Legal Commentary

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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.

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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.

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*:

Type	Application Circumstances
	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*: ■ 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.	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.	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.

Class	Online Release	Notification and Report	Filing	Progress Report	Final Report
		■ Report: report to the provincial MPA where the manufacturer 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.		
	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 1 day 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 1 day 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 day. ■ 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.
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	Article 16 of the 2022 *Measures*: ■ Time limit: within 3 days after the decision on drug	Article 16 of the 2022 *Measures*: ■ Time limit: within 3 days after the decision on drug	Article 17 of the 2022 *Measures*: ■ Frequency: every 3 days. ■ Report: report	Article 20 of the 2022 *Measures*: ■ Time limit: within 10 working days

Class	Online Release	Notification and Report	Filing	Progress Report	Final Report
	to release the recall information on the website of the provincial MPA.	recall is made. ■ Notification: notify the manufacturers, distributors, and entities using the drugs, etc.	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.	to the provincial MPA where the MAH is located.	after completing the recall. ■ Content: the information of the drug recall and disposal. ■ Report: report to the provincial MPA where the MAH 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

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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