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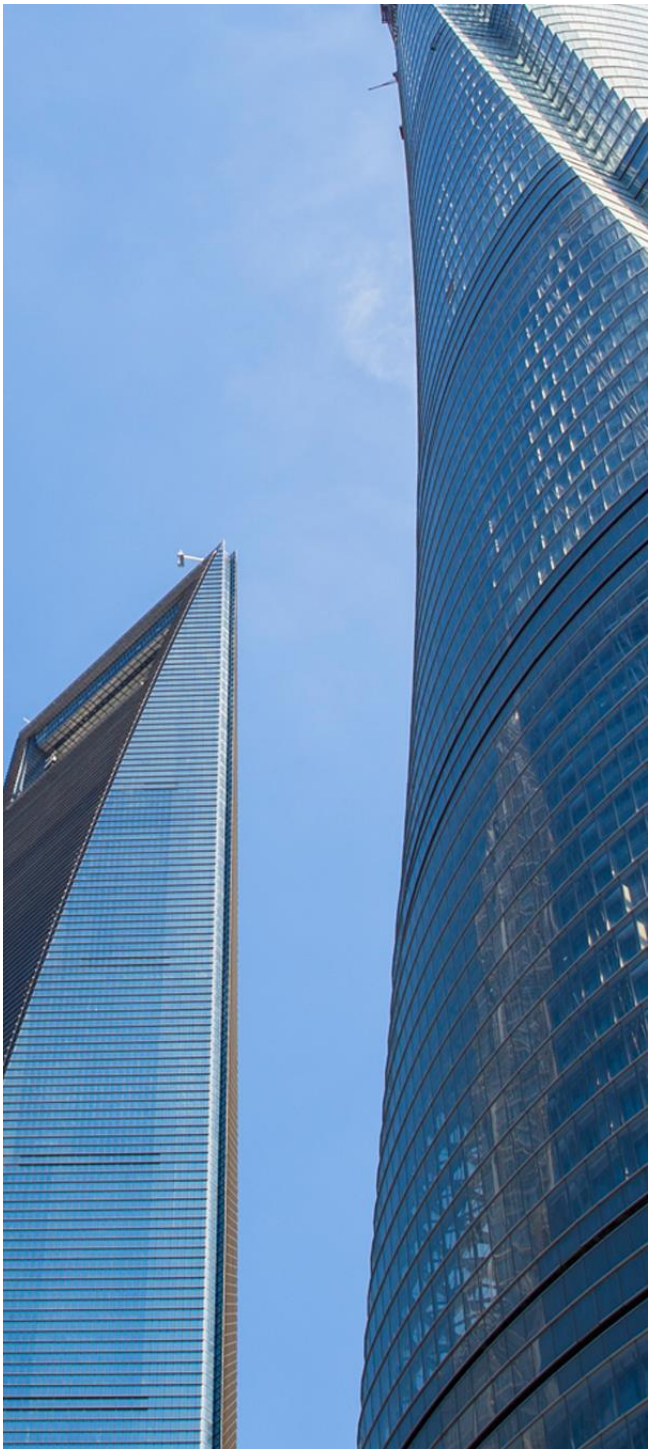
Pharmaceutical Marketing Authorization Holder System extended nationwide

Corporate legal flash

September 2019



Summary

On August 26, 2019, the 12th Session of the Standing Committee of the 13th National People's Congress ("NPC") approved the revision of the Drug Administration Law (the "Revised Drug Administration Law"), the first comprehensive overhaul since the 2001 revision.

One of the most significant changes the Revised Drug Administration Law brings to the pharmaceutical industry is the establishment of the Marketing Authorization Holder ("MAH") system.

MAH system under China's Revised Drug Administration Law

Despite being a widely accepted practice internationally, Chinese legislators did not adopt the MAH system until November 2015, when the Standing Committee of the NPC authorized the State Council to launch a pilot program to implement the MAH system in ten provinces and municipalities. On May 26, 2016, the State Council issued a detailed pilot plan (the "Pilot Program").

Before the Pilot Program, regulatory scrutiny tended to side with manufacturers. Only licensed drug manufacturers could become drug-registration holders and only GMP-certified drug manufacturers were allowed to carry out contract manufacturing. Pharma research and development institutions without manufacturing capacity had to profit through transferring or licensing their technologies to qualified manufacturers.

The introduction of the MAH system under the Pilot Program has enabled research and development institutions and individual researchers located in the pilot areas to participate further in bringing products into the market by allowing them to apply for drug registrations and become MAHs, which are liable at all stages of the drug life cycle. MAHs without production capacity must outsource the manufacture of products to licensed and GMP-certified drug manufacturers located in pilot areas.

The Revised Drug Administration Law includes the key aspects of the MAH system under the Pilot Program. It will come into force on December 1, 2019.

Highlights:

MAH

- Under the Revised Drug Administration Law, the State implements the MAH system in drug administration. MAHs are enterprises and pharma research and development institutions that have obtained a drug-registration certificate. MAHs are not necessarily licensed drug manufacturers or operators and, to produce or distribute approved drugs, MAHs without a manufacturing or sales qualification must commission qualified contract manufacturing organizations ("CMOs") or contract sales organizations ("CSOs").

- However, certain products are not eligible for contract manufacturing unless otherwise provided by the Drug Administration Department of the State Council:

blood products, narcotic drugs, psychotropic drugs, medical toxic drugs, and pharmaceutical precursor chemicals.

Foreign MAHs

- Foreign enterprises are not eligible to become MAHs under the Pilot Program. Instead, the Revised Drug Administration Law allows foreign enterprises to become an MAH, provided a domestic enterprise shall be designated to carry out the responsibilities of MAH and to be jointly and severally liable with the foreign MAH.

- Although the Revised Drug Administration Law does not impose further requirements on foreign MAHs, it still needs to be clarified whether foreign R&D institutions will be considered eligible for MAH.

MAH's responsibilities

- Under the Revised Drug Administration Law, MAHs may entrust CMOs or CSOs to produce or distribute approved drugs and must be legally responsible for the safety, efficacy and quality controllability throughout the stages of the drug life cycle. This includes pre-clinical research, clinical trials, production, distribution, post-market research and adverse drug reaction monitoring, and reporting and handling. Specifically, MAHs must:

  (i) establish a drug quality assurance system and have special personnel independently in charge of quality management;

  (ii) in case of contract manufacturing, enter into a contract manufacturing agreement and quality agreement with qualified manufacturer, strictly abiding by these agreements;

  (iii) in case of entrusted sales, commission qualified distributor and strictly abide by the commission agreement;

  (iv) assess quality assurance capacity and risk management abilities of any third parties entrusted for drug transportation or storage, supervising them at all times;

  (v) regularly evaluate the quality management system of its entrusted manufacturers and distributors (if any) to ensure their ongoing capacity for quality assurance and quality control;

(vi) establish procedural rules for releasing drugs into the market and examine the drugs released by drug manufacturers from factory, releasing them once they have been signed off by the persons responsible for quality;

(vii) establish and implement the drug-traceability system;

(viii) formulate a post-market risk management plan and carry out post-market research;

(ix) carry out monitoring of post-marketing adverse reactions of drugs and promptly take risk control measures for drugs with identified risks;

(x) report annually to the provincial authority regarding the situation of production and sales, post-market research and risk management; and

(xi) assume responsibility for product recall; and

(xii) conduct post-marketing evaluations of the safety, efficacy and quality controllability of marketed drugs on a regular basis.

Transferability

- Subject to the approval by the drug administration and supervision authority, MAHs may transfer the marketing authorization, provided the transferee has the capacity of quality control, risk prevention and compensation and is capable to perform an MAH's obligations.

Conclusion

The MAH system will be fully implemented when the Revised Drug Administration Law comes into force. From a market perspective, it is expected that this will further accelerate the drug marketing process and largely promote cooperation and competition among upstream and downstream enterprises. Specifically, the change will allow R&D institutions nationwide to profit from production and distribution, enabling licensed manufacturers to outsource work that is beyond their manufacturing capacity. It will also enable CMOs to explore the domestic market and facilitate the expansion of multinational CMOs in China. In addition, the liability exposure of MAHs under the MAH system is considered an opportunity for business insurance companies.

Date of issue: August 26, 2019. Effective date: December 1, 2019

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