

Notice of the General Affairs Department of the National Medical Products Administration on Ensuring the Proper Implementation of Work Related to the Segmented Manufacturing of Biological Products ¹

Authority: National Medical Products Administration

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To the Drug Administration Departments of all Provinces, Autonomous Regions, Municipalities Directly under the Central Government, and the Xinjiang Production and Construction Corps, and to the Center for Drug Evaluation of the National Medical Products Administration:

Since the launch of the pilot program on the segmented manufacturing of biological products, the National Medical Products Administration (NMPA) has advanced the work in a coordinated manner and achieved phased progress. The newly revised Implementing Regulations of the Drug Administration Law (hereinafter the “Regulations”) provide explicit provisions on segmented manufacturing and will soon enter into force. In order to strengthen policy alignment and maintain continuity and stability, the following matters concerning the segmented manufacturing of biological products are hereby notified:

1.

Provincial drug regulatory authorities shall properly carry out production licensing and related work. For applicants seeking to conduct segmented manufacturing of biological products, the provincial authority at the place of registration shall intervene at an early stage, strengthen guidance, and, in accordance with the Regulations and the Pilot Work Plan for the Segmented Manufacturing of Biological Products, review and assess whether the application meets the requirements for segmented manufacturing. For applications that meet the requirements, the authority shall, taking into account the characteristics of the specific product, formulate targeted regulatory plans and, pursuant to the Regulations and the Measures for the Supervision and Administration of Drug Manufacturing, lawfully issue or amend the Drug Manufacturing License. The authority shall also guide applicants in submitting the required marketing authorization or post-marketing variation applications. The provincial authority at

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the location of the entrusted manufacturer shall likewise perform production licensing and related duties in accordance with law.

2.

Provincial drug regulatory authorities shall ensure that enterprises fully assume their primary responsibilities. They shall strictly examine whether both the applicant/marketing authorization holder and the entrusted manufacturer have established a unified quality assurance system covering the entire manufacturing process and all manufacturing sites. In principle, at least one of the two parties shall have no fewer than three years of commercial manufacturing experience with biological products of the same dosage form. Where the circumstances fall under Item (2) or Item (4) of Paragraph 2, Article 17 of the NMPA Announcement on Strengthening the Supervision and Administration of Entrusted Drug Manufacturing (2025 No. 134), and upon written confirmation by the provincial authority at the applicant's location, the requirement may be expanded to include no fewer than three years of R&D or manufacturing experience with biological products of the same dosage form.

3.

The NMPA Center for Drug Evaluation shall, in accordance with the Measures for the Administration of Drug Registration, the Administrative Measures for Post-Marketing Changes of Drugs (Trial), and other applicable provisions, conduct strict technical reviews of marketing authorization and supplemental applications involving segmented manufacturing of biological products. The review shall focus on the rationality of process linkage and the controllability of quality throughout the entire manufacturing process. Review points shall be refined based on product characteristics, and review standards shall be unified to ensure scientific rigor, procedural standardization, and well-substantiated conclusions.

4.

For cross-border segmented manufacturing, when applying for an expansion of the manufacturing scope under the Drug Manufacturing License, relevant enterprises may submit production-related or product-related certification documents issued by domestic or foreign drug regulatory authorities in lieu of application materials that are not applicable.

5.

Provincial drug regulatory authorities shall effectively fulfill their territorial regulatory responsibilities, reinforce supervision and inspection of enterprises engaged in segmented



manufacturing of biological products, and urge enterprises to fully implement their primary responsibilities for drug quality and safety, ensuring that products are safe, effective, and quality-controlled.

6.

This Notice shall enter into force as of the date of issuance.



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