

National Reimbursement Drug List in China: Changing Dynamics and Trend and Price Determination of Formulation Innovation Drugs



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OBJECTIVE

- To explore the factors influencing the success of listing the National Reimbursement Drug List (NRDL) and price determination of formulation innovation drugs.

METHODS

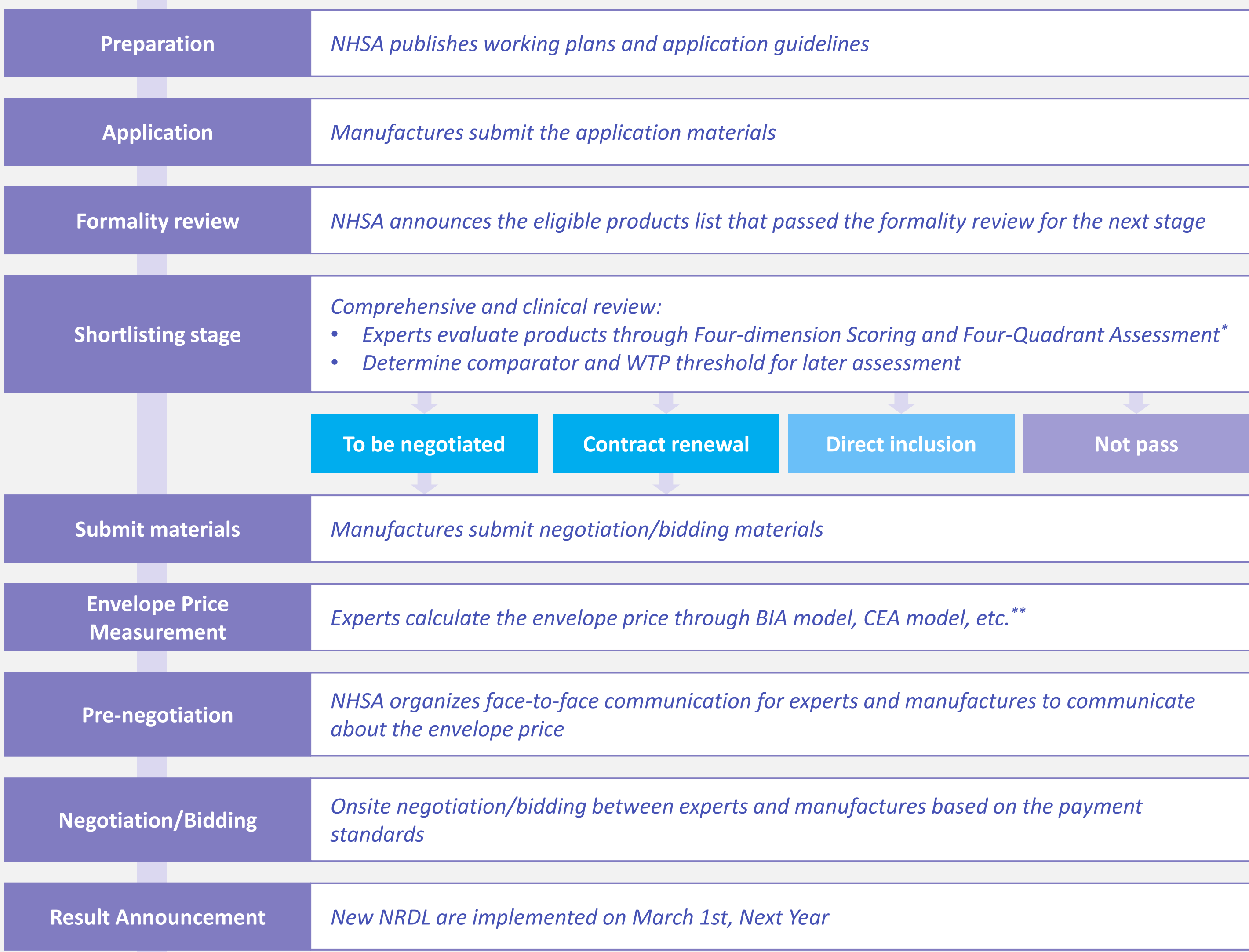
- A literature review was conducted on academic sources from PubMed, CNKI and official government documents to identify relevant studies.
- Interviews were conducted with experts who had NRDL experience in the past two years.
- Quantitative analysis of the NRDL's success rate and price reductions were performed using official data and price information published by the medical insurance authorities, focusing on the price determining factors of fixed dose combinations (FDCs).

RESULTS

National Negotiations Process and Results

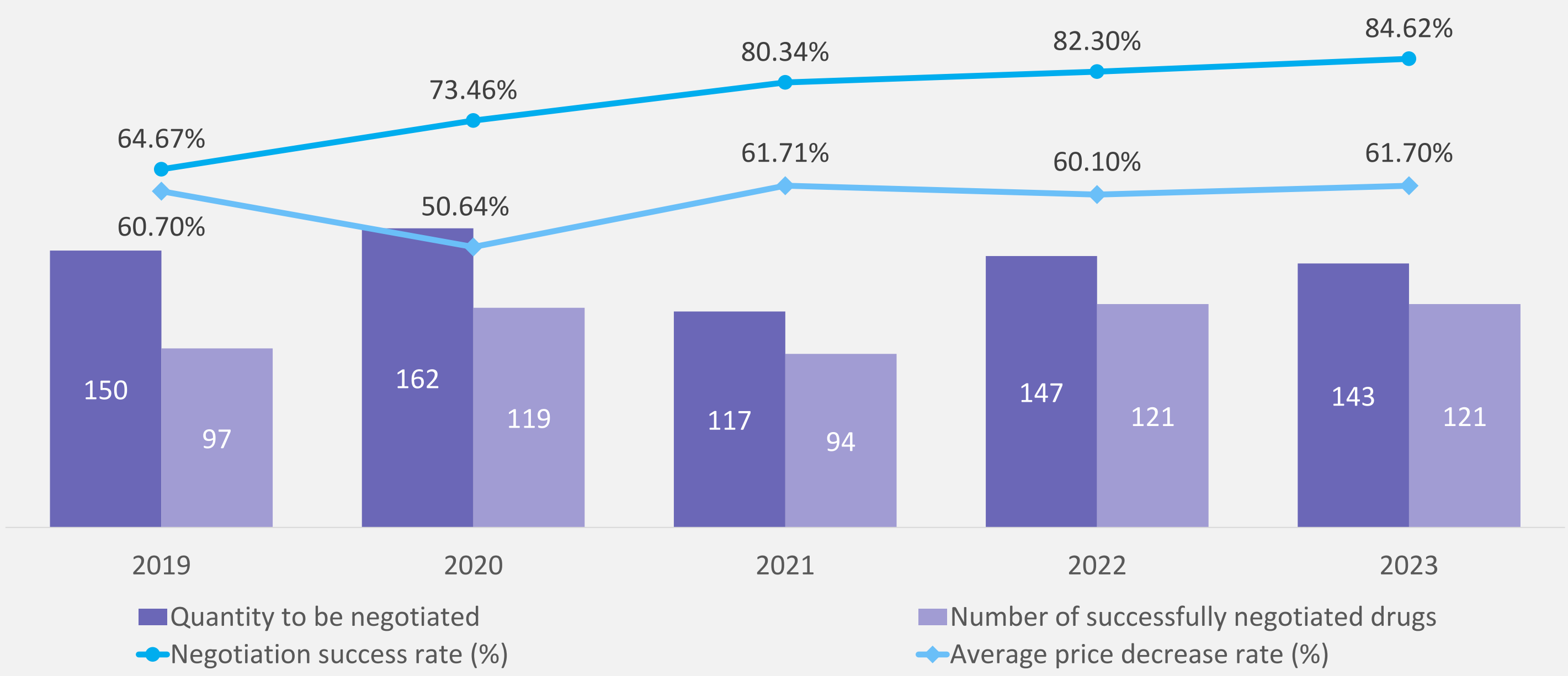
- The process of NRDL adjustment has become increasingly comprehensive based on the foundation of the previous years.

Figure 1. NRDL process overview in 2023



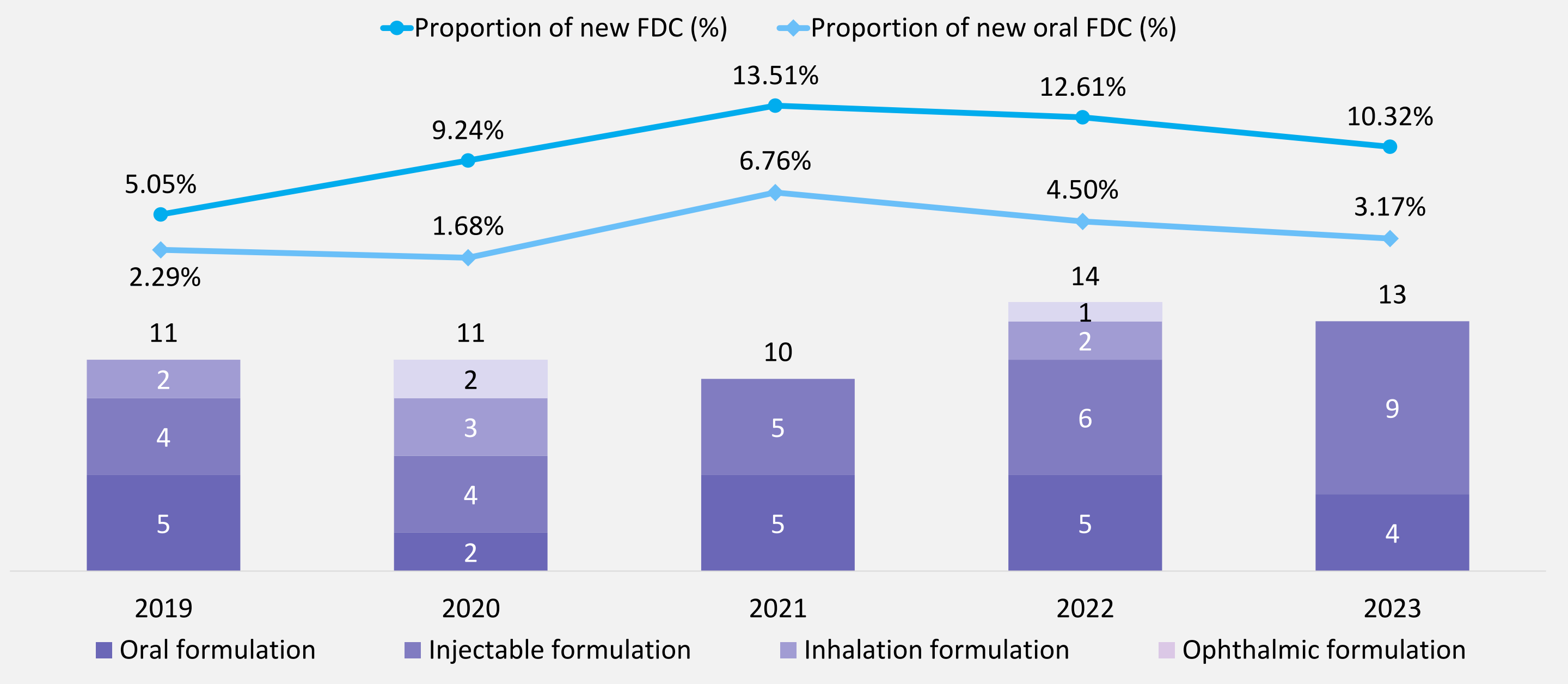
- From 2019 to 2023, the success rate of NRDL negotiation has steadily increased, averaging 77.08%, with rates around 80% in both 2022 and 2023. The average reduction in negotiated prices compared to launch prices was 58.97%, with reductions consistently around 60% since 2021.

Figure 2-1. Result of NRDL negotiation from 2019 to 2023



- The approval rates of oral FDCs remained low in 2022 and 2023, at 4.50% and 3.17% of all included varieties respectively.

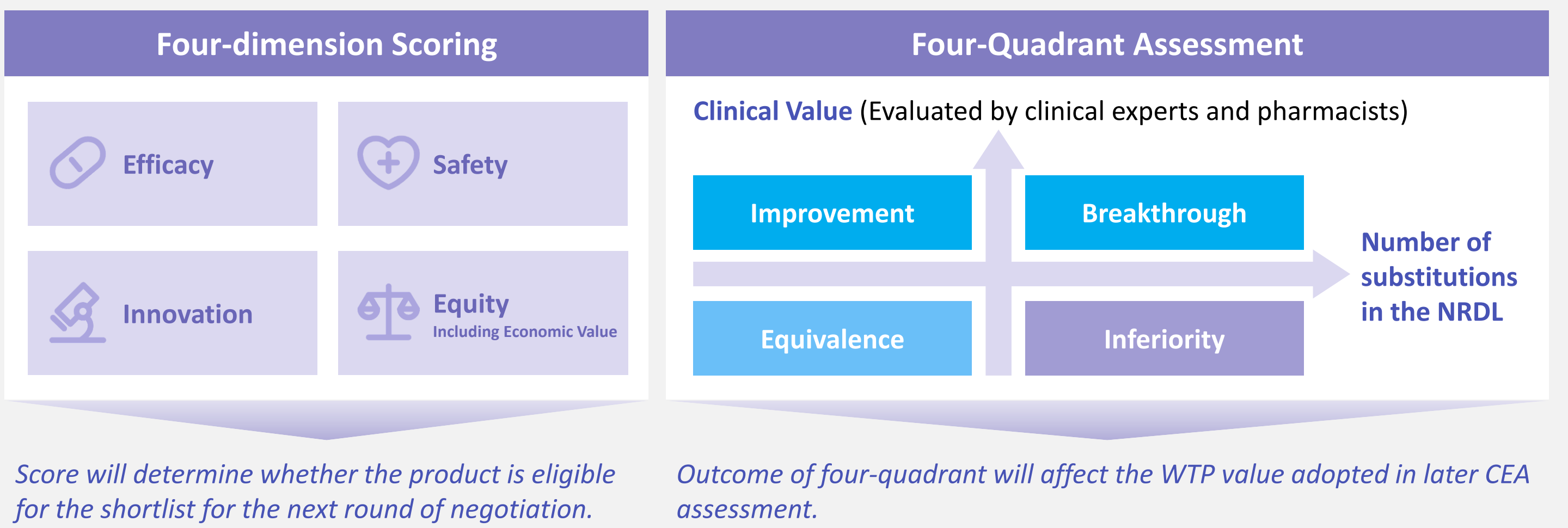
Figure 2-2. Negotiation result of FDCs from 2019 to 2023



Comprehensive Evaluation

- In 2023, the efficacy, safety, innovation and equity of the products were the four key dimensions in assessing product value.
- The degree of clinical value and substitutability compared to the products NRDL listed were critical factors in determining whether a product could pass the shortlisting stage.
- Based on the results of the four-dimensional scoring and four-quadrant assessment from the comprehensive evaluation, the key price determination of FDCs was the lowest price among the reference drug price, international reference price, or bidding procurement price.

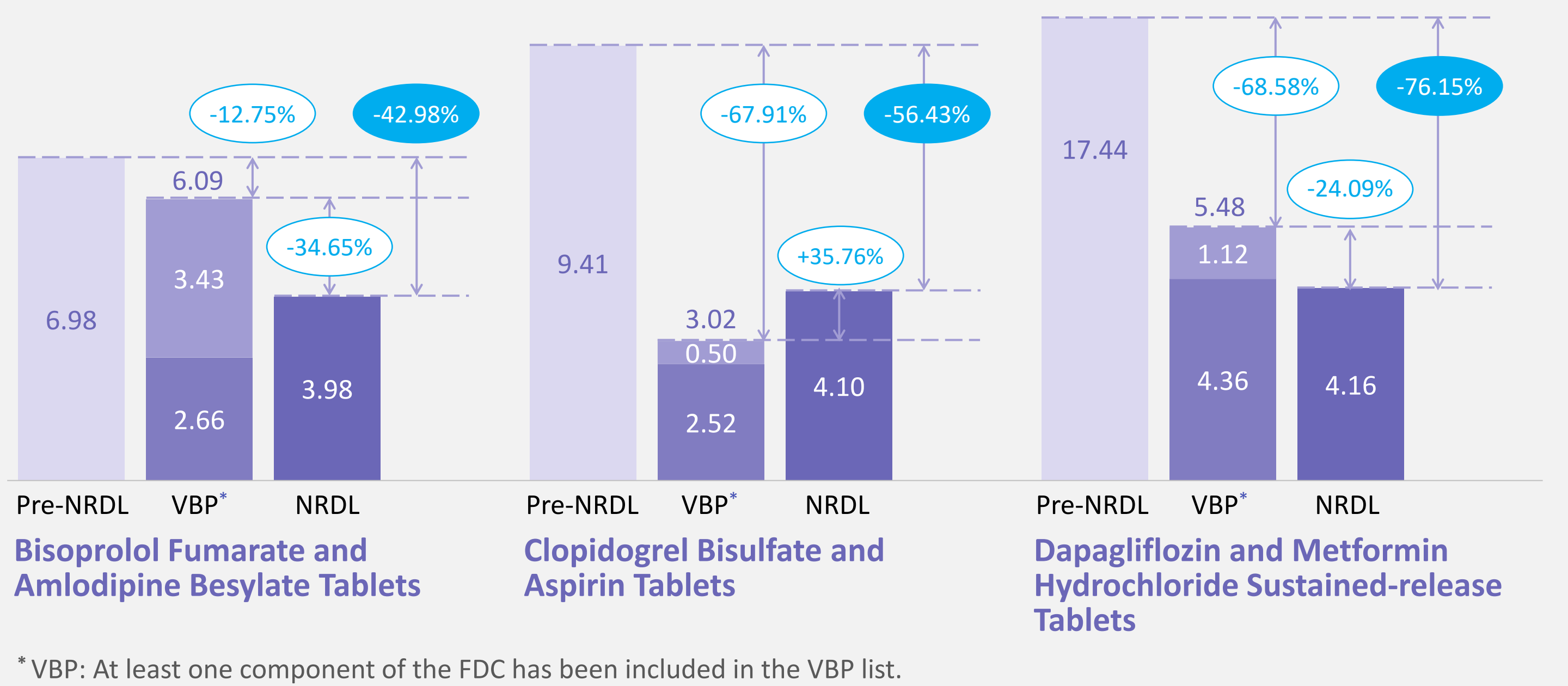
Figure 3. The four-dimension scoring and four-quadrant assessment



Pricing Trends of FDCs

- Case studies indicated that if one component of an FDC was on the Volume-based Procurement (VBP) list, the reimbursement standard was typically based on the sum of the VBP prices, averaging 58.52% lower than pre-NRDL negotiation prices.

Figure 4. Pricing trends of oral FDCs in NRDL negotiations from 2022 to 2023



CONCLUSIONS

- The NRDL evaluation process is continuously improving. For products with innovative dosage forms, the reimbursement standard tends to be relatively low in a highly competitive environment.