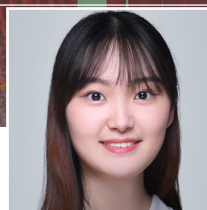


China's NRDL 2022 Update: A Snapshot and Overall Trends

Part 1 of 3

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The rapidly growing pharmaceutical market of China is now the second largest after the US. As the main avenue for public reimbursement, inclusion in the National Reimbursement Drug List (NRDL) is key for pharmaceutical products to gain wide market access. Initially established in 2000, the scope of NRDL has expanded to cover more innovative, patented therapies in recent years. The latest update—NRDL 2022—came into effect on March 1, 2023. By reviewing the outcomes this year, PRECISIONadvisors' Chloe Wang, Katherine Leong and Cherry Moldovan discuss key trends and strategic considerations for multinational companies in a series of 3 briefs.

What is new about this year's inclusion process? To apply for NRDL inclusion, previously all products needed to have been National Medical Products Administration (NMPA)-approved within the past 5 years; this year, the NHTA waived this eligibility criterion for:

- Rare disease products,
- Products on the Encouraged Generic Drug List, and
- Products on the List of Pediatric Drugs Encouraged for R&D.

Further, the NHTA introduced two rules to improve efficiency and transparency of the process:

1. **Bidding:** All generic drugs with the same active ingredient were grouped to undergo a bidding process. The lowest bid was accepted as the reimbursed price, which applied for all products under the same group regardless of the company.
2. **Simple contract renewal:** Negotiations were no longer mandatory for renewing contracts of branded drugs, if the actual national insurance expenditure was less than twice the amount estimated at inclusion and several other eligibility criteria were met.¹ Under simple contract renewal, price cuts ranging from 0-50% were applied based on the estimated, actual, and projected (if adding a new indication) expenditure.

How many new products entered the list?

111 new products entered the NRDL out of 198 that passed preliminary formality review, an overall inclusion rate of 56%. Most were patented products that went through price negotiations (Figure 1).

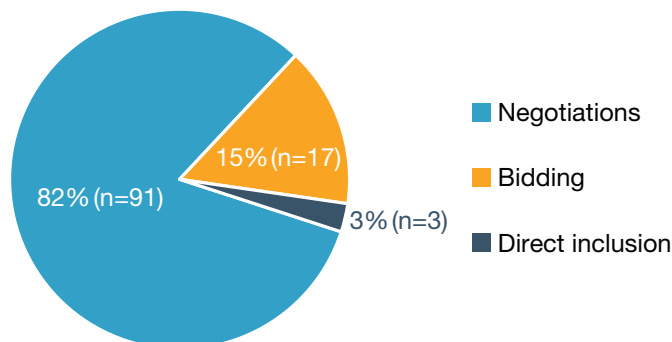


Figure 1: Inclusion Route of NRDL 2022 Entrants

How successful were the negotiations/biddings? Of the 147 shortlisted drugs, 121 had successful outcomes.² Although the overall success rate was the highest since 2018 (Figure 2), it is worth noting that the optimistic figure this year does not reflect companies who did not participate in negotiations (ie, 197 products that passed the preliminary formality review didn't proceed to the price negotiation).

What was the price cut? The average price cut of the negotiated entrants was 60.1%, similar to last year's discount of 61.7% (Figure 2).

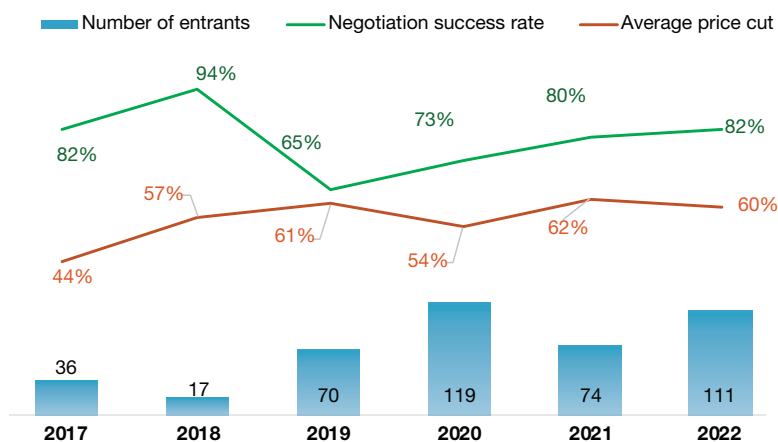


Figure 2: Trends in NRDL Inclusion³

Considerations and Conclusions

The NRDL is increasingly gearing towards providing access to innovative therapies, especially for oncology, rare diseases and pediatric populations. Latest policy changes reflect the NHSA's commitment to improving efficiency and transparency in their decision-making processes. With the introduction of simpler contract renewal, pharmaceutical companies now have greater predictability over renewal price cuts. To optimize the chance of successful NRDL inclusion, MNCs currently operating in or planning to launch in China should keep monitoring evolving trends and policy updates, and be prepared to tailor their market access strategies accordingly.

¹ If a new indication will be added, the corresponding increase in estimated expenditure should not exceed 100% of the amount estimated at inclusion. Candidates are eligible for simple renewal if there have been no significant changes in the market (eg, the drug having a significant price premium compared to other drugs in the same treatment area, the international price or patient assistance program price being significantly lower than the current payment standard, or similar competitors undergoing review in the same round).

² Including listing renewals.

³ 2018 NRDL update was a special round for oncology only; 2022 NRDL rates refer to an average across negotiations and bidding.

Abbreviations: MNC, multinational corporation; NHSA, National Healthcare Security Administration; NMPA, National Medical Products Administration; NRDL, National Reimbursement Drug List; R&D, research and development; TCM, traditional Chinese medicine

For any questions in relation to the NRDL updates or China access more generally, please don't hesitate to **reach out to our China Centre of Excellence:**

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