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China on the Move: Lessons from China's 2024 National Negotiation of Drug Prices

China's share of the global drug development pipeline grew from 3% in 2013 to 28% in 2023, positioning China as the second-largest region for clinical trials after the United States. Additionally, the proportion of drugs launched first in China increased from 9% in 2017 to 29% in 2023, placing China just behind the United States in terms of first-in-class launches. This trend highlights the contributions of domestic companies, whose pipelines are replenishing the global pharmaceutical landscape. As a result, NextPharma estimates that the combined value of China's licensing-out deals reached around $46 billion in 2024, up from $38 billion in 2023 and $28 billion in 2022.

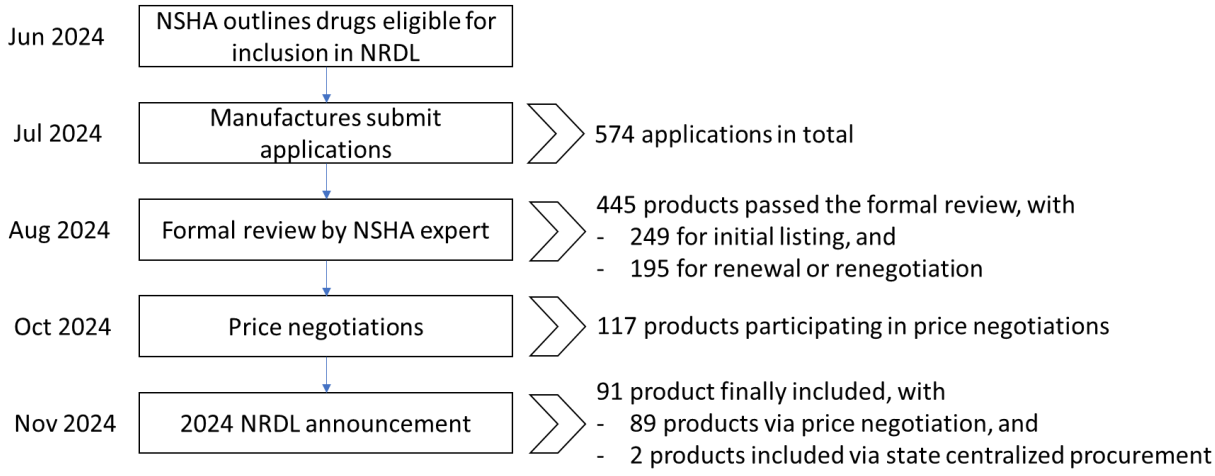
On the demand side, from 2019 to the first quarter of 2023, the National Healthcare Security Administration (NHSA) allocated 60% of savings from generic drug procurement to innovative drugs listed on the National Reimbursement Drug List (NRDL). This shift mirrors trends in developed markets where patented drugs dominate sales. By 2023, innovative drugs accounted for 15.1% of hospital drug expenditures in sample hospitals, up from less than 10% in 2018. However, affordability remains a challenge, which is significant as China continues to push for increased access to cutting-edge therapies.

The 2024 NRDL negotiations, which concluded in November 2024, offer insights into how China is addressing these affordability concerns while seeking to ensure access to innovative medicines. This GT Advisory explores five key takeaways from the 2024 NRDL negotiations and their potential implications for the future of innovative drug pricing and reimbursement in China.

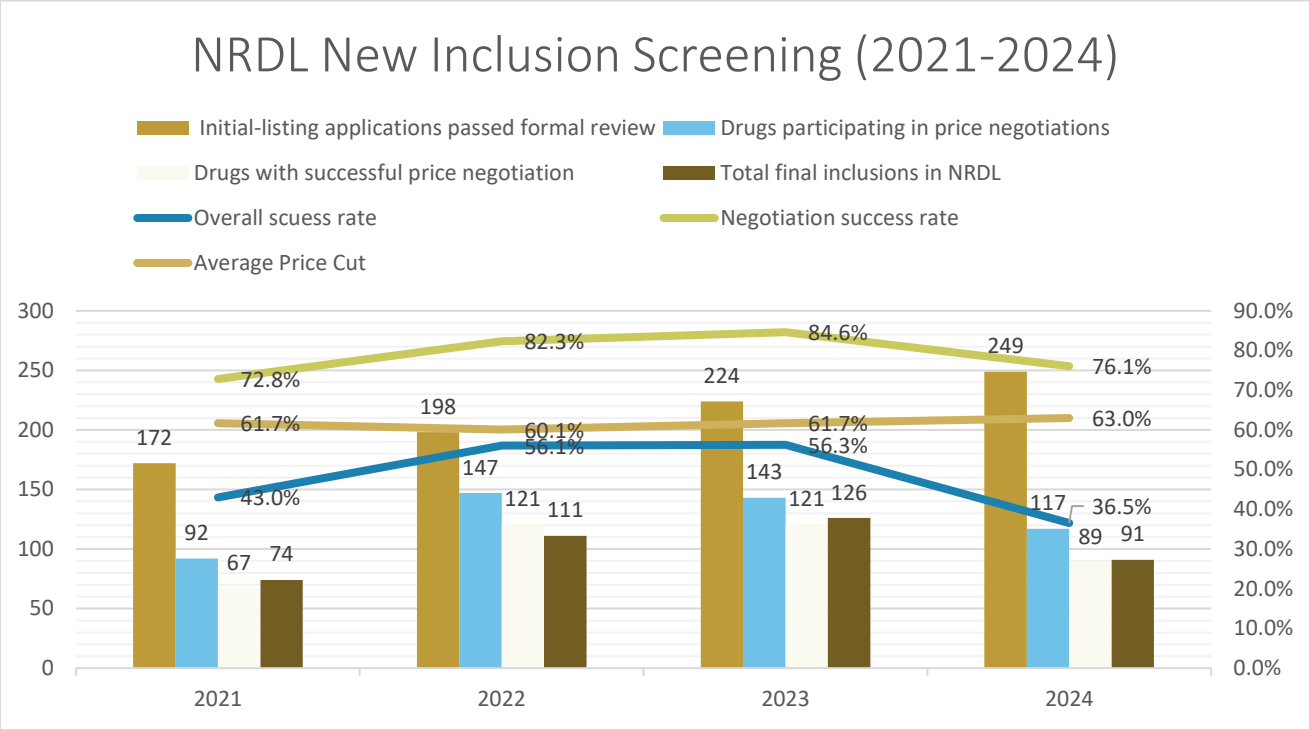
- A Contradiction Between NRDL Outcomes and the Growing Influence of Chinese Companies in Global Innovation
- Support for First-in-Class and Innovative Drugs
- BMI Fund Sustainability
- A Continuous Dilemma for Multinational Companies (MNCs)
- Reimbursement Coverage Expansion: Category C and Commercial Health Insurance

1. A Contradiction Between NRDL Outcomes and the Growing Influence of Chinese Companies in Global Innovation

The 2024 NRDL negotiations followed the same process as previous years, starting in July 2024, but concluded earlier, at the end of November. The timeline of 2024 NRDL negotiations is shown below.



This year saw a significant decline in the overall success rate, with 91 out of 249 drug candidates included in the final list, resulting in a success rate of approximately 37%. This was a decline from 56% in 2023, suggesting stricter pricing negotiations and a more selective approach. Additionally, the average price cut reached 63%, the highest in recent years. Forty-three drugs were removed from the 2024 NRDL, either replaced by more advanced drugs or due to production or supply cessation.



Source: NSHA press release

One trend is the growing dominance of domestic pharmaceutical companies. Of the 91 new drugs added to the NRDL in 2024, 65 were from domestic players (71%), while 26 were from imported brands (29%).

By therapeutic area, oncology continues to lead, with the highest number of new listings, totaling 26 new drugs targeting non-small cell lung cancer, small cell lung cancer, breast cancer, and cervical cancer, etc. The success rate in oncology stands at 52%. The average wait time for NRDL inclusion is 17 months, with half of them being added to the listing within 12 months of their regulatory approvals in China. The longest waiting period for NRDL inclusion is around 40 months, while the shortest period is six months. Twenty-two months after the receipt of regulatory approval and its first setback, Daiichi Sankyo-AstraZeneca's Enhertu can be included in NRDL 2024 even with a new indication in HER2-Low patients producing a larger budget impact.

Chronic diseases follow with 15 new drugs included. Rezurock utilized real-world evidence from its early access program in Hainan province to earn the listing decision.

Rare diseases saw 13 new inclusions, a slight decrease compared to 15 in 2023, but with 27 failures. Novartis' Fabhalta used its strong clinical data and real-world evidence to earn a spot on the new formulary by demonstrating the unmet needs of paroxysmal nocturnal hemoglobinuria in China. On the other hand, the implicit price ceiling for NRDL listing may be challenging for rare diseases drugs, including drugs that leading companies, such as BeiGene or CANbridge, have developed.

However, the growing strength of domestic companies presents a contradiction. As China seeks to establish itself as a major global innovation hub, it still struggles to incorporate high-priced international drugs into its reimbursement system. This growing divide between China's ambitions to foster domestic innovation and its struggles to accommodate international players reflects a contradiction between the

global aspirations of Chinese companies and the limitations the current reimbursement framework imposes.

2. Support for First-in-Class and Innovative Drugs

The 2024 NRDL negotiations emphasized support for first-in-class therapies and innovative drugs. Of the 91 new drugs included, 38 were recognized as "global first-in-class" therapies, and nearly all were launched within the past five years. This trend reflects China's evolving policy focus, which prioritizes cutting-edge innovation.

One example of this strategic push is Awiqli, a first-in-class therapy by Novo Nordisk that entered the NRDL in 2024. This drug received China's regulatory approval ahead of its U.S. FDA approval, illustrating the growing importance of China as an early adopter of novel treatments. Awiqli was included despite the higher cost typically associated with first-in-class therapies, signaling that China is placing value on innovative drugs that offer substantial clinical benefits.

This policy shift aligns with the Chinese government's broader goals outlined in the Action Plan for Full-Chain Support of Innovative Drug Development, which the State Council approved in July 2024. The plan aims to accelerate therapeutic development for oncology and rare diseases while striving to ensure global competitiveness by 2035. In 2024, for instance, the NHSA placed particular emphasis on innovative oncology drugs, with 26 new cancer treatments added to the NRDL.

Furthermore, as part of these efforts, the NHSA refined its pricing methodologies to comprehensively assess the clinical value of drugs. Negotiations weighed factors such as patient health benefits, safety, efficacy, and innovation, and allowed drugs with substantial patient benefits to secure higher price ceilings.

3. BMI Fund Sustainability

China's National Healthcare Security Administration (NHSA) uses volume-based procurement to balance affordability with innovation. Under this model, pharmaceutical companies agree to lower per-unit prices in exchange for guaranteed market access and volume commitments. Despite the favorable measures for innovative drugs, the NHSA continues to seek significant price concessions to ensure the sustainability of the Basic Medical Insurance (BMI) fund.

An example of this challenge is Polatuzumab Vedotin (Polivy®), an antibody-drug conjugate (ADC) by Roche. After China's National Medical Products Administration (NMPA) approved it in 2023, Polatuzumab Vedotin was added to the NRDL in 2024. However, the NHSA's stringent cost-containment measures forced Roche to limit the drug's treatment duration to six cycles to align with budget expectations. This pricing strategy reflects the NHSA's ability to exert significant control over pricing and its ongoing struggle to contain the financial burden of high-cost therapies, even when these drugs offer promising clinical results.

While these price negotiations seek to ensure the financial sustainability of the BMI fund, high-cost therapies such as ADCs and CAR-T therapies continue to face barriers, requiring strategic clinical and pricing adjustments to stay within the NHSA's budgetary thresholds.

4. A Continuous Dilemma for Multinational Companies (MNCs)

The 2024 NRDL negotiations underscore the growing dominance of domestic pharmaceutical companies, which secured 71% of new listings. This shift reflects China's goal to reduce reliance on foreign drugs and foster a self-sufficient biopharma industry. Local players such as BeiGene and Hengrui Pharmaceuticals have been particularly successful, benefiting from regulatory pathways that prioritize local innovation.

In contrast, multinational companies (MNCs) face greater difficulties. Only 26 imported drugs were included in the NRDL, with Roche and BMS leading the charge with 4 and 3 products, respectively. MNCs are increasingly turning to partnerships with local manufacturers to navigate the strict pricing and reimbursement requirements the NHSA sets.

A good example of this strategy is AstraZeneca's partnership with the Jinan Innovation Zone in Shandong province to advance research and development for rare diseases. This partnership leverages local resources to enhance the accessibility and affordability of therapies, particularly for high-cost treatments.

Despite these strategies, MNCs must weigh balancing price concessions to gain access to China's lucrative market against potentially losing market share to local competitors, who may be benefiting from more favorable terms.

5. Reimbursement Coverage Expansion: Category C and Commercial Health Insurance

China's NHSA has taken steps to expand reimbursement pathways, particularly with the introduction of the proposed Category C drug list and the integration of commercial health insurance. These changes may open new avenues for innovative therapies, especially for rare diseases and high-cost treatments.

1. **Category C Drug List**: This proposed supplementary tier to the NRDL aims to cover high-cost, high-innovation therapies such as CAR-T, advanced oncology drugs, and treatments for rare diseases. The NHSA plans to finalize the list in 2025, allowing for negotiations between insurers and drug manufacturers. The Category C list is expected to provide an alternative for drugs that may not meet NRDL price thresholds but still offer significant clinical benefits, especially for rare diseases. Domestic companies may leverage Category C as a fast track for commercializing novel therapies, particularly those targeting rare diseases. Given that price sensitivity tends to be lower in rare disease markets, domestic players might focus on rapid market penetration by offering moderate pricing, a strategy that may complement China's broader goal of fostering innovation.

For example, a domestic company working on a novel treatment for a rare condition might opt to list their drug under Category C, sidestepping the pricing expectations associated with NRDL inclusion. This pathway would allow for quicker access to patients while also enabling the company to avoid the discounts required for NRDL listing.

2. **Commercial Health Insurance**: To alleviate pressure on the BMI fund and further incentivize the use of innovative treatments, the NHSA is encouraging commercial health insurance to cover non-reimbursed drugs and high deductibles. Insurers such as Ping An and CPIC have started offering specialized insurance products designed for high-cost innovative drugs, and pilot programs in regions like Shanghai have begun covering expensive treatments like *Kymriah* (a CAR-T therapy). This may help expand access to cutting-edge therapies not included in the NRDL or Category C.

Partnerships with local insurers may further enhance market penetration, especially for rare disease therapies that may not be cost-effective for widespread public reimbursement. For example, insurers

could offer coverage for high-cost treatments excluded from the NRDL but included in Category C, which may allow patients to access life-saving medications outside of the national insurance framework.

However, this may present a dilemma for MNCs. MNCs face a choice between participating in the Category C listing with moderate pricing or prioritizing NRDL inclusion by offering discounts. While Category C allows for quicker commercialization, it may not offer the same patient access scale as NRDL inclusion, which is more widely recognized and integrated into the national reimbursement system. Alternatively, offering substantial price reductions to be included in the NRDL might provide immediate access, but at a cost that potentially impacts profitability and long-term market sustainability.

For example, an MNC offering a highly innovative oncology therapy might have to choose between a quick path to market under Category C with a lower price point or a slower process of negotiating steep discounts with the NHSA to secure NRDL inclusion, even if the eventual market access is broader.

Moreover, drugs excluded from both the NRDL and Category C risk becoming inaccessible to many patients. This situation underscores the need for adaptive pricing strategies that balance the demands of affordability and innovation. For MNCs, navigating this complex pricing landscape requires careful consideration of market positioning, clinical benefits, and their products' commercial viability.

Takeaways on the 2024 NRDL Negotiations

China's evolving pharmaceutical reimbursement system, as demonstrated by the 2024 NRDL negotiations, underscores a balance between affordability, innovation incentives, and fiscal sustainability. While aggressive price cuts and preferential treatment for domestic companies may present challenges for MNCs, they also highlight China's commitment to nurturing homegrown innovation. At the same time, new reimbursement mechanisms like the proposed Category C drug list and commercial insurance may help provide broader access to high-cost therapies.

As China continues to refine its reimbursement policies and navigate the complexities of its healthcare system, MNCs must remain agile and strategic in their approach. The 2024 negotiations highlight both the potential and the challenges of operating in China's pharmaceutical market, emphasizing the need for a nuanced understanding of pricing dynamics, policy shifts, and market access strategies.

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