Legal Commentary

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Strengthening Oversight of Imported Drugs: Key Takeaways into New Regulations on Domestic Responsible Entities

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On November 13, 2024, the National Medical Products Administration (the "**NMPA**") issued the *Interim Provisions on the Management of Domestic Responsible Entity Designated by Overseas Marketing Authorization Holders* (hereinafter referred to as the "**Regulations on Domestic Responsible Entities**"). This regulation will officially take effect on July 1, 2025 and has garnered significant attention from the industry. The introduction of the Regulations on Domestic Responsible Entities represents a major milestone in the evolution of China's Marketing Authorization Holder (MAH) regulations. The new regulation aims to clarify and reinforce the responsibilities of MAH and domestic responsible entities for imported drugs, thereby enhancing the safety of public medication use. In this article, we analyze several key points of the Regulations on Domestic Responsible Entities from a practical perspective, with the aim of offering valuable insights and encouraging discussion within the industry.

Interpretation of key points

I. Domestic responsible entities vs. domestic agents

Previously, the entity designated by overseas MAH to fulfill MAH's obligations in China is referred to as the "domestic agent" in China's regulatory regulation[2]. This time, the Regulation on Domestic Responsible Entities has updated the concept of "domestic agent" to "domestic responsible entities". Similarly, the *Draft Measures for the Administration of Pharmaceutical Representatives* issued in November 2024 specifies that the "domestic responsible entity" designated by the MAH for imported drugs is responsible for fulfilling MAH obligations. The change in terminology not only underscores the responsibilities of domestic entities but also reflects innovative developments in regulatory concepts and requirements.

It is worth noting that domestic responsible entities must still adhere to the regulatory requirements

[1] Jingjing XU have contributions to this article.

[2] The Article 20 of *the Drug Recall Management Measures*, the Article 4 of *the Provisional Measures for the Filing of Pharmaceutical Representatives*, the Article 2 of *the Draft Interim Provisions on the Management of Domestic Agents for Overseas Marketing Authorization Holders*, and the Article 44 of *the Draft for Comments on the Implementing Regulations of the Drug Administration Law of the People's Republic of China*.

previously applicable to domestic agents. These responsibilities include implementing drug recalls in accordance with *the Drug Recall Management Measures* and overseeing the filing and management of pharmaceutical representatives under *the Provisional Measures for the Filing of Pharmaceutical Representatives*.

II. Designation for domestic responsible entities

The roles of domestic responsible entities and registration agents are distinct. According to the Regulations on Domestic Responsible Entities, overseas MAHs are required to designate a domestic responsible entity before the initial importation and sale of the drug[3]. However, there is currently no explicit requirement to designate a domestic responsible entity during the clinical trial or registration application stages. In contrast, a registration agent is a domestic legal entity authorized by the MAH during the drug registration application phase to handle matters related to drug registration[4]. Thus, domestic responsible entities and registration agents serve separate functions, each with its own set of responsibilities.

In practice, domestic responsible entities and registration agents can be different entities. For instance, based on our project experiences, if an overseas company has confidentiality concerns about submitting registration materials through a domestic partner, the domestic responsible entity role can be assigned to a distributor or other partner, while registration agent responsibilities can be entrusted to a CRO or other specialized service provider, with assistance from lawyers. This flexible arrangement not only helps safeguard confidentiality but also enables companies to navigate complex market dynamics and increasingly stringent regulatory requirements more effectively.

III. Drug insert sheet: domestic responsible entities and domestic contact entities

In accordance with the requirements of the Regulations on Domestic Responsible Entities, the name, address, and contact information of the domestic responsible entities must be clearly listed in the drug insert sheet[5]. Additionally, under the current *General Format and Writing Guidelines for Drug Insert Sheet of Chemical Drugs and Biological Products*, imported drugs must also include in their drug insert sheet the relevant information of the domestic contact entities in China designated by the overseas MAHs. Such information should include the name, registered address, postal code, telephone number, fax number, and other details.

The Regulations on Domestic Responsible Entities are set to take effect, and the current *General Format and Writing Guidelines for Drug Insert Sheet of Chemical Drugs and Biological Products* remains in force. Therefore, the relationship between the domestic responsible entity and the

[3] The Article 5 of the *Regulations on Domestic Responsible Entities*: "Before the initial importation and sale of a drug, overseas holders shall report their designated domestic responsible entity to the drug regulatory authority of the province, autonomous region, or municipality where the domestic responsible entity is located via the National Drug Business Application System and upload the authorization materials for the designated domestic responsible entity".

[4] The Article 9 of the *Drug Registration Administration Measures (2020)*: "Applicants shall be enterprises or drug research institutions capable of assuming corresponding legal responsibilities. Overseas applicants shall designate a domestic legal entity in China to handle matters related to drug registration".

[5] The Article 7 of the *Regulations on Domestic Responsible Entities*: "…The name, address, and contact information of the domestic responsible entity should be listed in the drug insert sheet".

domestic contact entity has yet to be clarified. It remains uncertain whether the information of both entities will need to be listed in the drug insert sheet, along with their respective responsibilities, which are likely to be further clarified in subsequent regulations. Moreover, these uncertainties will also present new challenges for the drafting of drug insert sheets and impose higher requirements on corporate compliance and information disclosure.

IV. Selection and requirements for domestic responsible entities

The Regulations on Domestic Responsible Entities specifies the requirements for domestic responsible entities, mandating that overseas MAHs carefully consider relevant entities' quality management systems, personnels, facilities, and capabilities to fulfill relevant joint obligations when designating domestic responsible entities. The Regulations on Domestic Responsible Entities also emphasizes the requirements of the domestic responsible entities should closely align with those of overseas MAHs. However, the specific criteria and qualifications for these requirements still need further clarification. For instance, it remains unclear whether employees with labor relations in other entities within the same group as the domestic responsible entities can meet the requirement of "having dedicated personnel solely responsible for drug quality management". Considering the Article 17 of the Regulations on Domestic Responsible Entities authorizes local drug regulatory authorities to issue further implementation rules, it is recommended that overseas MAHs closely monitor the issuance of the rules by the provincial drug regulatory authorities where the domestic responsible entities are located, in order to make timely adjustments and responses.

We particularly advise that overseas MAHs carefully evaluate their selection of domestic responsible entities to comply with the Regulations on Domestic Responsible Entities and relevant laws and regulations. Similarly, domestic responsible entities should thoroughly assess their existing conditions and capabilities, ensuring that both parties can effectively cooperate in fulfilling joint obligations and avoid potential legal risks.

V. Authorization and responsibility allocation for overseas MAHs

We recommend that overseas MAHs select entities that meet the requirements of the Regulations on Domestic Responsible Entities before its official implementation and prepare and notarize the authorization responsibility list in advance. Based on our observation, many multinational pharmaceutical companies have already begun drafting authorization responsibility list. It is also advisable to closely monitor the issuance of detailed regulations or official document templates. Meanwhile, overseas MAHs should promptly complete the authorization and system reporting for the domestic responsible entities and timely revise the drug insert sheets to avoid penalties resulting from non-compliance once the transition period ends. If overseas MAHs have not completed the system reporting for the domestic responsible entities by April 30, 2025 (the deadline for the annual drug reporting[6]), they may still submit information for the previous year through the original channels. Furthermore, considering that overseas MAHs and domestic responsible entities bear joint liability, we

[6] The *Regulations on the Annual Reporting Management for Drugs*: "...The deadline for submitting the 2021 annual reporting information is August 31, 2022; starting from next year, the deadline for submitting the previous year's report information will be April 30 of each year".

recommend that overseas MAHs clearly define responsibilities and distribute obligations through internal agreements.

At the same time, we would like to emphasize that the differentiation and determination of responsibilities between the MAH and the domestic responsible entity is still an area that requires careful observation. Specifically, it remains to be seen whether authorization responsibility list and internal agreements can effectively serve as "firewall" to mitigate risks during regulatory enforcement. However, overall, the clearer the allocation of responsibilities, the better it will assist regulatory authorities in accurately distinguishing responsibilities during enforcement and reducing ambiguity.

Conclusion

The issuance of the Regulations on Domestic Responsible Entities marks a significant step in the normalization of China's pharmaceutical regulatory framework. However, the specific standards for the relevant requirements are still being explored and will be gradually implemented by medical industry and regulatory authorities. As the global pharmaceutical market continues to open, China's pharmaceutical industry is poised to encounter unprecedented development opportunities. This will not only promote the export and import of innovative drugs, but also facilitate the introduction of advanced international technologies and resources, injecting new energy into the domestic pharmaceutical market. In the future, we anticipate that a more regulated, open, and dynamic Chinese pharmaceutical market, supported by an increasingly refined regulatory framework, and as exemplified by the Regulations on Domestic Responsible Entities, will be able to provide higher quality medical products and services to both domestic and overseas patients.

Important Announcement

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