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# Opportunities and Challenges for Innovative Drugs in China: Strategies for successful reimbursement

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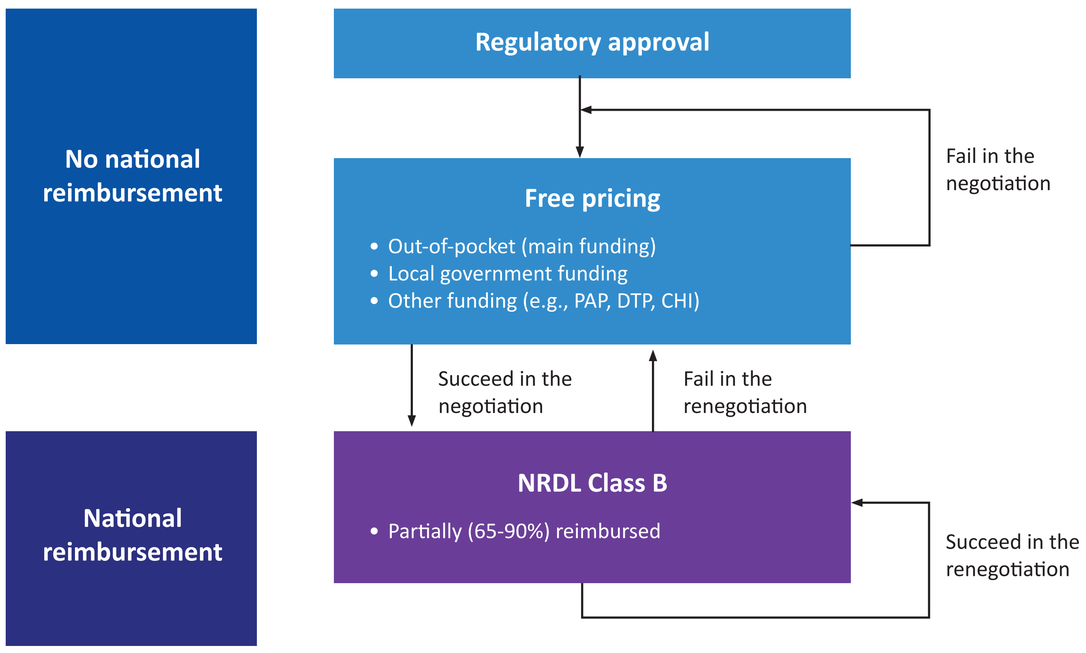
## Abstract

- **Background:** China's near-universal drug coverage has limitations due to high out-of-pocket costs for patients and poor coverage of innovative, premium-priced medicines. To increase access to high-cost innovative drugs, national drug price negotiations were introduced in 2015.
- **Objective:** To describe current opportunities and challenges for innovative drugs in China based on recent evidence from the new reimbursement decision making processes.
- **Method:** National Reimbursement Drug List (NRDL) related notices and articles by the Ministry of Human Resources and Social Security (MOHRSS) and National Healthcare Security Administration (NHSA) between 1st January 2015 and 31st May 2022 were reviewed and analysed.
- **Results:** Since 2016 when five negotiations took place with three drugs added to the NRDL, both the number of negotiations and listings have increased considerably with a total of 496 product negotiations. The success rate varied between 59% and 94% over the years and across initial and renegotiations. With the relatively high success rate, agreements have often been made with substantial discounts to drug prices. The average agreed drug price discount ranged between 44% and 62% over the years and exceeded 50% in the last two years. Regarding key assessment criteria, initial focuses on effectiveness, safety and reasonable pricing (2016) were broadened to include new aspects of innovation and equity (2021), with new pharmacoeconomic guidelines published in 2020. This indicates that manufacturers need careful planning to demonstrate broad aspects of value to meet evolving NRDL assessment requirements. In the future, we expect to see further reforms for rapid inclusions and reimbursement requirements of high price drugs in China.
- **Conclusion:** Pharmaceutical companies will need to track NRDL trends, monitor actual decisions by therapeutic areas, develop tailored strategies and demonstrate comprehensive value to achieve market access and reimbursement for innovative drugs in China.

## Background

- While China has achieved near-universal coverage with 97% of the population being covered by publicly funded basic medical insurance in 2018,[1] this coverage has limitations due to high out-of-pocket costs for patients and poor coverage of innovative, premium-priced medicines.
- To increase the coverage of high-cost innovative drugs, national drug price negotiation was introduced in China in 2015. After successful negotiation with the National Healthcare Security Administration (NHSA), approved innovative drugs are added to the National Reimbursement Drug List (NRDL) Class B and are partially (65-90%) reimbursed (Figure 1). Renegotiations take place every two years for drugs approved on the Class B list.
- The objective of our research was to review and assess national drug price negotiations over the past 6 years.




Abbreviations: CHI, Commercial Health Insurances; DTP, Direct to Patient financing; NRDL, National Reimbursement Drug List; PAP, Patient Assistance Program

**Figure 1. Market access, pricing and reimbursement flow for high-price innovative drugs in China**

## National Drug Price Negotiations: Past 6 Years

- In the pilot year (2016), five negotiations took place with three drugs added to the NRDL.
- Since then, both the number of negotiations and listings have increased considerably with a total of 496 product negotiations.
- The success rate varied between 59% and 94% over the years and across initial and renegotiations agreements have often been made with substantial discounts to drug prices. The average agreed drug price discount ranged between 44% and 62% over the years and exceeded 50% in the last two years (Table 1).
- With more focus on drug costs in 2021, the 67 drugs newly included on the NRDL had an average price discount of 62%, with the annual per-patient treatment cost for each drug added to the list being less than 300 thousand CNY (47 thousand USD).[2]

**Table 1. Review of National Drug Price Negotiation Results**

| Year | Initial negotiation / renegotiation | Number of negotiations | Number of successful negotiations | Success rate | Average discount |
|---|---|---|---|---|---|
| 2016 | Initial negotiation | 5 | 3 | 60% | 58% |
| 2017 | Initial negotiation | 44 | 36 | 82% | 44% |
| 2018 | Initial negotiation | 18 | 17 | 94% | 57% |
| 2019 | Initial negotiation | 119 | 70 | 59% | 61% |
| | Renegotiation | 31 | 27 | 87% | 27% |
| 2020 | Initial negotiation | 162 | 119 | 73% | 51% |
| | Renegotiation | | 23 | | |
| 2021 | Initial negotiation | 85 | 67 | 79% | 62% |
| | Renegotiation | 32 | 27 | 84% | NA |

## Strategies for Innovative Drugs in China

- The opportunity for innovative drugs to be reimbursed in China has improved, with reimbursement processes more transparent and predictable than in the past.
- Important considerations for successful market access for innovative drugs in China include:
  - Monitoring and considering key assessment aspects for NRDL and developing evidence of value beyond clinical and economic data – the changes introduced in 2021 indicate consideration of wider facets of value such as innovation and improved equity (Table 2).
  - Conducting clinical trials involving Chinese patients and collecting real-world evidence based on the Chinese population.
  - Building health economic models to support evidence dossiers is now a well-established requirement and should follow expected standards as outlined in the evolving pharmacoeconomic guidelines.[3]
  - Developing a tailored pricing strategy for all stages of the assessment process is critical.

**Table 2. Key Assessment Aspects for NRDL Listing from 2016**

| Year | Value assessment | Source |
|---|---|---|
| 2016 | Evaluation of clinical necessity, safety profile, clinical efficacy and reasonable pricing for drugs with the same indications, following pharmacoeconomic principles | Work plan for 2016 NRDL adjustment (draft for comments)[4] |
| 2018 | Assessment based on the drug safety, efficacy and economic evidence submitted by the manufacturers | Notice on the inclusion of 17 cancer drugs in the NRDL Class B[5] |
| 2019 | Similar drugs are compared in accordance with the principles of pharmacoeconomics and drugs with sufficient evidence to prove their clinical necessity, safety, efficacy and reasonable pricing are preferred | Work plan for 2019 NRDL adjustment[6] |
| 2021 | Evaluation of safety, effectiveness, economy, innovation and equity | NHSA press conference on 2021 NRDL adjustment[2] |

Abbreviations: NHSA, National Healthcare Security Administration; NRDL, National Reimbursement Drug List

- In the future, further reforms for fast inclusions and reimbursement requirements of high-price drugs are expected in China.
- Pharmaceutical companies will need to track NRDL trends, monitor actual decisions by therapeutic areas, develop tailored strategies and demonstrate comprehensive value to achieve market access and reimbursement for innovative drugs.

## References

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