ("the drug regulatory department of the State Council organizes the demonstration, with the approval of the State Council"), and the scope is relatively limited ("the drugs that are undergoing clinical trials, or the use of drugs that are not specified in the drug instructions").

SUPERVISION AND MANAGEMENT

This part of the Draft Revision mainly aims to clarify the administration responsibilities of the drug regulatory authorities at all levels for review, approval, inspection, and verification, and provides guidance for the regulatory authorities to perform their duties.

I. Extended Inspection

Notably, the Draft Revision clarifies that when the drug regulatory department conducts extended inspections, the inspected units and individuals should provide true, valid, and complete relevant materials and truthfully answer inquiries. If the refusal or non-cooperation makes it impossible to complete the inspection work and cannot prove that the manufacture and distribution activities meet the statutory requirements, it will be directly deemed as non-compliance with the regulations and normative requirements. This article stipulates the cooperation obligations of relevant inspected units and individuals, and the legal consequences for failing to cooperate that result in the failure to complete inspection activities from the perspective of allocating the burden of proof.

II. Restrictions on Leaving the Country

The Draft Revision adds a post-supervision measures, stipulating that, for major illegal acts and major safety hazards, the drug supervision and administration department will restrict the legal representative, main persons in charge, and persons directly responsible in charge of the relevant unit suspected of violating the law, and other directly responsible persons from exiting China.

PENALITIES

The Draft Revision updates the rules on administrative penalties, making itself consistent with the newly revised Law of the PRC on Administrative Penalty (2021) (the "**Administrative Penalty Law**"). Three points are worth noting:

I. Mitigation and Impunity

Drug legislation has repeatedly emphasized the "four strictests" in terms of regulatory standards, but the Draft Revision has some highlights in the legal liability chapter, which also reflect the spirit of scientific supervision. For example, in response to the penalties for non-compliance with quality management standards stipulated in Article 126 of the Drug Administration Law, Article 161 of the Draft Revision specifies that the MAH or other units do not meet the general project requirements, key projects and key project requirements or basic requirements in the relevant quality management standards during the development, manufacturing and distribution activities. The provisions of Article 126 of the "Drug Administration Law" should effectively impose corresponding rules such as punishment.

In addition, Article 168 (Waiver of Penalty) stipulates that no administrative penalty will be imposed if:

- the illegal act is minor and corrected in a timely manner, and no harmful consequences are caused;
- First-time offenders whose violations cause only minor harmful consequences and are rectified in a timely manner;
- Where the parties have sufficient evidence to prove that they have fully performed their duties, that there is no subjective fault, and that no harmful consequences have been caused or that the harmful consequences are significantly minor.

The above-mentioned law enforcement provisions are in line with the conditions and principles for circumstance of non-punishment established by the Administrative Penalty Law, effective July 15, 2021, and reflects the basic "penalty proportioned with violation" principle in administrative supervision.

II. Determination of Illegal Gains

The current Regulations do not define or provide a method for calculating illegal gains. The Draft Revision clarifies that illegal income includes all income obtained from the illegal manufacturing, illegal sale of drugs, or the illegal provision of services, and only the taxes and social insurance funds that the parties have paid can be deducted. It is notable that the provisions on illegal gains in the Draft Revision are different from those in the Administrative Penalty Law, which stipulates that "illegal gains refer to the gains obtained from a violation of law", and clearly increases the amount of illegal gains that can be obtained.

III. "Look-through Rule"

The Draft Revision clarifies that the primary responsible person stipulated in the Drug Administration Law refers to the person who is fully responsible for the organization and operation management of the enterprise and can actually control the company. Furthermore, the Draft Revision provides for a "look-through rule". If the actual controller of an enterprise is a legal entity, the primary responsible person refers to the principal natural person in charge of the actual controller. Compared with "piercing the corporate veil", this gives the law enforcement greater discretion, and personal liability can be imposed on the principal nature person in charge of the company's actual controlling shareholder. If this provision is adopted, companies should take a more prudent attitude on the arrangement of MAH and the individual liabilities of the primary responsible persons throughout the entire drug lifecycle.

Important Announcement

This Legal Commentary 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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