Announcement by the National Medical Products Administration on Further Enhancing Matters Related to the Issuance of the Drug Manufacturing License[1]

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To implement the requirements of the Guiding Opinions of the State Council on Strengthening the Construction of Digital Government, and to further improve the supervision of drug production and optimize the business environment through digital means, the following announcement is made regarding matters related to the issuance of the Drug Manufacturing License.

1.The Drug Administration Bureaus of all provinces, autonomous regions, municipalities directly under the Central Government, and the Xinjiang Production and Construction Corps (hereinafter referred to as "Provincial Bureaus") shall strictly carry out the issuance, reissuance, modification, and cancellation of the Drug Manufacturing License (including the Radiopharmaceutical Manufacturing License, hereinafter the same) in accordance with the relevant provisions of the Drug Administration Law, Vaccine Administration Law, Regulations for the Implementation of the Drug Administration Law, Regulations on the Administration of Radiopharmaceuticals, Measures for the Supervision and Administration of Drug Production, and the Announcement of the National Medical Products Administration on Matters Related to the Implementation of the Newly Revised Measures for the Supervision and Administration of Drug Production (2020 No. 47), as well as other relevant laws, regulations, rules, and normative documents, and shall not arbitrarily entrust or delegate these responsibilities.

2.For Drug Manufacturing Licenses issued after July 1, 2025, each Provincial Bureau shall uniformly manage them in the form of electronic license QR codes within their administrative region. Both the original and duplicate paper versions of the Drug Manufacturing License, as well as the electronic license, shall be marked with the respective QR codes. Information regarding the issuance, modification, entrustment, or delegation of Drug Manufacturing Licenses shall be uploaded to the Drug Manufacturing License management module of the National Medical Products Administration within five working days after the relevant work is completed.
If a Provincial Bureau is temporarily unable to manage electronic licenses via QR codes within its administrative region, it may continue to use the National Medical Products Administration's "Drug Manufacturing License" management module to generate QR codes. However, information on drug manufacturing licenses, changes, and delegation/entrustment within the administrative region must be uploaded to this module within 2 working days after the relevant tasks are completed.

[1] Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law

3.Starting from January 1, 2026, scanning the aforementioned QR codes should accurately display the 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.

4.Except for the initial application for a Drug Manufacturing License, any information that can be displayed by scanning the QR code no longer needs to be repeatedly printed or updated on the paper versions of the original and duplicate licenses. For applications submitted by enterprises for any reason, the Provincial Bureaus must promptly issue new paper originals and duplicates of the Drug Manufacturing License for the enterprise while collecting the previous versions.

5.The Information Center of the National Medical Products Administration will continuously improve the relevant information systems to ensure that the QR codes on the paper originals and duplicates of the Drug Manufacturing License are updated accordingly, timely revise the electronic license standards, and provide technical support and operational guidance.

Provincial Bureaus managing licenses through electronic QR codes within their administrative regions must improve their local information systems to ensure that the QR codes on both the paper originals and duplicates, as well as the electronic licenses, are consistently and correctly updated.

6.Drug regulatory authorities at all levels and their affiliated professional institutions should proactively use the information encapsulated in the QR codes of the original and duplicate Drug Manufacturing Licenses to carry out drug evaluation, inspection, testing, and other related work. Holders of drug marketing authorizations and drug manufacturing enterprises are no longer required to provide the paper originals or duplicates of the Drug Manufacturing License when conducting related business.

7.Provincial Bureaus must attach great importance to the issuance of Drug Manufacturing Licenses, effectively strengthen organizational leadership and policy guidance, reasonably plan the application and renewal processes, establish processing standards and procedural requirements, report updates in a timely manner, conduct strict review and control, prevent potential drug safety risks, and continuously improve service quality.

In the event of any inconsistency with previous regulations, this announcement shall prevail.

This is hereby announced.

National Medical Product Administration

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