

National Reimbursement Drug List Negotiation in China: Factors Influencing Pricing and Value Considerations



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BACKGROUND

- A unique and regular price negotiation mechanism was conducted annually for the National Reimbursement Drug List (NRDL) updates since 2017 in China.
- The National Healthcare Security Administration (NHSA) has been established in 2018 and takes charge of NRDL updates.
- Currently, there is no up-to-date study summarizing the outcomes of NRDL negotiations in China. Existing studies mainly focus on the process, stakeholders, and negotiation results, but rarely examine the influencing factors of the negotiation results and its implications.

OBJECTIVES

- To analyze the results of NRDL negotiations, as well as the influencing factors of NRDL payment standards.
- To understand value considerations of NHSA in its reimbursement decisions.

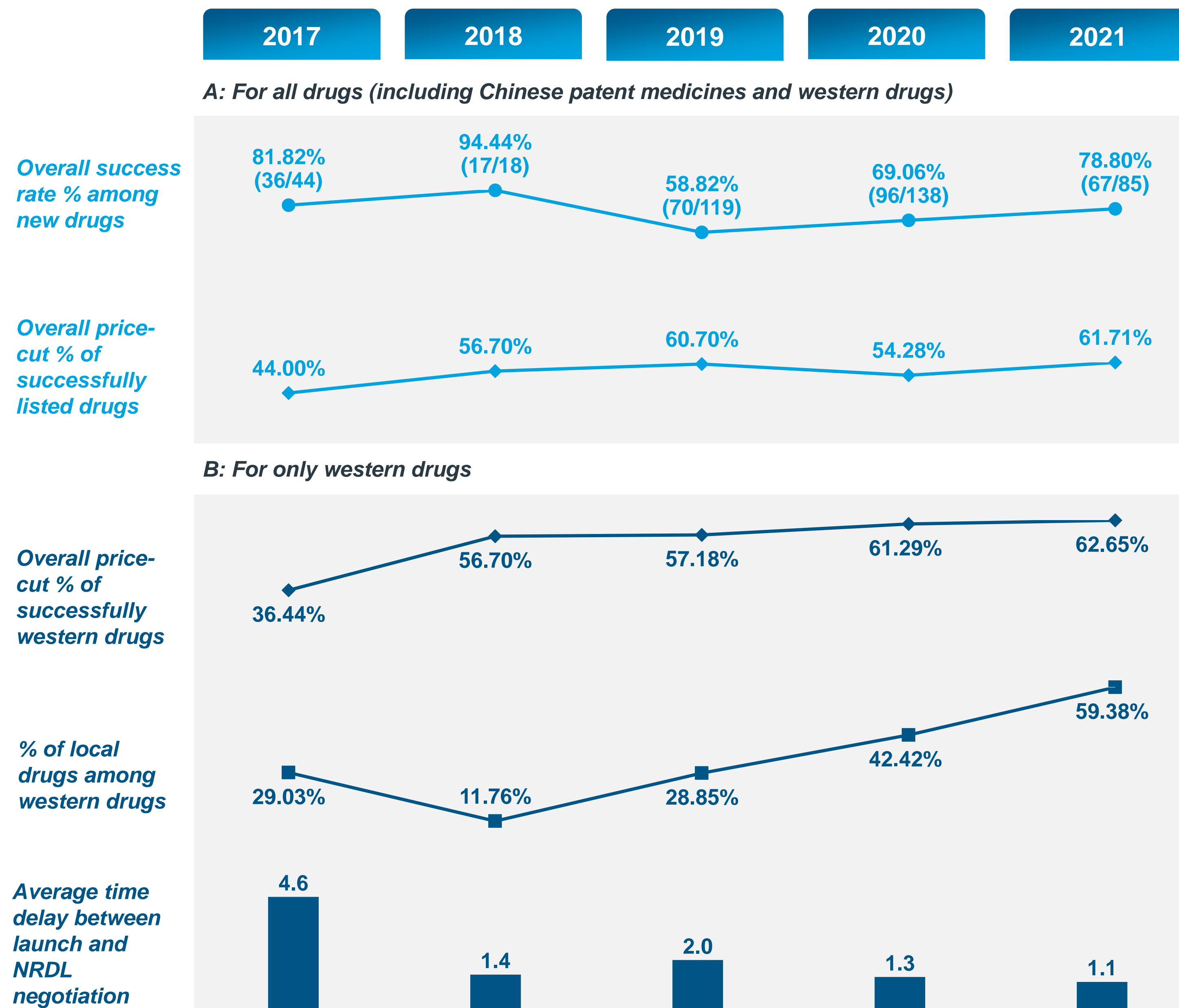
METHODS

- A comprehensive literature review was conducted to identify relevant studies, including academic literature from PubMed, CNKI, Wan Fang and ISPOR website, and documents from government agencies.
- Quantitative analysis was conducted to analyze and validate the key factors influencing the NRDL payment standards, using the best available sales and price data before and after NRDL negotiations.
- Descriptive statistics was used to summarize the NRDL negotiation outcomes.

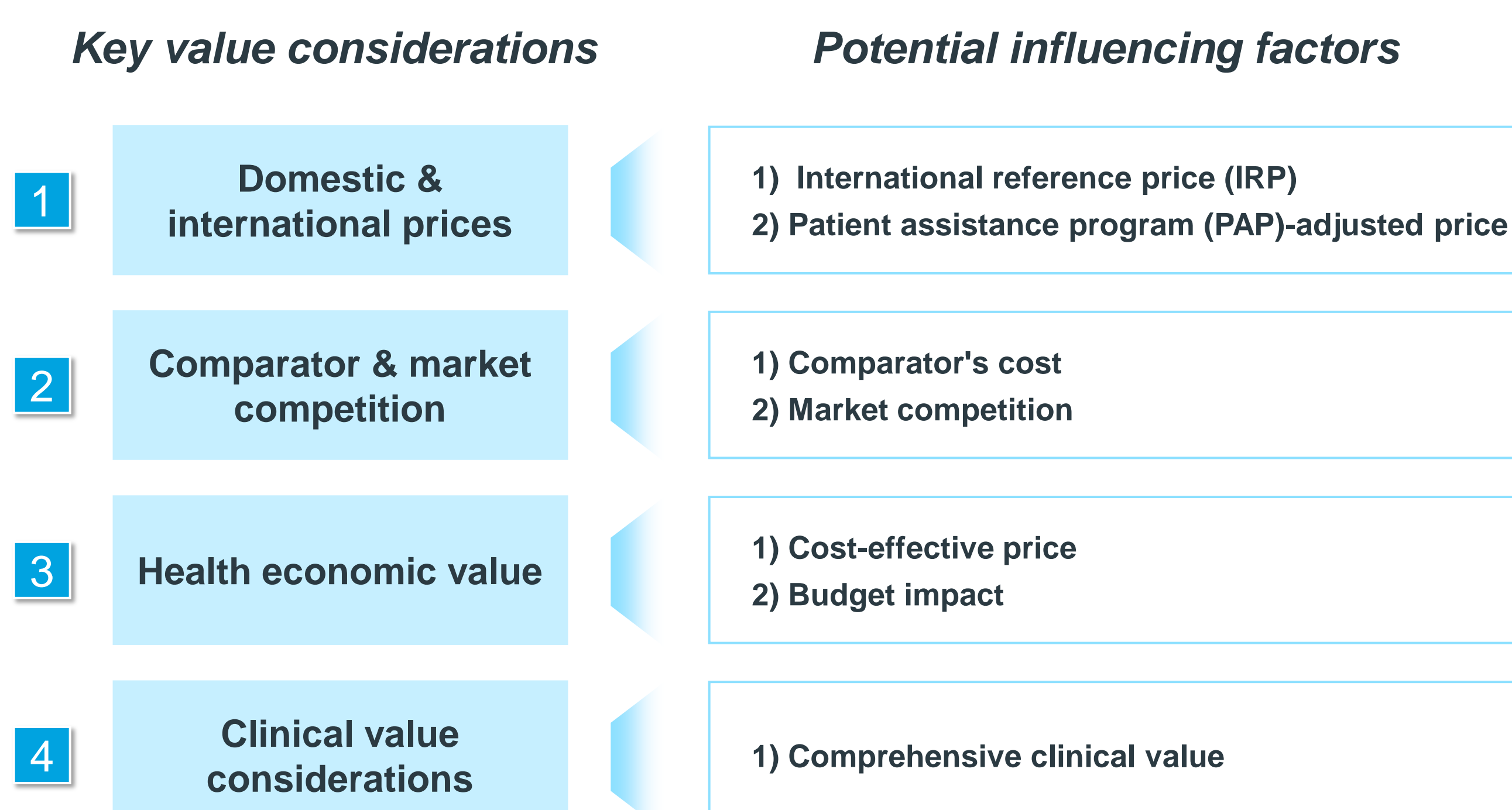
RESULTS

1. 286 drugs were included in NRDL with average price cuts of 44% to 61.7% during the 2017-2021 negotiations

Figure 1: Overview of the NRDL negotiations for new drugs



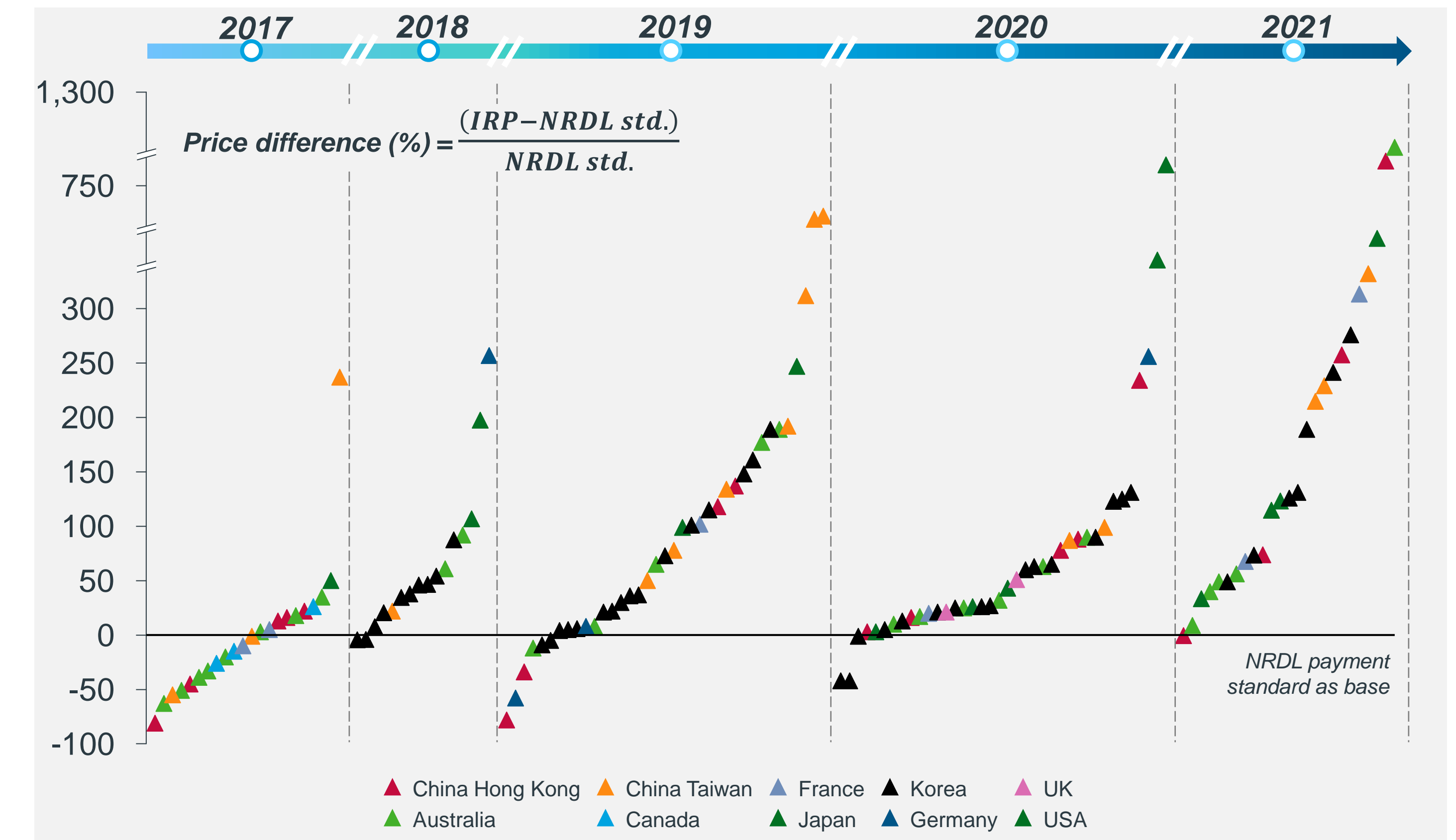
2. Four key value considerations and seven influencing factors were identified in the NRDL negotiation



Note: The factors that influenced the NRDL payment standard were summarized based on comprehensive secondary research, and then were validated through quantitative analyses and case studies.

3. The % of drugs with a negotiated price lower than the lowest IRP in reference markets increased from 45% in 2017 to 84%-96% in 2018-21

Figure 2: Price gap between the lowest IRP and China NRDL payment standard among negotiated drugs with IRP



Note: Each dot denotes the drugs' lowest IRP; The lowest IRP excludes India & Turkey; There were 10 reference markets in 2017 including USA, Japan, UK, Canada, Australia, Germany, France, China Hong Kong, China Taiwan, and India; 12 reference markets in 2018 with India removed and South Korea, New Zealand and China Macao added compared with 2017; 12 reference markets in 2019 & 2020 with New Zealand and China Macao removed and Italy and Turkey added; 12 reference markets in 2021 was the same as that of 2020

4. Most of the negotiated NRDL payment standards turned out to be lower than the PAP-adjusted price

- Among 230 western drugs listed in NRDL via negotiation in 2017-2021, 69 had PAP discounts prior to price negotiation. 48 of them were oncology drugs and 21 were non-oncology drugs.
- This percentage of drugs with a negotiated price lower than the PAP-adjusted price increased from 75% in 2017 to 93.3%-100% in 2020-2021.
- Among those drugs with a PAP, the 2017 and 2018 negotiated prices were 9.6% - 11.4% lower than the PAP-adjusted price. In the 2020-2021 NRDL negotiations, this percentage increased to 38.5% - 46.3%.

5. Comparator & market competition are also important in the value consideration and decision-making process in NRDL negotiations

- A comparator-based price could be calculated by benchmarking the drugs' per-cycle cost (e.g., daily cost or annual cost) with further considerations of price premium which is determined by their comparative safety and effectiveness.
- Additionally, the impact of the NRDL comparator could also be reflected in cost-effectiveness analysis.
- Moreover, there is a special situation of price negotiation called "competitive negotiation", which may be initiated in some fiercely competitive markets with multiple players, resulting in generally larger price-cuts.

6. Health economic evidence is increasingly used in determining the final acceptable price for NRDL negotiation

- All drugs that participate in the NRDL negotiation are required to submit pharmacoeconomic evidence as stated in the 2020 Interim Measures.
- There are no published incremental cost-effectiveness ratio (ICER) thresholds for reimbursement decision-making in China. Nevertheless, one to three times the GDP per capita in China was most often mentioned in literature.
- Localized budget impact analysis became mandatory since 2018. Comparing the budget impact estimate submitted by the manufacturer with the actual budget impact incurred during the contracted period is fundamental in contract renewal negotiations if the IRP, market competition, and indications are not changed significantly.

7. One of the key factors for selecting applicants and drugs for NRDL negotiation is the clinical value in addressing relevant unmet needs

- Experts scored each drug by considering its value in safety, efficacy, economics, innovation, and equity. This score determined whether a drug is qualified for NRDL negotiation.
- This score is further leveraged in determining the acceptable price for NRDL negotiation.

DISCUSSION & CONCLUSION

- Patient access to innovative drugs in China is significantly improved with the introduction of NRDL negotiation.
- There is increasing value consideration and use of health technology assessment (HTA) methodology in the appraisal and the determination of payment standards.
- This study is the first to identify the potential factors influencing the NRDL payment standard based on secondary research. These influencing factors were validated with the best available quantitative data and case studies.
- China's experience in the NRDL negotiation could provide important lessons for international markets of low- and middle-income countries.