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Han Kun Newsletter

Issue 187 (11th edition of 2022)

Legal Updates

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1. Highlights on the New HGR-Related Administrative Penalty Rule

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Background

As the regulation system on human genetic resources ("**HGR**"), biosecurity and laboratory animals is experiencing continuous improvement, enforcement actions of the Ministry of Science and Technology ("**the MOST**") have become more active and tight in recent years. Taking into account the actual situation in law enforcement and to meet the increasing demands for law enforcement guidance, the MOST issued the *Measures for the Implementation of Administrative Penalty of the Ministry of Science and Technology (Draft for Comments*) ("***Measures for the Implementation***") on November 16, 2022.

In July 2021, the revised *Law of the People's Republic of China on Administrative Penalty* ("***Administrative Penalty Law***") was formally implemented. The central government values and sets high expectations to the effective implementation of the *Administrative Penalty Law*. In November 2021, the State Council issued the *Notice of Further Implementing the Law of the People's Republic of China on Administrative Penalty*, requiring the departments to formulate or revise supporting policies for administrative penalties to ensure that the procedural requirements are well implemented.

In this article, we will briefly analyse the *Measures for the Implementation* and summarise the enforcement provisions and tendency of the MOST, expecting to provide some guidance to the industry for complying with compliance requirement related to the MOST.

Brief introduction of the measures

As regards of its nature, the *Measures for the Implementation* are procedural and departmental rules, which specifies the procedures for the implementation of administrative penalties rather than creating substantial compliance obligations for the industry and companies within. The *Measures for the Implementation* aims to regulate the administrative penalties and to safeguard their effective implementation.

In line with the *Administrative Penalty Law*, which is of higher legal hierarchy, the administrative objects under the *Measures for the Implementation* are also citizens, legal persons and other organizations. In addition, the *Measures for the Implementation* restricts the scope of law enforcement to illegal acts within the territory of the People's Republic of China, indicating that the *Measures for the Implementation* has no extraterritorial jurisdiction or force. In the *Measures for the Implementation*, *Law of the People's Republic of China on Progress of Science and Technology*, *Law of the People's Republic of China on Promoting the Transformation of Scientific and Technological Achievements*, *Law of the People's Republic of China on Popularization of Science and Technology*, *Biosecurity Law of the People's Republic of China*, *Regulations of the People's Republic of China on the Administration of Human Genetic Resources ("**HGR Regulations**")*, *Regulation on National Science and Technology Awards* and *Regulation on the Administration of Laboratory Animals* are all enumerated as the applicable penalty basis for administrative

penalties. It is worth noting that, since the MOST is responsible for the administration of laboratory animals nationwide, laboratory practice involving laboratory animals shall also fall under the supervision of the MOST, and thus be subject to regulations of the *Measures for the Implementation*. Furthermore, list of penalty basis above is not exhaustive and documents related to the MOST such as the *Interim Provisions on Handling Violations of Regulations in Scientific and Technological Activities* are not listed therein.

Analyses of key provisions

I. Implementation authorities and the implementation entrustment

According to Article 5 of the *Measures for the Implementation*, the MOST shall impose administrative penalties within the scope of its functions and powers and no administrative penalties shall be imposed in the name of any internal organs of or public institutions directly under the MOST. With regard to the statutory scope of functions and powers of the MOST, taking the administration of HGR as an example, according to the *HGR Regulations*, the power of administrative penalty involving the punishment of most serious illegal utilization of HGR is conferred upon the MOST while provincial science and technology departments (commissions, bureaus) are only entitled to the authority to impose administrative penalties on relatively minor illegal acts (see the table below for more details). Moreover, according to the *Rule for Implementation of the Regulations on Administration of Human Genetic Resources (Draft for Comments)*, although science and technology departments at provincial level may be entrusted by the MOST to conduct investigation of illegal acts within their respective jurisdiction, the power to impose administrative penalties remains with the MOST. Therefore, according to laws and regulations including but not limited to *Law of the People's Republic of China on Progress of Science and Technology*, *HGR Regulations* and *Regulation on the Administration of Laboratory Animals*, the MOST has a relatively broad authority to impose penalties, and the corresponding enforcement of administrative penalties are subject to the provisions of this *Measures for the Implementation*, the importance of which cannot be overlooked.

Scope of penalty authority of the MOST under *HGR Regulations*	Scope of penalty authority at provincial level under *HGR Regulations*
■ **Without Approval**, to sample China's HGR of Important Genetic Families and HGR of Specific Regions or to sample HGR meeting the threshold of types or quantities prescribed by the MOST. ■ **Without Approval**, to biobank China's HGR. ■ **Without Approval**, to conduct international cooperation scientific research involving China's HGR. ■ **Without Security Review**, to give external provisions or open access of HGR information that are likely to affect public health, state security or public interest of China to foreign parties. ■ **Fail to submit fillings** before the conduct of	■ **Failing to pass the ethical review**, to sample, biobank, utilize or conduct external provision of China's HGR. ■ **Failing to obtain prior informed consents of the providers or obtain the consents by means of concealment, misleading statement or deception,** to sample China's HGR. ■ To sample, biobank, utilize or conduct external provision of China's HGR **in violation of relevant technical norms**. ■ …

Scope of penalty authority of the MOST under *HGR Regulations*	Scope of penalty authority at provincial level under *HGR Regulations*
international cooperation clinical trial. ■ **To provide false materials or by any other deceptions** to obtain administrative license. ■ **Fail to submit annual report** when biobanking China's HGR. ■ **Overseas organizations or institutions established or actually controlled by overseas organizations or foreign individuals to violate the regulation,** through sampling, biobanking, utilizing or conducting external provisions of China's HGR. ■ …	

Article 6 of the *Measures for the Implementation* provides that specific cases shall be respectively administrated by the functionary departments of law enforcement of the MOST ("**Functionary Departments**") according to their regulatory fields. In addition, the *Measures for the Implementation* particularly emphasizes that the Legislative Affairs Office and the Information Disclosure Institution of the MOST shall be responsible for legal review and information disclosure.

Article 7 and 8 of the *Measures for the Implementation* stipulate the entrustment of penalty enforcement. In a comprehensive view, the requirements of the *Measures for the Implementation* in respect of written entrustment, entrustment disclosure, content of entrustment letter, the subject name of penalty and non-delegation are consistent with the provisions of the *Administrative Penalty Law*.

As for the conditions of entrustment, the *Measures for the Implementation* requires the entrusted organization to be administrative organ or institution with the function of managing public affairs, in line with the requirements of the *Administrative Penalty Law*. In addition, according to Article 21 of the *Administrative Penalty Law*, the entrusted organization shall meet the following conditions: (a) it is formed in accordance with law and has the function of managing public affairs; (b) it is staffed with personnel who are familiar with relevant laws, administrative regulations and government rules and experienced in the work, and who have obtained qualifications for administrative law enforcement; and (c) it has the means to organize and conduct technical tests or technical appraisals where necessary. As for the aforementioned requirements, science and technology department at provincial or municipal level both met the qualification requirements and could be entrusted by the MOST to implement administrative penalties. Based on the MOST's consideration of practical needs for penalty enforcement reflected in the *Explanations for the Drafting*, it is very likely that the MOST will actively apply the entrustment method and delegate part of its authority to science and technology departments at provincial level, so as to expand the administrative enforcement forces, invigorate the administrative enforcements activities and enhance the effectiveness of administrative management. However, according to the *Administrative Penalty Law* and the *Measures for the Implementation*, if provincial department is authorized to impose administrative penalties, it cannot further authorize other administrative organs or organizations, i.e. the authority of the MOST cannot be delegated by the

provincial department to the municipal department directly. Nevertheless, since the *Measures for the Implementation* imposes no limitation on the levels of entrustment and the qualification requirements for delegated organizations are relatively lenient, the municipal science and technology departments, other administrative organs and other institutions with the function of administering public affairs may also be entrusted by the MOST to implement corresponding administrative penalties in the future.

II. Confidentiality and penalty publication

Article 4 of the *Measures for the Implementation* provides for the confidentiality and is consistent with the provisions of Article 50 of the *Administrative Penalty Law*, requiring that the confidential scope includes state secrets, trade secrets and personal privacy and the abovementioned information "shall be kept confidential" without room for discretion on this point. Meanwhile, the recognition of trade secrets is still at the discretion of administrative authorities. In determining whether the information involves trade secrets, whether such information meets the three elements - confidential, valuable and protected - provided in Article 9 of the *Anti-Unfair Competition Law of the People's Republic of China* shall be a major consideration. In addition, the *Measures for the Implementation* refines the requirements for subjects with confidentiality obligations, extending its scope from "staffs of administrative organ" as stipulated in Article 50 of the *Administrative Penalty Law* to "relevant personnel participating in the case handling", which enlarges the scope of subjects with confidentiality obligations. This will be more conducive to safeguarding the legitimate rights and interests of the administrative counterparts in respect of their trade secrets and personal privacy.

Article 14 of the *Measures for the Implementation* stipulates the publication of administrative penalty decisions, which is consistent with the provision in Article 48 of *Administrative Penalty Law*, setting "having certain social impact" as the standard for deciding whether a penalty decision shall be made public. However, it is worth noting that the determination of "having certain social impact" has always been controversial since the amendment of *Administrative Penalty Law*. It is likely that the MOST will be entitled to wide discretion in its determination and the subsequent practice is worthy of further attention. In addition, uncertainty remains in the disclosure forms of the administrative penalty decisions. Taking local practices as examples, the requirements stipulated in the *Measures for Voluntary Disclosure of Information on Administrative Penalty Cases in Shanghai* ("***Shanghai Disclosure Measures***"), the *Interim Measures for Online Disclosure of Administrative Punishment Results in Zhejiang* ("***Zhejiang Disclosure Measures***") and the *Measures for Voluntary Disclosure of Information on Administrative Penalty Cases in Luzhou* ("***Luzhou Disclosure Measures***") are not identical. With regard to the scope of disclosure, *Shanghai Disclosure Measures* requires the abstract of penalty decisions to be disclosed, and the full text of penalty decisions to be disclosed conditionally; the *Zhejiang Disclosure Measures* provides that the full text or the abstract of penalty decisions shall be disclosed at option and the *Luzhou Disclosure Measures* provides that the full text of the penalty decisions should be disclosed. With regard to the context of the abstract, differences exist between the *Shanghai Disclosure Measures* and the *Zhejiang Disclosure Measures*: the former requires that the abstract shall include the "cause of penalty", while the latter only requires that such abstract shall include the "main facts of violation". It waits for what form the MOST will adopt to disclose administrative penalty decisions and how the MOST will balance the requirements of confidentiality

management and penalty disclosure.

Specific procedural requirements

I. Clue registration

The *Measures for the Implementation* stipulates that the Functionary Departments shall be responsible for the registration of clues. The registration scope includes: (a) clues discovered during supervision or administration; (b) complaints or reports received; (c) clues transferred by other departments of the MOST or other authorities. According to the requirements, the Functionary Departments shall register the clues upon receipt and proceed with preliminary verification process. It is evident that the MOST attaches great importance to reports and whistleblowing in the investigation and punishment of illegal activities, and the industry should not underestimate the intensity of future enforcement.

II. Case filing

With regard to the procedures of case filing, the *Measures for the Implementation* stipulates that the Functionary Departments shall, within 15 working days as of the date of clue registration (extended to a maximum of 30 working days), preliminarily verify the clues, provide suggestions on whether to file the case and report to the director of the MOST to make final decisions. It further clarifies the procedures and requirements for case filing on the basis of the *Administrative Penalty Law*.

III. Investigation and evidence collection

With regard to investigation and evidence collection procedures, Section 3 of the *Measures for the Implementation* proposes more detailed requirements for procedures including but not limited to evidence collection, investigation measures, sealing up and distraining, which is conducive to regulating the law enforcement activities of administrative organs and its officers.

IV. Penalty

For cases where the illegal subject and the fact of violation is clear, which fall within the jurisdiction of the MOST and in which the illegal activity is not beyond the statutory limitation, the MOST will deliver an Administrative Penalty Opinion Notification to parties concerned. The parties concerned have the right to state, defend and request a hearing in accordance with the law.

All in all, it is apparent that the *Measures for the Implementation* provides more detailed procedures for the MOST's specific administrative penalty implementation. Based on our experience, these detailed provisions will continue to be optimized and refined until its official implementation.

Legal review

Article 45 and 46 of the *Measures for the Implementation* stipulates the procedures for the legal review. The legal review system for major law enforcement decisions is one of the three systems mentioned in the *Guiding Opinions on Comprehensively Implementing the Administrative Law Enforcement Publication System, the Recording System of Law Enforcement in the Whole Process and the Legal Review System of Major Law Enforcement Decisions* ("***Guiding Opinions***") issued by the General Office of the State

Council in 2018. The *Guiding Opinions* emphasizes that legal review is crucial to ensure the legitimacy and effectiveness of major law enforcement decisions and no major law enforcement decision shall be made without the legal review or passing the legal review. In this regard, Article 58 of the *Administrative Penalty Law* revised in 2021 enumerates the circumstances that shall be subject to the legal review, and the provisions of Article 45 of the *Measures for the Implementation* are consistent with this enumeration.

Connections between administrative and criminal procedures

Article 62 of the *Measures for the Implementation* stipulates the procedures for the connections between administrative and criminal procedures, requiring that the responsible persons in charge and the directly liable persons who commit such illegal acts as breach of privilege, corruption, bribery, dereliction of duty and others shall be held liable in accordance with the law and discipline and criminal liabilities shall be taken in case of a crime. From the perspective of the subject of responsibility, this article regulates the law enforcement personnel who implement the administrative punishment rather than the administrative objects.

For companies, the two-way transfer mechanism for administrative and criminal procedures provided in the *Administrative Penalty Law* is more relevant. Article 27.1 of the *Administrative Penalty Law* stipulates that where a violation of law is suspected of constituting a crime, the administrative organ handling it shall transfer the case to a judicial organ in a timely manner for investigation of criminal liability in accordance with law. Where criminal liability does not need to be investigated or it can be exempted in accordance with law, but an administrative penalty shall be imposed, the judicial organ shall transfer the case to the relevant administrative organ in a timely manner.

Impact on the industry

As mentioned before, the *Measures for the Implementation* are procedural rules that only specify the procedural requirements rather than creating substantial compliance obligations. Accordingly, the administrative penalty enforcement system strengthened by the regulations has distinguished impact on companies with different levels of compliance management:

- For companies with relatively high levels of compliance management, the *Measures for the Implementation* will have less impact on them, and under a tighter law enforcement environment, they would enjoy and show more obvious competitive advantages;
- For companies with relatively low levels of compliance management or whose compliance system is still in the process of establishment, the *Measures for the Implementation* is likely to higher their risks of being investigated or even punished. It is highly recommended that such companies chase to window before the implementation of the *Measures for the Implementation*, and make business adjustments and formulate internal compliance systems in a timely manner.

Epilogue

Similar to our previous analysis in *Highlights on the Draft HGR Regulations Implementing Rules*, once the policy is implemented, it is very likely that the MOST may delegate part of enforcement authority to local

authorities. The most immediate impact of the arrangement is the multiplication of law enforcement forces, leading to more active enforcement of administrative penalties. This will definitely bring compliance challenges to companies involved in activities within the MOST's regulatory scope, including but not limited to the utilization of HGR in China.

Changes in regulatory system present more than just challenges to corporate compliance. Since local authorities are respectively more familiar with companies within their jurisdictions, the corresponding communication will be more convenient and smoother, which will help companies to make reasonable defenses or arguments, and probably avoid rigid or mistaken law enforcement. We sincerely hope that the further development of regulatory system will provide a stable institutional environment for China's high-tech industry, promote the flourishing of science and technology, including life sciences.

2. An Overhaul of the PRC Banking Supervision Law – Why Now?

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On 11 November 2022, the China Banking and Insurance Regulatory Commission ("**CBIRC**") issued for public consultation a draft revision to the *PRC Banking Supervision Law* (the "**Consultation Draft**")[2].

The current *PRC Banking Supervision Law* was first promulgated in February 2004 and was amended once in 2006 (the "**Current Law**"). As a specialized banking supervision and regulatory law, the Current Law promotes the steady operation of banking industry, rectifies disorder in banking market and mitigates banking risks. In recent years, with continuous opening up and innovation, the assets in the banking industry have continued to grow and the degree of financial marketization is increasing. However, some provisions in the Current Law have not kept pace and gaps exist in certain significant areas, which may not meet the needs of regulatory practice. In this regard, an overhaul of the Current Law appears necessary at the current stage.

New requirements/major changes of the Consultation Draft on top of the existing laws and regulations

CBIRC has released a table which compares the differences between the Current Law and the Consultation Draft. It is worth noting that since the promulgation of the Current Law, CBIRC has formally issued a series of regulations in areas of regulatory supervision, banking personnel management, corporate governance, equity management, etc. Some of the revisions proposed to the Current Law found in the Consultation Draft are not new, but rather reiterate and summarize at the legislative level these regulations, which have already been implemented in practice.

In order to facilitate readers' understanding on the key implications of the Consultation Draft for the banking industry and personnel, we have conducted an overall gap analysis against the existing banking regulations. In the following sections, we will highlight and comment on the **new requirements/major changes** in the Consultation Draft on the basis of the existing regulatory framework.

Part I: incremental requirements/notable changes regarding banking personnel management

The Consultation Draft proposes to raise the cost of law violations and to comprehensively supplement new regulatory provisions and penalties for directors, **supervisors, senior management personnel and other persons who perform important duties.** Notable changes mainly include the following.

1. Supplementing duties for **supervisors and other persons who perform important duties**, generally aligned with those of directors and senior management personnel:

A. adding qualification pre-approval requirements for the above personnel *(Art. 25 of the Consultation Draft)*;

[1] Vito Wang (intern) has made contribution to this article.

[2] The Consultation Draft (in Chinese only) is accessible at: http://www.cbirc.gov.cn/cn/view/pages/ItemDetail.html?docId=1081221&itemId=925&generaltype=0.

B. adding information disclosure requirements for the above personnel changes *(Art. 56 of the Consultation Draft)*;

C. adding compulsory measures for the above personnel when a bank violates prudential operation rules *(Art. 57 of the Consultation Draft)*; and

D. regulatory measures taken against the above personnel when a bank is under takeover, reorganization, and shut-down, or **other major risks arise.** *(Art. 70 of the Consultation Draft).*

2. Intensifying the dual-penalty system for banks and their personnel *(Arts. 77, 80 and 81 of the Consultation Draft)*

On top of the existing laws and regulations, the Consultation Draft has increased monetary penalties for most of violations. In addition to the existing high-level personnel penalty rules, the Consultation Draft also explicitly sets out the following scenarios for triggering these dual-penalties:

A. conducting material equity investments or other material business activities without prerequisite approval *(Arts. 77 and 81 of the Consultation Draft)*;

B. performance of duties by the relevant personnel without qualification approval *(Arts. 77 and 81 of the Consultation Draft)*;

C. serious violation of prudential supervision rules which results in a criminal case, significant risks or serious damage to the legitimate rights and interests of depositors and other customers (*Art. 81 of the Consultation Draft)*;

D. refusing or obstructing off-site supervision or on-site inspection *(Art. 81 of the Consultation Draft)*;

E. providing false statements, reports or other documents, materials or data overseas *(Art. 81 of the Consultation Draft)*; and

F. illegal provision of documents, materials or data overseas *(Art. 81 of the Consultation Draft)*.

Part II: Incremental requirements for the supervision of major shareholders and actual controllers

The Consultation Draft proposes to strengthen supervision of major shareholders and actual controllers and to establish a whole-process supervision system, which ranges from pre-establishment approval and ongoing supervision to post-event punishment.

1. Analysis of major shareholders

A. Pre-establishment approval and ongoing supervision

For the supervision of major shareholders, the requirements for pre-establishment and ongoing supervision are, to a large extent, taken from legal and regulatory provisions such as the *PRC Commercial Banking Law*, the *Interim Measures for the Administration of Equity of Commercial Banks,* and the *Measures for the Supervision of the Conduct of Major Shareholders of Banking and Insurance Institutions (for Trial Implementation)*.

B. Post-event punishment

On top of the existing shareholder management rules and requirements, the Consultation Draft proposes important changes to the penalties on major shareholders:

- revising the penalty provisions for major shareholders, adding punishable circumstances and increasing the amount of monetary penalties *(Arts. 79, 82 and 83 of the Consultation Draft)*;
- expanding the scope of shareholders to be ordered to transfer equity and be subject to rights restrictions, and specifying that there is a time limit for transfer of equity (as a preparation for compulsory enforcement of equity transfer) *(Art. 57 of the Consultation Draft)*;
- detailing regulatory enforcement actions for violations by major shareholders *(Art. 58 of the Consultation Draft)*;
- specifying that CBIRC may apply for compulsory enforcement in court where the relevant shareholder is ordered to transfer equity and the equity transfer is not completed within the time limit *(Art. 59 of the Consultation Draft)*; and
- specifying the restrictions on shareholders and shareholders' meetings during takeovers *(Arts. 62 and 64 of the Consultation Draft)*.

2. Analysis of actual controllers

Under current law, the regulatory requirements for actual controllers are less robust compared with the requirements on shareholders. The Consultation Draft makes significant improvements and enhancements in this regard.

A. Pre-establishment approval and on-going supervision

- providing CBIRC authority to review actual controllers (during pre-establishment approval and when any actual controller changes) *(Arts. 19 and 20 of the Consultation Draft)*;
- supplementing CBIRC's review authority for the actual controller's source of funds, financial status, capital replenishment capacity, equity structure and creditworthiness (during pre-establishment approval and when any actual controller changes) *(Art. 22 of the Consultation Draft)*; and
- specifying the actual controller's reporting duties and compliance obligations with laws and regulations on related-party transactions and information disclosure. Actual controllers may not abuse their position to harm the legitimate rights and interests of financial institutions and depositors and other customers *(Arts. 29 and 48 of the Consultation Draft)*.

B. Post-event punishment

- specifying penalties for actual controllers who breach their reporting obligations *(Art. 79 of the Consultation Draft)*;
- specifying CBIRC's regulatory and compulsory measures for actual controllers, those who fail to make corrections within the time limit or whose breaches are particularly serious may be prohibited from

investing in banking financial institutions *(Art. 58 of the Consultation Draft)*;

- specifying that CBIRC may apply for compulsory enforcement in court where the actual controller is ordered to transfer equity controlled by it and the equity transfer is not completed within the time limit *(Art. 59 of the Consultation Draft)*;
- specifying CBIRC's power to stop issuing loans and other credit funds provided by the financial institution to its actual controller during a takeover *(Art. 64 of the Consultation Draft)*; and
- proposing incremental penalties for actual controllers, among others, penalties for the actual controller who have obtained administrative approvals by improper means *(Arts. 82 and 83 of the Consultation Draft)*.

Part III: New requirements for bank risk resolution matters

Viewed from the current regulatory regime, the provisions for bank risk disposal and market exit are relatively general and principled, with outstanding issues such as an imperfect early intervention mechanism and lack of effective disposal solutions.

The Consultation Draft aims to improve the risk disposal mechanism and further refine mechanisms in terms of daily supervision, early intervention, takeover, bankruptcy and liquidation. Notable changes in the Consultation Draft against the existing regulatory framework for resolving bank risk include:

1. specifying CBIRC's discretionary power to require a banking financial institution to formulate and implement recovery and disposal plans *(Art. 41 of the Consultation Draft)*;
2. specifying daily supervision from CBIRC, such as regulatory dialogue, risk warning, and proposing regulatory opinions *(Art. 55 of the Consultation Draft)*;
3. supplementing and detailing specific content of regulatory compulsory measures, including, among others, limiting the scale of risk assets and adjusting the requirements for regulatory indicators *(Art. 57 of the Consultation Draft)*;
4. establishing an early intervention mechanism and proposing early intervention measures *(Art. 60 of the Consultation Draft)*;
5. detailing takeover and market-exit mechanisms:

A. specifying legal status of the takeover team, refining of its statutory duties and specific takeover measures *(Arts. 61-64 of the Consultation Draft)*;

B. supplementing the administrative restructuring mechanism *(Art. 66 of the Consultation Draft)*;

C. supplementing industry protection fund management institutions to participate in risk disposal procedures *(Art. 67 of the Consultation Draft)*; and

D. specifying two ways a bank may enter bankruptcy *(Art. 68 of the Consultation Draft)*.

Other notable highlights of the Consultation Draft

I. Understanding "other persons who perform important duties"

"Other persons who perform important duties" is a new concept in the Consultation Draft. Its meaning and scope is worth analyzing.

1. The expression has not yet appeared in other regulations, and the Consultation Draft does not provide a clear definition or scope.

2. In the Consultation Draft, where there are provisions applicable to directors, supervisors, senior management personnel, "other persons who perform important duties" have been identically applied to, such as provisions on qualifications management, disclosure of changes in personnel, penalties for performing duties without approval, regulatory compulsory measures, restrictive measures on personnel under significant risks, personnel penalties, etc.

3. **"Other persons who perform important duties" is NOT equivalent to "any other persons who have decision-making rights in business management or play a significant role in risk control".**

   The concept of "any other persons who have decision-making right in business management or play a significant role in risk control" has been mentioned in administrative licensing rules for foreign-funded and Chinese-funded banks.

   Foreign-funded Banks*:* Art. 134 of the *Measures for Implementation of Administrative Licensing Items for Foreign-funded Banks* defines other personnel of foreign banks as **"any other persons who have decision-making rights in business management or play a significant role in risk control"**.

   Chinese-funded Banks: Pursuant to Art. 78(4) of the *Measures for Implementation of Administrative Licensing Items for Chinese-funded Commercial Banks*, *"those who hold none of the afore-mentioned positions, **but who actually perform the duties of directors or senior executives as listed in the preceding three paragraphs, or those in the management of the head office or branch who have the decision-making power or an important influence in the operation management or risk control of such institution shall be granted with the qualification for holding positions**"*. The rule requires that personnel who actually perform the duties of directors or senior management should also be equally subject to a qualification review.

   Then here is the question - is "other persons who perform important duties" the same as "any other persons who have decision-making right in business management or play a significant role in risk control"? Our view is that the above terms cover different personnel.

   Art. 3 of the *Measures for the Administration of Qualifications of Directors and Senior Management of Banking Financial Institutions* stipulates that senior management refers to all types of personnel in the management of the headquarters and branches of a financial institution who have decision-making power or significant influence on the operation and management and risk control of the institution. Therefore, "any other persons who have decision-making rights in business management or play a significant role in risk control" is covered under senior management personnel. However, in the Consultation Draft, "other persons who perform important duties" are independent from and parallel

with directors, supervisors and senior management personnel. The purpose of introducing "other persons who perform important duties" is to cover persons **other than** directors, supervisors and senior management personnel.

4. By reference to other CBIRC-issued personnel management rules, the *Guiding Opinions of the China Banking and Insurance Regulatory Commission on the Challenge System for Employees of Banking and Insurance Institutions in Duty Performance* refers to the concept of "key personnel and important posts". Items (4) and (9) generally define "**key personnel and important posts" as "the management members at all levels and persons-in-charge of internal departments who have important influences in terms of business operation, internal control management and risk prevention and employees at key business posts**".

   These guiding opinions apply to the specific context of the challenge system for employees to perform their duties. It may differ from the context of **overall bank supervision and management** in the Consultation Draft. It remains uncertain whether CBIRC will make direct reference to "key personnel and important posts" when defining the term "other persons who perform important duties".

5. Our understanding: The scope of "other persons who perform important duties" in the Consultation Draft may include:

- personnel who do not formally hold the positions of directors, supervisors or senior management personnel, but who actually perform the duties (e.g., acting roles); and
- meanwhile, for prudential purposes and for the legislative intent of enhancing personnel supervision, it remains possible that CBIRC makes reference to "key personnel and important posts" when defining "other persons who perform important duties".

Given that the Consultation Draft retains a certain degree of flexibility, it still requires further attention and prudent observation.

II. Requirements for personnel departure

Art. 70 of the Consultation Draft on restrictions on the departure of personnel has been modified and improved.

*"During the period of assumption of control, reorganization, shut down for liquidation or **the event of significant risk**, the following measures may be adopted against the directly liable directors, **supervisors**, senior management personnel, **other persons who perform important duties** and other directly liable personnel upon the approval of the person-in-charge of the banking regulatory authority of the State Council:*

*(1) if the departure of the directly liable directors, **supervisors**, senior management personnel, **other persons to perform important duties** and other directly liable personnel from China will cause major losses to State interests, **the decision to prevent their departure would be made and the immigration authorities shall be notified to implement;** and*

(2) apply to the judicial authorities to prohibit their transfer or assignment of property or attachment of

other rights to their property."

Compared with the existing regulatory provisions, the Consultation Draft proposes the following three major changes:

1. Supplementing applicable scenarios: upon the occurrence of "significant risk"

The Consultation Draft does not specify the definition or scope of "significant risk". We understand that major risk events or crises in the areas of liquidity risk, credit risk, market risk, operational risk, etc. encountered by commercial banks during business management would be included and may trigger restrictions on the departure of personnel.

2. Supplementing in-scope personnel: Supervisors and "other persons who perform important duties"

In terms of in-scope personnel, the Consultation Draft unifies the new management requirements for supervisors, reflecting the practical need to establish an improved professional banking supervision system in China. In addition, the scope of "other persons who perform important duties" has been analyzed in above sections of this newsletter.

3. Further clarifying procedures

In terms of the procedure for placing restrictions on the departure of personnel, the Consultation Draft clarifies the power of the CBIRC to "decide" to restrict personnel departures, but the draft provisions appear to propose no substantive practical changes. The above revision only clarifies the process that CBIRC will **(1) decide to restrict personnel departures; and (2) notify the immigration authorities to implement it**. This change in statement is consistent with the provision of the *PRC Exit and Entry Administration Law*.

III. Extraterritorial application

Art. 47 of the Consultation Draft provides for extraterritorial application of the law:

"Where the banking financial activities outside the territory of the People's Republic China have endangered the sovereignty, security and development interests of the People's Republic of China, disrupted the market order within the territory and damaged the legitimate rights and interests of investors within the territory, such activities shall be investigated for legal responsibility in accordance with the laws."

The provision has sparked widespread concern within the banking industry. It is worth noting that the Consultation Draft is not the first try to apply extraterritorial jurisdiction provisions among multiple laws and regulations governing the financial sector—relevant provisions have already been introduced in the securities and futures industries.

1. Current regulations and consultation drafts in other financial industries

Extraterritorial jurisdiction provisions were added to the *PRC Securities Law* in 2019.

"Where the issuance and transaction of securities outside the territory of the People's Republic China

have disrupted the market order within the territory of the People's Republic of China and damaged the legitimate rights and interests of investors within the territory, such activities shall be handled and investigated for legal responsibility in accordance with the relevant provisions of this Law."

The extraterritorial jurisdiction provisions in the *PRC Futures and Derivatives Law* in 2022:

"Where the transaction and other related activities of futures and derivatives outside the territory of the People's Republic of China have disrupted the market order within the territory of the People's Republic of China and damaged the legitimate rights and interests of investors within the territory, such activities shall be handled and investigated for legal responsibility in accordance with the relevant provisions of this Law."

In addition, the *PRC Commercial Banking Law of the People's Republic of China (Draft Revision)* issued in 2020, also explores extraterritorial application.

"Where the commercial banking services to individuals or institutions within the territory of the People's Republic of China provided by institutions outside the territory have damaged the legitimate rights and interests of individuals or institutions within the territory, such activities shall be handled in accordance with the relevant provisions of this Law."

The above provisions show a certain degree of similarity, but the extraterritorial jurisdiction provision of the Consultation Draft further expands the scope of application.

2. Understanding the scope of the extraterritorial jurisdiction provision in the Consultation Draft

Based on the Consultation Draft, all such activities outside mainland China may be subject to Chinese law, so long as they have an impact within the territory that endangers state security, disrupts the market and damages the legitimate rights and interests of investors. Such general and broad extraterritorial jurisdiction provision is more inclusive and flexible. It can also give regulators greater discretion to respond to various situations that may occur in practice.

Three possible scenarios in which the provision could apply include:

A. offshore banks provide regular commercial banking services (such as deposits, loans and settlements) which damages the legitimate rights and interests of the PRC individuals or institutions;

B. offshore banks engage in product management/distribution of banking financial products outside the territory which damages the legitimate rights and interests of PRC investors; and

C. offshore third-party support services (such as information technology) for offshore banking activities damage the legitimate rights and interests of PRC investors.

Compared with extraterritorial jurisdiction provisions of the *PRC Securities Law* and others, the Consultation Draft adds "having endangered the sovereignty, security and development interests of the People's Republic of China" to reflect the increasing importance of national security in recent years.

3. Other content to observe

Art. 47 of the Consultation Draft is a principled provision, which only proposes a general expression of

the provision on extraterritorial jurisdiction. This provision does not set clear criteria for judging the impact in China, nor does it explain the specific legal liability that may be imposed. Further clarification of the provision is expected in the future.

IV. Understanding on "providing data to offshore without authorization"

Cross-border data transfers are also one of the hot issues in the market. Art. 8 of the Consultation Draft stipulates that banks may not provide documents, information or data related to their business activities outside the territory of the People's Republic China without authorization, except as otherwise provided by laws, administrative regulations and CBIRC rules. Arts. 78 and 81 would add *"providing documents, information and data outside the territory in violation of regulations"* as an illegal act of the banks, and the banks would be ordered to make corrections, forfeit their illegal income, and be fined. Banks may be ordered to suspend business for rectification, revoke licenses, or even be held criminally liable in serious cases. The relevant responsible personnel may also be punished.

For the above provisions, we have analyzed the interpretation of Arts. 8, 78 and 81:

Analysis	Art. 8	Arts. 78 and 81
Scope of data transfer	Art. 8 on cross-border supervisory cooperation limits the scope of data transfers to *"in connection with business activities*". We understand that the context of Art. 8 is cross-border supervisory cooperation, which is intended to emphasize that the banks may not provide "business data" outside the territory without authorization in the process of cross-border business supervision.	In contrast to Art. 8, Arts. 78 and 81 do not set the similar limits of *"in connection with business activities".* With reference to "violation of regulations", the regulatory intention is that the banks must comply with all relevant laws and regulations on data transfers. The scope of data transfers should be broadly understood, not limited to data "related to business activities" under Art. 8.
Data receivers	Art. 8 is under the context of "cross-border supervisory cooperation". Since the requirements for *"not providing documents, information and data related to business activities outside the territory without authorization"* is among the following paragraphs under the same article, data receivers naturally refer to foreign judicial and law enforcement authorities.	In addition to providing data to foreign judicial and law enforcement authorities, banks are also required to comply with China's relevant laws and regulations on cross-border data transfers; thus, we should adopt a general understanding towards data receivers, not limited to offshore judicial and law enforcement authorities. According to the current data compliance requirements, **banks should pay specific attention to the following scenarios**: (a) AML data transfer requirements;

Analysis	Art. 8	Arts. 78 and 81
		(b) personal financial information transfer rules under the supervision of financial regulators; (c) personal information and important data transfer requirements under the supervision of cybersecurity administration departments; and (d) data transfer rules under the context of cross-border business supervision. Banks should act in strict accordance with the applicable data transfer rules according to their specific circumstances.

We have presented our preliminary understanding and analysis of the above issues, which remain subject to change during the legislative process, or further written rules or guidance issued by CBIRC in the future. We will also continue to monitor relevant regulatory updates and share our views with readers in a timely manner.

3. Highlights on the New Drug Recall Regulation of 2022

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On October 26, 2022, the National Medical Products Administration ("**NMPA**") issued the newly revised *Measures for the Administration of Drug Recalls* ("**the 2022 *Measures***") that has just been formally adopted. The former *Measures for the Administration of Drug Recalls* ("**the 2007 *Measures***") was issued and implemented on December 10, 2007. Since then, the *Drug Administration Law* has been amended several times, and the Marketing Authorization Holder (MAH) system was officially implemented in 2019. As a result, the 2007 *Measures* needs to be amended so that it can align with the current *Drug Administration Law*. On October 13, 2020 and September 26, 2021, NMPA has released two drafts for comments of the Measures for the Administration of Drug Recalls ("***Draft for Comments***") respectively, and has officially adopted the 2022 *Measures* on October 24, 2022. The 2022 *Measures* is effective since November 1, 2022. This article will summarize some important modifications in the 2022 *Measures* compared with the 2007 *Measures*.

Subjects of responsibility

I. Responsibility of the MAH

Comparing with the 2007 *Measures*, **the 2022 *Measures* has changed the subjects responsible for drug recalls from the drug manufacturers (including overseas manufacturers of imported drugs) to the MAH**. The first paragraph in Article 5 of the 2022 *Measures* explicitly stipulates that the MAHs are the subjects responsible for controlling risks and eliminating potential hazards. They shall establish and improve their drug recall system, collect relevant information of drug quality and drug safety, investigate and evaluate potential quality issues or other potential safety hazards, and timely recall the drugs with quality issues or other potential safety hazards.

This modification is consistent with the 2019 *Drug Administration Law* which has officially established and implemented the MAH system nationwide. Since the MAH are the subjects responsible for the quality of the drug's whole life cycle, there is no doubt that they shall be responsible for drug recalls.

II. Assisting obligations of other subjects

The **second paragraph in Article 5 of the 2022 *Measures* has specified the assisting and cooperating obligations of the manufacturers, distributors and other entities using the drugs.** They shall actively assist the MAH in the investigation and evaluation of the drugs that may have quality issues or other potential safety hazards. They shall cooperate with the MAH in fulfilling the obligation of recalling the drugs, timely transmit the information of drug recalls in accordance with the recall program, and control and collect the drugs that have quality issues or other potential safety hazards.

[3] Leyi Wang and Shuwen Sun have also contributed to this article.

Scope of application

Firstly, Article 3 of the 2022 *Measures* specifies that the targets of drug recalls shall be "the drugs that have been on the market and have quality issues or other potential safety hazards". **Therefore, drug recalls do not apply to investigational drugs as they have not obtained market authorization and are not on the market.** We understand that for investigational drugs that have quality issues or other potential safety hazards, the *Good Practice for Clinical Trials of Drugs* (GCP) and other relevant regulations shall apply instead.

Secondly, comparing with the 2007 *Measures* and the 2021 *Draft for Comments*, Article 4 of the 2022 Measures has expanded the scope of "quality issues or other potential safety hazards". **In addition to "unreasonable dangers of drugs that may endanger human health and life safety", "failure to meet the statutory requirements" may also trigger drug recalls.** The latter includes quality issues and other potential safety hazards caused by non-compliance with the *Good Manufacturing Practice for Drugs* (GMP), the *Good Supply Practice for Pharmaceutical Products* (GSP) and other currently valid regulations on drug quality due to reasons of research and development, manufacturing, storage, transportation and labeling, as well as the defects in labels and instructions for users (IFUs). As a result, the application scope of drug recalls under the 2022 *Measures* is larger than the 2007 *Measures*. Correspondingly, the 2022 *Measures* also provides more measures for the disposal of recalled drugs, which will be addressed in Part III below.

Content of drug recalls

I. Types of recalls

Under both the 2007 and the 2022 *Measures*, the types of drug recalls include voluntary recalls and compulsory recalls. The following table shows their application circumstances:

Type	Application Circumstances
Voluntary Recalls	The 2007 *Measures*: The manufacturers have found that the drugs have potential safety hazards. *The term "potential safety hazards" here refers to the unreasonable dangers of drugs that may endanger human health and life safety due to the reasons of research and development, manufacturing, etc.
	The 2022 *Measures*: The MAH have confirmed that the drugs have quality issues or other potential safety hazards. *The term "potential safety hazards" here refers to the failure of drugs to meet the statutory requirements or other unreasonable dangers of drugs that may endanger human health and life safety due to the reasons of research and development, manufacturing, storage, transportation, and labeling, etc.
Compulsory Recalls	The 2007 *Measures*: Where the Medical Products Administration ("**MPA**") believes upon investigation and evaluation that there exists any potential safety hazard as mentioned in Article 4 of the 2007 *Measures*, and the manufacturer fails to voluntarily recall the drugs that should be recalled.
	The 2022 *Measures*:

Type	Application Circumstances
	■ Where the MPA believes upon investigation and evaluation that the MAH fails to voluntarily recall the drugs that should be recalled. ■ Where the MPA believes upon reviewing the results of the voluntary recall that the MAH has not conducted the voluntary recall thoroughly.

In comparison, as to the application scope of voluntary recalls, the 2022 *Measures* has expanded it by expanding the scope of "potential safety hazards". As to the application scope of compulsory recalls, the 2022 Measures has expanded it by adding the circumstances where the MAH have carried out voluntary recalls, but the recalls are unthorough.

II. Recall classification

Both the 2007 *Measures* and the 2022 *Measures* have divided drug recalls into three classes based on the seriousness of quality issues or other potential safety hazards. According to Article 13 of the 2022 Measures, a first-class recall happens when use of the drugs may cause or has caused serious harm to health; a second-class recall happens when use of the drugs may cause or has caused temporary or reversible harm to health; and a third-class recall happens when use of the drugs will not cause harm to health in general, but the drugs should be recalled due to other reasons. The 2007 *Measures* and the 2022 *Measures* both provide a series of specific obligations and procedures for different classes of drug recalls, as detailed in the following table:

Class	Online Release	Notification and Report	Filing	Progress Report	Final Report
First-class recall	The 2007 *Measures:* /	Art. 16 of the 2007 *Measures:* ■ Time limit: within 1 day after the decision on drug recall is made. ■ Notification: notify the relevant distributors and entities using the drugs to stop the sale and use of the drugs. ■ Report: report to the provincial MPA where the manufacturer is located.	Art. 17 of the 2007 *Measures:* ■ Time limit: within 1 day after initiating the drug recall program. ■ Filing: the manufacturer shall file for record the investigation and evaluation report and the recall program with the provincial MPA where it is located. ■ Report: The provincial MPA shall report the investigation and evaluation report and the recall program on the drug recall it has received to the NMPA.	Art. 21 of the 2007 *Measures:* ■ Frequency: every day. ■ Report: report to the provincial MPA where the manufacturer is located.	Art. 23 of the 2007 *Measures:* ■ Time limit: after completing the recall. ■ Report: report to the provincial MPA where the manufacturer is located.
	Article 15 of the 2022 *Measures*:	Article 16 of the 2022 *Measures*: ■ Time limit: within 1 day after the	Article 16 of the 2022 *Measures*: ■ Time limit: within 1 day after the decision	Article 17 of the 2022 *Measures*: ■ Frequency: every day.	Article 20 of the 2022 *Measures*: ■ Time limit: within 10

Class	Online Release	Notification and Report	Filing	Progress Report	Final Report
	The MAH shall apply to release the recall information on the website of the provincial MPA.	decision on drug recall is made. ■ Notification: notify the manufacturers, distributors, and entities using the drugs, etc.	on drug recall is made. ■ Filing: the MAH shall file for record the investigation and evaluation report, the recall program, and the recall notice with the provincial MPA where it is located.	■ Report: report to the provincial MPA where the MAH is located.	working days after completing the recall. ■ Content: the information of the drug recall and disposal. ■ Report: report to the provincial MPA where the MAH is located.
Second-class recall	The 2007 *Measures:* /	Art. 16 of the 2007 *Measures:* ■ Time limit: within 2 days after the decision on drug recall is made. ■ Notification: notify the relevant distributors and entities using the drugs to stop the sale and use of the drugs. ■ Report: report to the provincial MPA where the manufacturer is located.	Art. 17 of the 2007 *Measures:* ■ Time limit: within 3 days after initiating a drug recall program. ■ Filing: the manufacturer shall file for record the investigation and evaluation report and the recall program with the provincial MPA where it is located. ■ Report: The provincial MPA shall report the investigation and evaluation report and the recall program on the drug recall it has received to the NMPA.	Art. 21 of the 2007 *Measures:* ■ Frequency: every 3 days. ■ Report: report to the provincial MPA where the manufacturer is located.	Art. 23 of the 2007 *Measures:* ➢ Time limit: after completing the recall. ➢ Report: report to the provincial MPA where the manufacturer is located.
	Article 15 of the 2022 *Measures*: The MAH shall apply to release the recall information on the website of the provincial MPA.	Article 16 of the 2022 *Measures*: ■ Time limit: within 3 days after the decision on drug recall is made. ■ Notification: notify the manufacturers, distributors, and entities using the drugs, etc.	Article 16 of the 2022 *Measures*: ■ Time limit: within 3 days after the decision on drug recall is made. ■ Filing: the MAH shall file for record the investigation and evaluation report, the recall program, and the recall notice with the provincial MPA where it is located.	Article 17 of the 2022 *Measures*: ■ Frequency: every 3 days. ■ Report: report to the provincial MPA where the MAH is located.	Article 20 of the 2022 *Measures*: ■ Time limit: within 10 working days after completing the recall. ■ Content: the information of the drug recall and disposal. ■ Report: report to the provincial MPA where the MAH

Class	Online Release	Notification and Report	Filing	Progress Report	Final Report
					is located.
Third-class recall	The 2007 *Measures:* /	Art. 16 of the 2007 *Measures:* ■ Time limit: within 3 days after the decision on drug recall is made. ■ Notification: notify the relevant distributors and entities using the drugs to stop the sale and use of the drugs. ■ Report: report to the provincial MPA where the manufacturer is located.	Art. 17 of the 2007 *Measures:* ■ Time limit: within 7 days after initiating a drug recall program. ■ Filing: the manufacturer shall file for record the investigation and evaluation report and the recall program with the provincial MPA where it is located. ■ Report: The provincial MPA shall report the investigation and evaluation report and the recall program on the drug recall it has received to the NMPA.	Art. 21 of the 2007 *Measures:* ■ Frequency: every 7 days. ■ Report: report to the provincial MPA where the manufacturer is located.	Art. 23 of the 2007 *Measures:* ■ Time limit: after completing the recall. ■ Report: report to the provincial MPA where the manufacturer is located.
	The 2022 *Measures*: /	Article 16 of the 2022 *Measures*: ■ Time limit: within 7 days after the decision on drug recall is made. ■ Notification: notify the manufacturers, distributors, and entities using the drugs, etc.	Article 16 of the 2022 *Measures*: ■ Time limit: within 7 days after the decision on drug recall is made. ■ Filing: the MAH shall file for record the investigation and evaluation report, the recall program, and the recall notice with the provincial MPA where it is located.	Article 17 of the 2022 *Measures*: ■ Frequency: every 7 days. ■ Report: report to the provincial MPA where the MAH is located.	Article 20 of the 2022 *Measures*: ■ Time limit: within 10 working days after completing the recall. ■ Content: the information of the drug recall and disposal. ■ Report: report to the provincial MPA where the MAH is located.

Comparing the procedures of drug recalls under the 2007 *Measures* and the 2022 *Measures*, several noteworthy modifications can be found:

- The 2022 *Measures* **adds the obligation of the MAH to apply to release the recall information on the website of the provincial MPA** in the case of first-class and second-class recalls.
- The 2022 *Measures* extends the time limits for the MAH to notify the manufacturers, distributors and entities using the drugs. For second-class recalls, the time limit has been adjusted from 2 days to **3**

days after the decision on drug recall is made. For third-class recalls, the time limit has been adjusted from 3 days to **7 days** after the decision on drug recall is made.

- The 2022 *Measures* clarifies that the time limit for the MAH to submit the Final Report shall be **within 10 working days** after the completion of the recalls.

III. Measures for disposal of the drugs after the recalls

Regarding the measures for disposal of the recalled drugs, Article 22 of the 2017 *Measures* only provided that the drugs that must be destroyed shall be destroyed under the supervision of the MPA. In comparison, the 2022 *Measures* has offered new measures for disposal in addition to the destruction of recalled drugs. Although in principle the recalled drugs cannot be put on market again, Article 19 of the 2022 *Measures* provides that **the drugs of which the potential hazards can be eliminated by replacement of labels, modification and improvement of IFUs, repackaging and other means can be put on market after taking the appropriate measures**. These new measures are consistent to the new scope of application of drug recalls under the 2022 *Measures* as mentioned above.

New rules for overseas recalls

Comparing with the 2007 *Measures* and the 2021 *Draft for Comments*, the 2022 *Measures* has added new rules for overseas recalls. For overseas manufactured drugs involving recalls in China, the first paragraph in Article 21 of the 2022 *Measures* provides that the domestic agents of the overseas MAH shall organize the recall and report to the provincial MPA and the provincial Health Commission. For overseas manufactured drugs not involving recalls in China, the second and third paragraph in Article 21 indicated that **if an overseas MAH carries out an overseas drug recall and is found to fall under the following circumstances after comprehensive assessment, its domestic agent shall, within 10 working days after the overseas recall is initiated, report the name, specification, batch, reason for recall and other information to the provincial MPA where it is located: (1) the recalled drugs are the same varieties of the drugs on domestic market, but their specifications, batches or formulations do not involve the drugs on domestic market; (2) the recalled drugs share the same production lines with the domestically marketed drugs; (3) other circumstances that need to be reported to the MPA. The overseas MAH shall carry out comprehensive study on the implementation situation of overseas recalls and decide whether to implement domestic recalls. If domestic recalls are needed, the first paragraph of Article 21 shall be applied.**

Accordingly, the domestic agents of the overseas MAH have the obligation to report the information of overseas recalls to the provincial MPA after such recalls take place. After reporting, the overseas MAH shall carry out comprehensive study and decide whether to implement domestic recalls through their domestic agents. In other words, the rules for voluntary recalls and compulsory recalls will be applied after reporting. We understand that **the 2022 *Measures* has set up a relatively flexible mechanism. Overseas recalls will only trigger the obligation to report instead of automatically triggering the obligation to carry out domestic recalls.** We understand that overseas recalls may occur for a variety of reasons, such as the IFUs and labels of the drugs do not meet local regulations. Therefore, when an overseas recall happens, it does not necessarily mean that the corresponding domestically marketed drugs

also have quality issues or other potential safety hazards, thus the sales and use of such drugs in China will not necessarily be affected. **It should be noted that even if the drugs for overseas marketing and for domestic marketing are not of the same type, the reporting obligation will still be triggered if they share the same production lines. No exemption for this circumstance was provided under the 2022 *Measures*.**

Previously, some multinational pharmaceutical companies often exclude China from their global drug recalls, which has triggered great concern of the public. Thus, effective rules are needed to address this issue. The 2007 *Measures* simply indicated that "an overseas manufacturer of imported drugs shall report to the NMPA in time when it intends to carry out a recall overseas". In comparison, the 2022 *Measures* has further detailed the specific obligations of overseas MAH and their domestic agents. We believe that this will greatly help improve quality of drugs and safety of patients in China.

Correspondingly, Article 31 of the 2022 *Measures* adds the obligation of the domestic MAH to report to the drug regulatory authorities and purchasers in the importing country (region) and to recall overseas when discovering quality issues or other potential safety hazards of the exported drugs. This new rule is conducive to strengthening intergovernmental cooperation, enhancing the international credibility of China's drug supervision and management, and showing the image of a responsible major country.

Legal liability

Same as the 2021 *Draft for Comments*, the 2022 *Measures* has deleted Chapter V (Legal Liability) of the 2007 *Measures* in its entirety. Instead, it indicates that **Article 135 of the *Drug Administration Law* shall apply to any violation of the 2022 *Measures***. Specifically, where a MAH is ordered by the provincial MPA to recall drugs but refuses to do so, it shall be subject to a fine ranging from 5 to 10 times the value of the drugs to be recalled; where the value of the drugs is less than RMB100,000, the fine shall be RMB100,000. In serious cases, the drug approval certificate, manufacturing license and distribution license shall be revoked; the legal representative, the key person-in-charge, the directly accountable person-in-charge and other accountable personnel shall be subject to a fine ranging from RMB20,000 to RMB200,000. Where a manufacturer, distributor or medical institution refuses to cooperate in the drug recall, it shall be subject to a fine ranging from RMB100,000 to RMB500,000. Comparing with the 2007 *Measures*, the 2022 *Measures* has strengthened the penalties. The amount of a fine imposed on the MAH has increased from 3 times to 5-10 times of the value of goods.

Communication among regulatory authorities

The 2022 *Measures* specifies that the MPA may, when necessary and in accordance with its authority, notify the Health Commission at the same level of relevant information while disclosing the drug recall information to the public. This rule helps ensure the synchronization and circulation of relevant information related to drug safety among different regulatory authorities. It also clearly places the responsibilities of drug safety under the authority of multiple regulatory bodies, which releases a signal that the government will strengthen the force and scope of regulation in this field.

Important Announcement

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