

# China Drug Market Changes: How to Navigate the Future of Reimbursement in China

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## Introduction

China established the National Healthcare Security Administration (NHSAs) on March 17, 2018, which is a sub-ministry-level government agency directly under the State Council of China. The NNSA was established to manage the Basic Medical Insurance (BMI), which is the public insurance scheme that covers >95% of the Chinese population<sup>1</sup>. One of the key reforms the NNSA has implemented is an annual negotiation process for including new and innovative drugs on the BMI drug coverage list, or the National Reimbursement Drug List (NRDL). This major change leads to significant opportunities as well as several hurdles for manufacturers based on the past negotiation outcomes.

### Opportunities

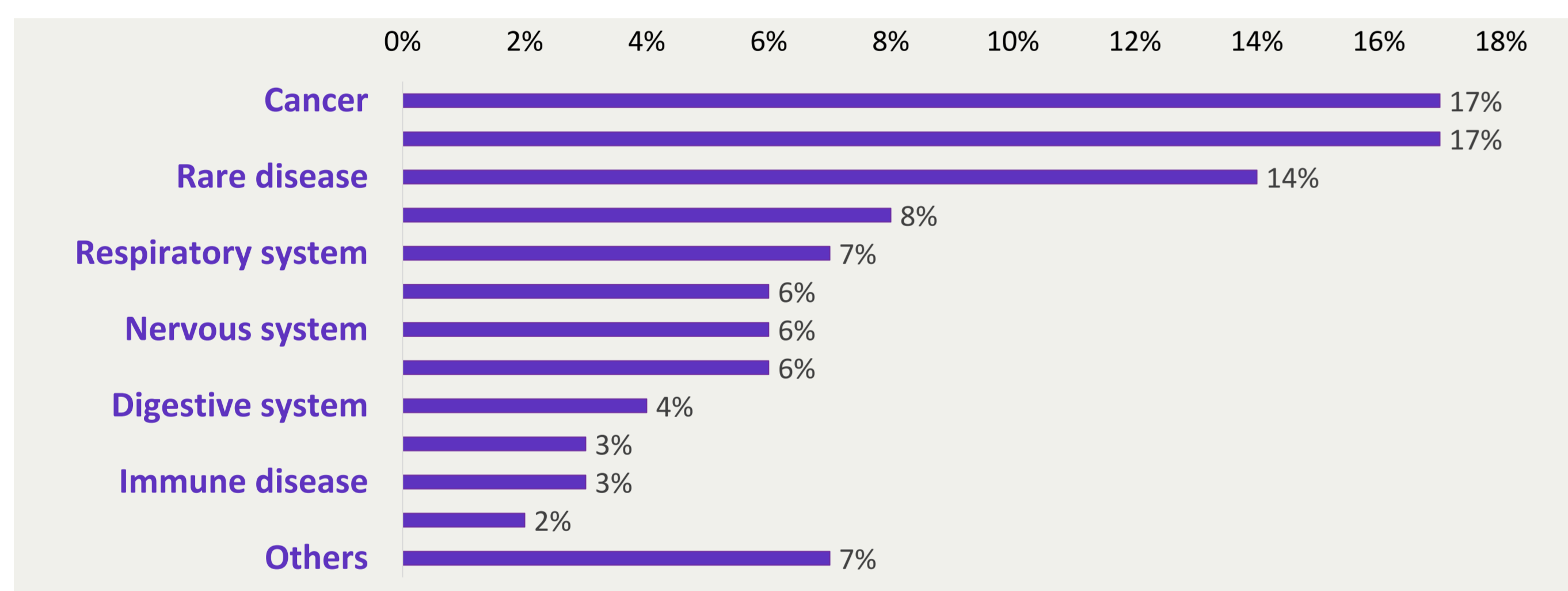
- A systematic structure with standardized process to demonstrate pharmaceutical products' value
- Achievable speedy access within the same year after product registration: 44 drugs in 2022 obtained registration approval and applied for NRDL negotiation within the same year<sup>2</sup>

### Challenges

- Significant price reduction due to heavy focus on budget impact
- Fierce competition with domestic competitors: none of the western PD-1 and PD-L1 products have entered the NRDL as of 2022 due to competition with domestic PD-1 products

While the general NRDL negotiation structure has matured, process guidelines are improved and optimized each year. Key changes in 2022 include increasing policy support for orphan drugs and pediatric drugs, further clarification on application material packages, optimizing the expert review process, and introducing a competitive bidding step for non-exclusive products.

**Figure 1: In 2022, oncology, anti-inflammation, and rare disease are the top 3 therapeutic areas of drugs entering the NRDL negotiation<sup>3</sup>**



## Objectives

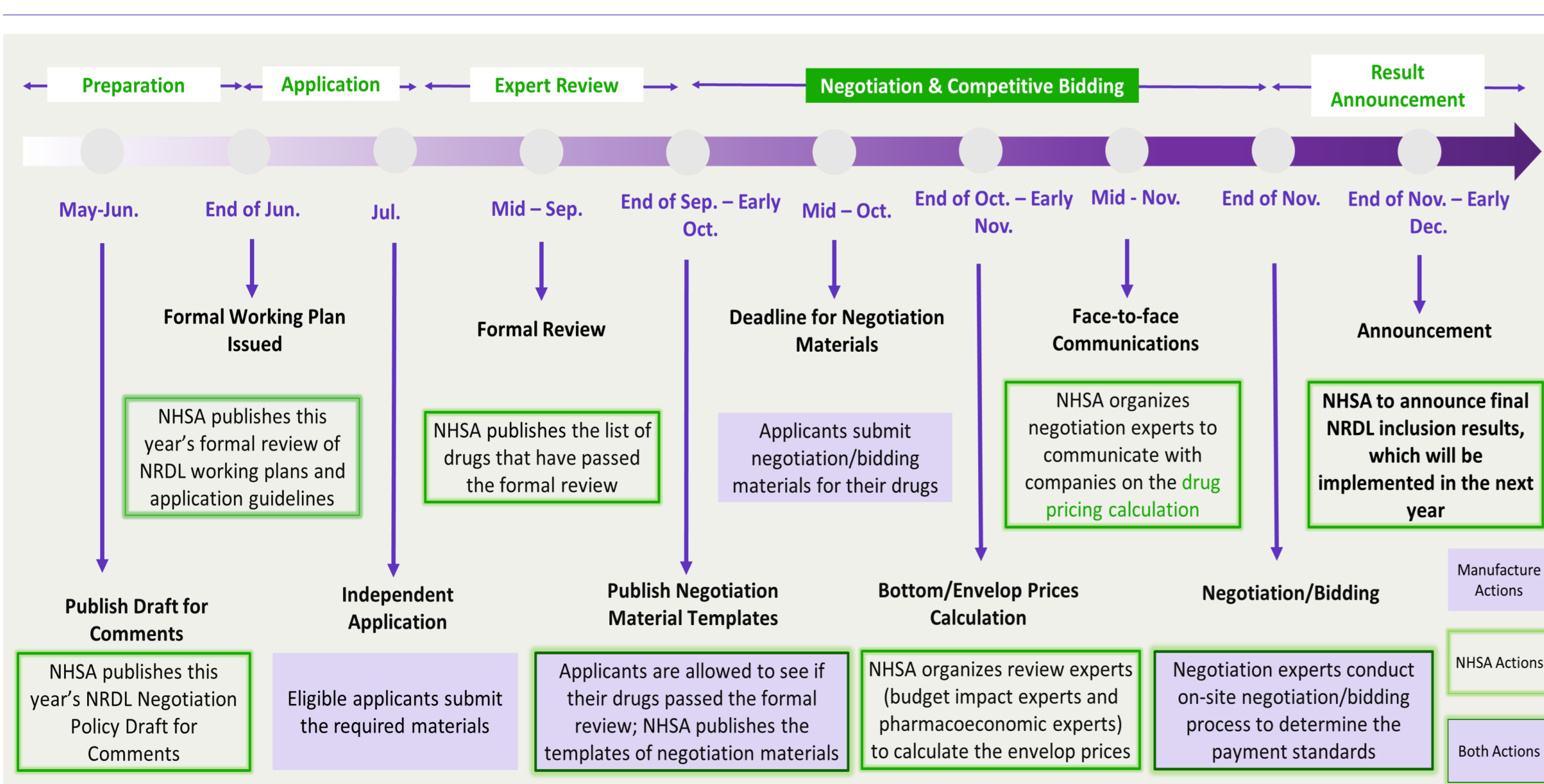
To determine the policy changes, market nuances and key pricing factors in China and how these affect the future Chinese market access landscape:

- The aim of this study is to determine how to best position new drug launches given the frequency of updates in the NRDL to be more inclusive of innovative western medicine that can be accessed within China;
- This study will also help standardize the decision-making process during phases of pre-launch, launch and post-launch.

## Methods

Through secondary research and primary research with key stakeholders, we looked at the new policy changes (updates directly from the Chinese Government) as well as interpreted the evolving market landscape and the implications of pricing and reimbursement in China.

**Figure 2: Annual National Reimbursement Drug List (NRDL) Adjustment Timeline**



## Results

The NNSA and its advisors take **six major factors** into consideration when deciding reimbursement benchmarks for any candidate drug. Prices are independently generated, and **the lowest price is most likely to become the bottom/envelope price on the negotiation table.**<sup>4</sup>

**Table 1: Six Factors Impacting NRDL Price Setting**

<p><b>FACTOR 1: ACTUAL MARKET PRICE</b> Companies tend to launch an innovative drug with a relatively high price at first and use a Patient Assistance Program (PAP) or company-sponsored insurance scheme to lower the actual patient out-of-pocket (OOP) cost, which is normally 30%-50% lower than the launch price. <b>The NNSA considers the actual patient OOP as the ceiling price for negotiation.</b></p>	<p><b>FACTOR 2: INTERNATIONAL REFERENCE PRICES</b> The NNSA leverages the reimbursement prices of a bundle of 12 countries and regions: the US, Japan, UK, Canada, Germany, France, Australia, Italy, Turkey, Korea, Taiwan, and Hong Kong. Based on analysis of the previous negotiation results, <b>China's reimbursement benchmarks are in general 5%-10% lower than the lowest price of reference countries.</b></p>
<p><b>FACTOR 3: COST-LEVEL OF COMPARATOR DRUGS</b> A comparator drug will be assigned to any drug which enters the evaluation process. The comparator drugs are used to treat the same diseases (not necessarily the same indications) as the candidate drug. <b>Experts who participate in the review process decide on the comparator drug.</b> In addition to being the clinical comparators, <b>they are also economic comparators in the pharmacoeconomic evaluation</b>, impacting NRDL price setting.</p>	<p><b>FACTOR 4: BUDGET CONSTRAINT</b> Budget constraint evaluates the BMI's funding capability and whether the funding each year can afford the incremental expenses for including more drugs. <b>The NNSA measures each therapeutic area's overall budget allocation.</b> Additionally, <b>the incremental expenses of including new drugs must be affordable within the NNSA's allocable budget in each year.</b></p>
<p><b>FACTOR 5: PHARMACOECONOMIC EVALUATION</b> Cost-effectiveness assessment (CEA) is the most common method in the pharmacoeconomic evaluations. Even though there is no publicly available source stating the rule of threshold setting, <b>experts believe that most WTP/QALY values were below 1 GDP per capita.</b><sup>5</sup></p>	<p><b>FACTOR 6: COST CEILING</b> The NNSA holds a cost ceiling for most drugs as an unwritten rule. The industry believes that the ceiling price is <b>&lt; RMB 500,000 (71,429 USD) annual treatment cost.</b> Based on past experiences, products that were successfully included in NRDL tend to have an annual treatment cost of RMB 300,000 (42,857 USD).</p>

### Pre-Launch to Strategically Select Products Aligning with Government Priorities

The Chinese government is concerned with insufficient accessibility and affordability of medical services, pharmaceuticals, and devices. Poverty caused by critical illness has become prevalent as medical expenses have grown faster than income, which threatens poverty alleviation efforts in China. The NRDL process was established to ease the economic burden of life-threatening illness on patients. Currently, the central government highly prioritizes oncology drugs as this therapeutic area is believed to cause significant financial burden on Chinese families. As a result, oncology products tend to experience relatively higher attention in the process, including a relatively higher willingness to pay (WTP) from the government. Orphan drugs have also been emphasized in multiple policy developments in recent years.

### Launch to Be First and Prioritize Indications with Large Patient Volume

"Be first" will allow the product to benefit from a relatively high NRDL price in its category for two years. Additionally, the status as negotiation drugs will lead to favorable hospital listing, allowing the first NRDL-included drug to take large market share. In past experiences, the price of the first NRDL-included drug is normally 20%-30% higher than its followers unless the late comer has significant clinical advantages. Prioritizing indications with a large patient volume at launch is a common strategy to avoid further price cuts in the long run. Conversely, adding an indication that has a large patient volume to the listed indications typically requires significant price-cuts in the NRDL renewal process.

### Post-Launch to Accelerate Commercialization

Successful NRDL inclusion does not guarantee commercial success in China. More specifically, given the competitive landscape in China, the window of opportunity for most innovative products is the first one to two years after negotiation. Thus, companies need to own a salesforce that can realize hospital listing and academic promotion in at least the top 1,000 hospitals in more than 200 Chinese cities in one to two years. For companies with limited presence in China, it is recommended to outsource partial or full business to a partner with strong commercial capacity in China, including multinational manufacturers or local contract sales organizations (CSO). Lastly, companies should consider working with emerging commercial partners in retail channels including retail pharmacies to develop innovative commercialization models; for example, online-to-offline (O2O) and business-to-consumer (B2C).

## Conclusion

China has established a mature and systematic national coverage and reimbursement process, and the policy shaping opportunities are closed for major changes to the current system. However, smaller adjustments are ongoing, for example, the recent central government emphasis on improving access to rare disease treatment. As a result, successful planning and implementation of new product launch strategies in China requires in-depth and agile understanding of these policy adjustments. Additionally, understanding the key elements of price setting in the NRDL process will enable companies to adopt a cautious pricing strategy with a long-term vision as well as a full lifecycle strategy for new products, seizing the opportunity at hand.

## References

1. June 2022. NNSA. National Healthcare Security Development Statistics Report.
2. NNSA Announcement, Drugs to Enter 2022 NRDL Negotiation.
3. Clarification: If a drug has multiple indications such as orphan and oncology indication, it is either categorized as a rare disease drug or a cancer drug without double counting; nutrition supplements include parenteral nutrition, enteral nutrition, amino acid supplementation, electrolyte supplementation and alkalinizing agents to prevent vitamin deficiency; others include psychiatric drugs, anesthesia drugs, emergency care drugs, peritoneal dialysate, male erectile dysfunction drugs, vaginal delivery drugs, and kidney transplant rejection drugs.
4. Stakeholder interviews and consultation with industry experts who are experienced in product launch in China.
5. Willingness to pay (WTP) per quality-adjusted life year (QALY).