Further Enhancing Matters Related to the Issuance of the Drug Manufacturing License

China – NMPA National Medical Products Administration

Main information

Scope of Application:

Full implementation of the Digitalization process for release, update, renewal and cancellation of Drug Manufacturing License in China

Effective Date:

April 2nd, 2025 (fully operational, Jan 1st, 2026)

Related Provisions:

- Drug Administration Law
- Regulations for implementation of the Drug Administration Law
- Guiding Opinions of the State Council on Strengthening the Construction of Digital Government (State Council, GuoFa 2022 no. 14)

Pharm.east.

Key Topics

Framework

- **Implementation of Digital Government in Drug Manufacturing License, applicable to Licenses issued from July 1st, 2025**

- According to the Guiding Opinions of State Council on Digital Government, the notice “Establish a national unified and dynamically managed government data catalog, implement "**one number, one source, one standard**", and realize the inventory management of data resources”

What’s new

- **Promptly available through QR code all relevant information** - enterprise’s basic information, workshop and production line details, delegated/entrusted production status, change records, and other information from both the original and duplicate licenses - ensuring that **the information shown via the QR code is dynamically and promptly updated.**

- Nor MAH neither Drug Manufacturers are anymore required to provide the paper originals or duplicates of the Drug Manufacturing License when conducting related business.

- Information available via QR code shall be used by Drug regulatory authorities at all levels and their affiliated professional institutions to carry out drug evaluation, inspection, testing, and other related work.

Sensitive Factors

- **MAH are advised to cooperate with their manufacturers to make the information about manufacturing site promptly updated**
- **Applicable to all drug manufacturers located in China, including those producers of drugs previously manufactured abroad**

Drivers

- **Real-Time update:** Transparency is a driver for the Manufacturer: the QR code makes the information available without time lapse between updating and publicity. Compliance with GMP is a further goal of the Real-Time update policy.
- **Protection of third parties:** Third parties bona fide is protected by accessing in real-time to the updated information.
- **Dematerializing:** The implementation of a fully digital Drug Manufacturing License further strengthen the process of License de-materializing, applicable to several types of licenses (Digital Business License; Digital Drug Marketing Authorization, etc.)