Legal Commentary

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Key Takeaways from China's Pilot Plan for Segmented Production of Biological Products

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Recently, the National Medical Products Administration (the "**NMPA**") issued the "Pilot Work Plan for the Segmented Production of Biological Products" (the "**Pilot Plan**"), introducing a pilot initiative for the segmented production of biological products. This represents a breakthrough in the regulation of segmented production, a long-awaited achievement in the biopharmaceutical industry. This breakthrough suggests the possibility of cross-provincial and even cross-border production of biological products, which marks the significant progress in optimizing resource allocation, reducing production costs, and improving production efficiency, and will promote the integration of China's biopharmaceutical industry into the global market, enhancing international competitiveness. In this article, we analyze the impact of the Pilot Plan, including the types of pilot products, requirements for pilot enterprises, international/cross-border collaboration, and tightened regulatory requirements. We hope to share our insights from these perspectives to provide a reference for the industry.

Background overview

Prior to the issuance of the Pilot Plan, China had not explicitly prohibited by law the exploration of the segmented production of biological products, thereby leaving flexibility to explore future practices in this area. As the principal law governing drug regulation, the *Drug Administration Law* does not specifically prohibit the segmented production of biological products[2]. The draft amendment to the Regulations for Implementation of the *Drug Administration Law*, published in 2022, first proposed that innovative drugs or urgently needed drugs in clinical practice with special requirements could be approved for segmented production[3]. In addition, the *Provisions on Administration of Production and Distribution of Vaccines*

[1] Jingjing XU has contributions to this article.

[2] Article 32 of the *Drug Administration Law* (2019): MAHs may either manufacture drug products by themselves or entrust a drug manufacturer with production…The contract manufacturing of blood products, narcotic drugs, psychotropic substances, toxic drugs for medical use, and pharmaceutical precursor chemicals is prohibited, unless otherwise stipulated by the drug regulatory department under the State Council.

[3] Article 69 of the draft amendment to the *Regulations for Implementation of the Drug Administration Law* (2022): For innovative drugs or urgently needed drugs in clinical practice with special requirements for manufacturing process or facility, segmented production can be permitted upon approval by the State Council's drug regulatory authority.

, published in 2022, also clarified that, with the consent of the NMPA, vaccine solutions (in Chinese: 原液) and formulations (in Chinese: 制剂) can be manufactured separately through contract manufacturing[4]. In practice, since 2021, regions such as Suzhou and Shanghai have begun to implement and explore this policy[5]. These preliminary endeavors have resulted in valuable experience for the issuance of this Pilot Plan, which is the first official national-level initiative to promote the segmented production of biological products.

Key takeaways from the Pilot Plan

I. Types of pilot products

The Pilot Plan covers several popular biological products available in the market, including PD-1 inhibitors, GLP-1 agonists, and antibody-drug conjugate (**ADC**) products[6]. Currently, cell and gene therapy (**CGT**) products are not explicitly covered by the Pilot Plan, and they await further clarification and guidance from regulatory authorities. The Pilot Plan also stipulates that pilot products may include other biological products as specified by the NMPA, potentially allowing CGT products to fall within the scope of the pilot products. Additionally, the Pilot Plan adopts the principle of "each product has its own policy" (in Chinese: 一品一策), i.e., distinct policies and measures will be developed for different biological products. The Pilot Plan shows that it considers the characteristics of different biological products and their specific regulatory needs, providing diverse measures for segmented production across different product types.

Notably, the recently issued *Notice on Carrying Out Pilot Programs to Expand Opening-Up in the Healthcare Sector*, foreign-invested enterprises in such pilot initiatives are also permitted to engage in the development and application of human stem cells, gene diagnostic and therapy technologies (for highlights of this notice, please refer to our article: *China Pilots Lifting Restrictions on Foreign Investment in Stem Cell, Gene Therapy, and Genetic Diagnosis Sectors in Four Free Trade Zones*). We look forward to the potential synergy between these two pilot initiatives in the future, which may facilitate segmented production of CGT products to reduce production costs and enhance R&D efficiency.

II. Requirements for pilot enterprises

The Pilot Plan imposes stringent requirements for qualified pilot enterprises. Notably, pilot enterprises must apply with their originally-developed products[7]. However, further clarification is needed

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[4] Article 12 of the *Provisions on Administration of Manufacturing and Distribution of Vaccines* (2022): The scope of contract manufacturing shall encompass the whole processes of vaccine manufacturing. If necessary, the contract manufacturing of combined or multi-component vaccines can be conducted separately for the vaccine solution manufacturing stage and the formulation manufacturing stage with the consent of the NMPA after discussion and approval.

[5] For example, the exploration of segmented production of biological products has been initiated in the Suzhou Industrial Park in 2021, and the Shanghai Medical Products Administration's 2024 initiative "Measures on Continuously Creating a first-class Business Environment in the Drug Regulatory Field" has mentioned promoting pilot work on the segmented production of biological products.

[6] The Pilot Plan states that the pilot products shall generally be innovative biological products, biological products of urgent clinical need, or other biological products specified by the NMPA, including combination and multivalent vaccines, antibody biological products, ADC products, GLP-1 products, and insulin products.

[7] Policy interpretation of the Pilot Work Plan for Segmented Production of Biological Products: The pilot products should be

regarding the definition of "originally-developed products", particularly in cases involving collaborative R&D or licensed-in projects for innovative biological products. The interpretation of this requirement will significantly impact the Pilot Plan's applicability to biological products in licensing and co-development projects, requiring close attention in future regulatory practices.

Additionally, entrusted manufacturing enterprises must implement a unified quality management system with entrusting enterprises and must have at least three years of commercial production experience in biological products. The entrusting enterprises must designate at least two qualified technical personnel to be stationed on-site to ensure unified standards and seamless coordination. This requirement goes beyond conventional contract manufacturing requirements, which typically only mandate that an entrusting enterprise conduct on-site audits of the entrusted manufacturing enterprises' quality management system. These more stringent requirements reflect higher standards for inter-company collaboration, operational coordination, and quality management necessary in the segmented production of biological products.

III. Cross-provincial/cross-border collaboration

The Pilot Plan supports cross-provincial segmented production of biological products. For cases where the contracting parties are located in different provinces, the Pilot Plan requires the regulatory authorities from both provinces to collaboratively develop and formulate regulatory plans. Furthermore, the Pilot Plan allows foreign applicants/holders of imported drugs to participate in the pilot program, signaling support for cross-border segmented production of biological products. This represents a significant breakthrough, particularly considering China's historical requirement that imported drugs be produced overseas. Looking ahead, more flexible manufacturing arrangements may emerge, such as producing the vaccine solutions within China while completing formulation production abroad — an arrangement that exemplifies "each product has its own policy", the regulatory approach outlined in the Pilot Plan.

IV. Tightened regulation

Under the Pilot Plan, pilot enterprises and pilot products are bound to face stricter regulation. Provincial medical products administrations will implement annual comprehensive inspections and sampling inspections on pilot products and will actively accept entrusted inspections from enterprises. Regular GMP compliance inspections and unannounced inspections are also likely to become a routine to ensure the quality of products in segmented production. Additionally, cross-provincial regulatory coordination has always been a major challenge. Differences in regulatory experience and resources among provinces may affect the effectiveness of supervision over cross-provincial segmented production. As the pilot work progresses, we anticipate that regulatory authorities will accumulate experience and establish effective cross-provincial regulatory plans.

V. Pilot regions and timeline

The pilot regions include provincial administrative areas that that have been proposed to explore new

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the originally-developed products of the pilot enterprises.

policies under the national strategy and provincial administrative areas with real project needs, industrial foundations, and strong regulatory capabilities. It is expected that these regions will include Shanghai, where the policy to promote pilot work on segmented production of biological products was proposed in March this year. We also look forward to more regions implementing the Pilot Plan in the future.

As for the timeline, enterprises must submit pilot applications by December 31, 2025, and the pilot work will conclude by December 31, 2026. We hope that the experience accumulated over two years of pilot work will lay a foundation for the subsequent official implementation of segmented production of biological products.

Conclusion

The Pilot Plan is of great significance for China's biopharmaceutical industry. The implementation of this Pilot Plan is expected to bring important opportunities to the industry, including optimizing production division, improving industrial efficiency, and strengthening regional and international cooperation. However, during the implementation of the Pilot Plan, it remains to be explored how to ensure product quality, achieve effective regulation, and coordinate cross-regional and cross-border regulatory cooperation under the segmented production model. We believe that industry participants and regulatory agencies may work together to refine the details of the Pilot Plan. Through steady advancement and experience accumulation, the regulatory authorities may overcome potential challenges, stimulate the vitality of the market participants, and promote the high-quality development of China's biopharmaceutical industry.

Important Announcement

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