

# Legal Commentary

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## Strategic Insights for the Localization of Pharmaceutical and Medical Device Manufacturing in China

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In recent years, an increasing number of multinational pharmaceutical and medical device companies have been exploring local manufacturing options in China. Many of the licensing transactions that have surged in recent years also involve technology transfer and plans for the future localization of imported products. The trend is driven not only by the need for cost control and supply chain optimization but also aligns with China's policy incentives for industrial localization. Companies can pursue localization through various pathways, such as establishing their own production facilities, collaborating with contract manufacturers, or partnering with local licensees through licensing arrangements. However, China's regulatory framework for drug and medical device localization remains complex and constantly evolving. Companies often encounter challenges related to registration classification, application requirements, Marketing Authorization Holder (**MAH**) and manufacturing arrangements, as well as the recognition of originator drug status, etc. In practice, we frequently receive inquiries on these topics. Drawing from our experience and observations, this article aims to share key insights and perspectives to help navigate the evolving landscape.

### Policy overview on the localization of imported drug and medical device manufacturing

#### I. Registration pathways for drugs and medical devices in China

In China, the regulatory pathways for "imported" and "domestic" drugs and medical devices are clearly differentiated. A product registered as "imported" must be manufactured overseas and is generally required to have a foreign company as the MAH, along with the designation of a local entity in China serving as the domestic responsible person or agent. By contrast, a product registered as "domestic" must be manufactured within China and is required to have a Chinese company as the MAH.

Therefore, given the distinct regulatory pathways for imported and domestic products, the localization of imported drugs and medical devices essentially constitutes a re-registration as a new product, rather

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than a simple amendment or transfer of the MAH or registration certificate. For instance, imported innovative drugs seeking localization must be submitted under China's generic drug classification. That said, the localization process often benefits from policy incentives, such as simplified registration documentation, and there may also be room to preserve certain benefits of originator status, as further discussed below.

## II. Regulatory requirements for the localization of imported drug manufacturing

With regard to the localization of imported drugs, in the past, foreign manufacturers of imported drugs were permitted to transition production to China through a supplemental application. However, this pathway has since been discontinued. Currently, the transfer of manufacturing from overseas to China can no longer be completed via simple transfer and must instead proceed through re-registration. In 2024, the Center for Drug Evaluation (CDE) under the National Medical Products Administration (NMPA) issued specific requirements for re-registration of imported chemical and biological products, thereby providing clearer regulatory guidance for the optimized registration pathway for localization.

Under current regulations, the following are the key regulatory points for the optimized registration pathway for the localization of imported drugs:

- **Applicant requirements:** any entity based in China is eligible to apply under the optimized registration pathway for localization, such as a Chinese subsidiary or licensing partners of the MAH of the imported drug; in cases where the domestic applicant shares the same parent company with the MAH or manufacturer of the imported product, documentation requirements may be further simplified.
- **Application requirements:** the localization of biological products and originator chemical drugs may qualify for a simplified application process, with certain documentation exempted. Localization of originator drugs may also be eligible for priority review and approval under an expedited review timeline, as stipulated by law.
- **Management of amendment registration:** to qualify for a simplified application process, it is recommended that manufacturing processes, formulation composition, and control of active pharmaceutical ingredients and excipients remain consistent between the localized and imported products. However, certain amendments – such as modifications to the manufacturing processes or packaging materials – are also permitted, provided that appropriate supporting documentation is submitted as required.
- **Transfer restrictions:** an imported drug must be localized under one domestic MAH; multiple transfers or allocation of different product specifications to separate MAHs are not permitted.
- **Manufacturing arrangements:** in principle, domestic products must be manufactured within China. Recently, both national regulators and local authorities in cities such as Beijing and Shanghai have proposed to explore cross-border contract manufacturing for drugs and devices, as well as segmented cross-border production of biological products, which is expected to enhance the flexibility of localization arrangements. In practice, pilot cases of segmented cross-border production for biological products have already emerged. We will continue to monitor

these developments (for our analysis on China's new policies on cross-border contract manufacturing for drugs and devices and segmented production of biological products, please see "[汉坤·观点 | 终于等到你 — 解读粤港澳大湾区药品医疗器械跨境委托生产新政](#)" and "[Key Takeaways on China's Pilot Plan for Segmented Production of Biological Products](#)").

### III. Regulatory requirements for the localization of imported medical device manufacturing

China has also established an optimized registration pathway for the localization of imported medical devices. In 2020, the NMPA issued the landmark Announcement No.104, which introduced an expedited route for medical device localization. In 2025, the NMPA further refined the regulatory framework through Announcement No.30. Under current regulations, the key regulatory points for the optimized registration pathway for imported medical devices are as follows:

- **Applicant requirements:** unlike in the cases of drugs, applicants seeking to utilize the optimized registration pathway for the localization of imported medical devices must meet stringent equity or controlling requirements regarding their relationship with prior MAHs.
- **Product scope:** the optimized registration pathway for imported medical devices is only applicable to Class II and Class III medical devices – products classified as higher-risk products under China's classification system.
- **Management of amendment registration:** localized products must remain consistent with the imported product in terms of key raw materials and main manufacturing processes; their quality management system shall demonstrate "substantial equivalence" to that of the imported product.
- **Favorable policies:** registration application for imported medical devices may be subject to simplified documentation requirements. Innovative imported medical devices may also qualify for priority review and expedited process for applying registration and manufacturing license. Local authorities have also introduced supporting measures – for example, the Shanghai Medical Products Administration recently issued policies offering streamlined documentation and inspection procedures.
- **Manufacturing arrangements:** contract manufacturing is not permitted. In practice, companies should carefully assess any contemplated contract manufacturing arrangements and engage in proactive communication with regulators before proceeding.

Unlike drugs, which are uniformly regulated by the NMPA regardless of their classification, domestic medical devices are subject to a tiered regulatory system in China: only Class III device registrations are overseen by the NMPA, while Class I and Class II device filings and registrations fall under the supervision of provincial-level medical products administrations. Based on our practical experience, certain provincial authorities may allow medical device companies to apply through the normal procedures while accepting previously filed documents for imported products to expedite the process. Such procedures may not require applicants to meet the equity or controlling requirements mentioned above and may also impose fewer restrictions on contract manufacturing arrangements.

## Strategic considerations for the localization of imported drugs and medical devices in China

In practice, we frequently receive inquiries from pharmaceutical and medical device companies on a range of issues related to localization, such as project structuring, clinical development strategies, licensing arrangements, originator drug status, registration classification, and the coordinated management of multiple amendment registrations. Below is a brief overview of our observations and key considerations for industry reference.

### I. Collaboration structuring for localization projects

When entering the Chinese market, companies typically consider various models such as establishing their own manufacturing facilities, collaborating with CROs/CDMOs, or entering into licensing agreements with Chinese partners. Each approach entails different implications in terms of profit allocation, risk distribution, control over project assets, and reliance on partners. Companies need to conduct a comprehensive assessment based on their specific circumstances, such as whether it is a small startup biotech, its funding scale, existing partnerships, and its strategic objectives and desired level of control over the project.

### II. Clinical development arrangements

Clinical study in China is increasingly favored in global clinical development programs due to its efficiency and high quality. It is important to note, however, that based on our project experience, the regulatory authority currently does not accept the transfer or amendment of clinical trial sponsorship from an overseas applicant to a Chinese applicant and would require a new application. Therefore, during the IND submission phase, it is advisable to comprehensively assess the product's development and registration strategy to ensure an efficient path to product approval.

In addition, for investigator-initiated trials (IITs), companies need to pay attention to regulatory requirements regarding human genetic resources, personal information and data protection compliance, as well as the potential risk of violating anti-corruption regulations. For example, from the perspective of human genetic resources regulation, it is important to consider whether foreign companies should seek Chinese partners to fund IIT projects. (For key insights on human genetic resources regulatory requirements, please refer to our articles: "[Highlights on HGR Regulation Implementation Rules](#)" "[Key Takeaways on the New HGR FAQs issued by the MOST of China](#)" and "[汉坤·快评 | 〈人类遗传资源管理条例〉再次修订](#)" Regarding recent risk alerts in China drug clinical studies, please refer to our article: "[Compliance Highlights and Strategies in High-Risk Clinical Research Landscape](#)").

### III. Key strategic considerations for licensing transactions

In the life sciences sector, technology transfer and licensing transactions are very common and hold significant strategic value. We have extensive experience advising on such transactions, including advising on several high-profile deals related to China this year (for our insights on licensing and NewCo transactions, please see "[2024 Data Analytics: China Life Sciences NewCo & Licensing Terms](#)" and "[Six Key Insights into China Biotech's NewCo Model](#)" and "[Insights into China Biotech's New](#)

[Approach: Spin-off-NewCo Model](#)). These agreements are typically complex and require careful negotiation to ensure the protection of company's interests.

When using a licensing transaction as a vehicle to achieve the localization of imported drugs and medical devices, both parties involved should pay close attention to key provisions such as the Chinese partner's diligence obligations, non-compete commitments, and project decision-making rights. For example, licensors are advised to clearly define specific diligence standards requiring the partner to actively advance product development, prevent diversion of resources to competing products and consider retaining control over critical decisions, such as those related to clinical studies.

#### **IV. Originator drug status**

Innovative drugs are eligible for a range of policy incentives, including recognition as innovative drugs and reference formulations, the protections related to patent rights and clinical data, as well as the benefits related to brand names (for the latest developments on China's regulatory data protection system, please refer to our interpretive article: "[Analysis of China's New Draft of Drug Regulatory Data Protection Rule: A New Perspective on Innovative Drug Transactions](#)"). Under current China's regulations, imported innovative drugs undergoing localization must be registered under the generic drug classification, which may affect their originator drug status. However, based on our experience, certain aspects of such status – such as recognition as a reference formulation or retention of the brand names – may, in some cases, be preserved under certain conditions, although specific situations still need to be analyzed on a product-specific basis.

Overall, China's regulatory framework regarding originator status for localized products is currently not entirely clear, and this issue continues to attract close attention from the industry. We also look forward to further regulatory clarification that would more clearly recognize the originator status of localized products, thereby promoting the localization of more high-quality drugs and medical devices in China.

#### **V. China registration classification for drugs and medical devices**

For innovative drugs and medical devices, the registration classification in China may sometimes differ from that in foreign markets. Companies must determine the classification based on Chinese regulations to ensure accurate registration pathways. For instance, the regulatory categorization of certain novel drug-device combinations in China – whether they are classified as combined products, or as separate drug and medical device – may require reference to relevant laws, regulations interpretations, existing precedents, and consultation with regulators. In some cases, a formal classification request may also be necessary.

#### **VI. Coordinated management of multiple amendment registrations**

In practice, localization projects may involve various scenarios, such as asset acquisitions within pharmaceutical or medical device groups, or license-in arrangements for imported drugs and medical devices. These projects often entail multiple concurrent amendment registrations, such as alteration of MAH, manufacturing site and active pharmaceutical ingredient (API). Based on our experience in assisting such complex amendment projects, it is crucial to carefully arrange the sequence and timing

of various amendment registrations and to coordinate different regulatory requirements to ensure the smooth progress of the project.

## **Conclusion**

As the global supply chain landscape constantly changes and China's localization policies advance, the localization of drugs and medical devices is increasingly viewed not just as a cost-efficiency measure, but as a strategic move for multinationals to strengthen their market presence and long-term competitiveness in China. However, the regulatory environment remains intricate and continuously evolving, posing significant implementation challenges. Given the scope of this article, we provide only a concise review of selected regulatory highlights. It is important to note that the critical considerations in such projects may differ based on product type and deal structure. We recommend that companies proactively consult with internal and external experts to develop feasible and compliant strategies. We will also continue to monitor policy developments closely and share more observations and insights with the industry.

***Important Announcement***

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