

Advisory | Health Care & FDA Practice



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China on the Move: Lessons from China's 2023 National Negotiation of Drug Prices

In December 2023, China's National Healthcare Security Administration (NHSA) published the 2023 National Reimbursement Drug List (2023 NRDL), implementing a comparable level of pricing discounts to those seen in 2021.

This GT Advisory explores the following:

- A total of 126 drugs were added to the 2023 NRDL, and one drug was removed. Out of 143 negotiated drugs/drugs participating in bidding, 121 drugs were successfully included in the final NRDL, a historic high. The success rate was 84.6%, and the average price cut of the 121 drugs was 61.7%, close to 2022's 60.1%.
- Like previous years, the majority of newly added drugs come from domestic companies, while several multinational companies still struggle to strike a deal with NHSA for their products.
- 15 orphan drugs were included in the 2023 NRDL, nearly twice as many as 2022 and the highest number in the last four years.
- To support innovation in China's pharmaceutical industry and the export of cutting-edge treatments, the NHSA has taken measures to encourage the inclusion of innovative drugs on the NRDL, covering the stages of NRDL adjustment from application to negotiation.

- Price threshold remains a barrier for certain innovative products, such as CAR-T therapies, antibody drug conjugates (ADCs), and PD-(L)1, to be included in the NRDL. A compromise must be reached on the price of these products before they can be included in the NRDL.
- The simple renewal mechanism was refined in 2023, and the price adjustment mechanism was also introduced to cover the entire drug lifecycle, leading to a further slowdown in the rate of price cuts and providing a more predictable market access environment to pharmaceutical companies.
- The Chinese government's ambition to promote Chinese innovation around the world has been realized through a series of strategic moves, including in the area of drug pricing and reimbursement and by curtailing health care expenditure in an effort to provide greater resources to local innovations.
- 1. NRDL negotiation mechanism is standardized, with a more predictable price discount range and an increased participation rate of industry players.

On Dec. 13, 2023, the NHSA held a press conference on the 2023 revision of the NRDL and officially released the results of the 2023 NRDL negotiations. A total of 126 drugs were added in the 2023 revision and one drug was removed – Merck Sharp & Dohme's Elbasvir and Grazoprevir Tablets for the treatment of hepatitis C, which may soon be withdrawn from China's market.

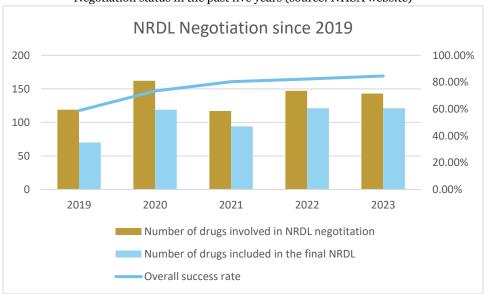
From 2018 to 2023, China completed six rounds of NRDL negotiations, during which the negotiation mechanism was gradually finalized. Post-COVID-19, the 2023 NRDL negotiation process resembles the pre-pandemic process.

Time Frame	Stage	Description
May-June 2023	Preparation	The NHSA led the revision and improvement of the constitution documents for drug review and evaluation, established the working institutions, and expanded the expert pool.
July-August 2023	Application	 Eligible pharmaceutical companies applied to the NHSA within the scope of NRDL adjustment. Subsequently, the NHSA conducted preliminary reviews to assess (i) the effectiveness, safety, innovation, and fairness of the applied products and (ii) the integrity of the submitted documentation. The NHSA then determined the list of products eligible to advance to the expert review stage. On Sept. 1, 2023, the NHSA announced the final list of drugs that successfully passed the preliminary review, with 386 products advancing to expert review out of the 590 initially submitted.
August-September 2023	Expert Review	Based on the applications from pharmaceutical companies, the NHSA organized a pool of experts to evaluate the applied drugs, ultimately formulating proposed opinions for the applied products, including (i) direct inclusion, (ii)

The 2023 NRDL revision consists of five stages: preparation, application, expert review, negotiation/bidding, and announcement of results. The following table explains each stage.

Time Frame	Stage	Description
		pending inclusion based on negotiation/bidding, (iii) direct exclusion, and (iv) renewals according to relevant rules.
		Eventually, 143 out of the 386 drugs progressed to the negotiation/bidding stage.
September- November 2023	Negotiation/Bidding	Experts conducted on-site negotiations with pharmaceutical companies based on evaluation opinions to determine a nationwide unified NRDL payment standard.
		Out of 143 drugs in the negotiation/bidding phase, 121 drugs were successfully included in the final NRDL.
December 2023	Announcement of Results	The NHSA announced the results of the adjustment and released the 2023 NRDL.

In 2023, a total of 226 drugs outside the NRDL passed the preliminary review stage, with 143 advancing to the negotiation/bidding stage and 121 ultimately being included in the NRDL. This is an 84.6% success rate, demonstrating enthusiasm from participating pharmaceutical companies and a steady upward trend. The overall price cut in 2023 was 61.7%. Both abovementioned figures are comparable to the 2022 results. Considering the reductions in the reimbursed drug prices, and relevant medical insurance reimbursement factors, patients' financial burden will likely be reduced by over RMB 40 billion in the next two years.



Negotiation status in the past five years (source: NHSA website)



Average price cut over the past five years (Source: NHSA website)

2. Enhanced coverage for rare diseases implemented for the first time.

Orphan drugs, pharmaceuticals that remains commercially undeveloped owing to limited potential for profitability, remain a key focus in the 2023 NRDL revision. In the 2022 NRDL revision, the NSHA introduced a new policy allowing orphan drugs approved by the NMPA before June 30 of that year to apply for inclusion in the 2022 NRDL. The 2023 NRDL Revision Work Plan ("2023 Work Plan") maintained this policy, allowing all orphan drugs that obtained NMPA approval for market authorization before June 30, 2023, to apply for inclusion in the 2023 NRDL. Furthermore, the generic drugs for rare diseases listed in the *Catalogues of Encouraged Generic Drugs* (《鼓励仿制品药目录》) were also permitted to apply for inclusion in 2023.

Seven orphan drugs were included in the 2019, 2021, and 2022 versions of the NRDL, and six were included in 2020. The 2023 NRDL reached a record high, with 25 orphan drugs passing the preliminary review, and 15 of them making the list.

These 15 products include Efgartigimod from Zai Lab, Ozanimod from Bristol Myers Squibb, Eculizumab from AstraZeneca, Siltuximab from BeiGene, and Satralizumab from Roche, covering Gaucher disease, myasthenia gravis, and neuromyelitis optica spectrum disorders, etc.

Many orphan drugs were not published with their negotiation prices upon the release of the 2023 NRDL. For example, Zai Lab's Efgartigimod Injection, previously priced at over RMB 10,000 per vial, with an annual treatment cost exceeding RMB 300,000 for adults (calculated based on an 80kg weight), was marked with a "*" for its negotiation price in the 2023 NRDL. According to the regulation released by NHSA in 2023, the asterisk indicates that local health care security departments may not disclose their negotiation prices through public documents, press releases, or other public information disclosure. However, as explained in Section 4 below, a considerable price cut should have been made to be included in the NRDL based on our experience.

3. Preferential treatment is specifically developed for innovative drugs.

During the 2023 NRDL adjustment, a total of 25 innovative drugs (including Class 1 chemical drugs, Class 1 therapeutic biological products, and Class 1 and Class 3 traditional Chinese medicines according to the current drug registration management measures and classification standards) participated in the negotiations. Among them, 23 products were included in the final list, achieving a 92% success rate, which is 7.4% higher than the list's overall success rate of 84.6%, and an average price cut of 57.3%, which is 4.4% lower than the list's overall price cut rate of 61.7%.

From a policy perspective, the NHSA is committed to supporting the development of the innovationbased drug industry, and to gradually build up support for innovative drugs to be included in the NRDL. Specifically, the NHSA has implemented the following measures:

- a) <u>Grant priority access for innovative drugs</u>. During the expert review stage, the NHSA actively instructed experts to focus on the evaluation of the candidate drugs' innovation and clinical value. If such drugs meet the access criteria, they will pass the preliminary review automatically.
- b) Amend the simple renewal mechanism for innovative drugs, with an option for renegotiation. The NHSA further amended the rules for simple renewal in 2023 (for more details about the 2022 simple renewal mechanism, please see our previous issue), granting pharmaceutical companies the option to apply for a renegotiation if the price reduction rate based on the simple renewal mechanism is not satisfactory. The price reduction rate achieved in renegotiation may be less than the one calculated using the simple renewal mechanism. These amended renewal rules enable innovative drugs with high clinical value to be renewed at more reasonable prices, thereby increasing benefits to patients and promoting growth in innovative drug revenue.

According to the **2023 NRDL**, about 70% of the 100 drugs were renewed at their original prices. Thirty-one drugs were renewed at reduced prices because they exceeded the expected sales volume, with an average price cut of 6.7%. Meanwhile, 17 drugs adding new indications were renewed at their original prices.

c) Establish an annual revision practice and expand the pool of drugs eligible for NRDL. The NHSA has shortened the revision cycle for new drug inclusion from a maximum of eight years to one year. This means innovative drugs may be included in the NRDL much more quickly. Additionally, the application for inclusion no longer depends only on experts' recommendations; now, it also considers pharmaceutical companies' own applications, and all new drugs NMPA-approved for market authorization within the past five years are allowed to participate in the application. All of these measures accelerate the timeline for inclusion of innovative products in the NRDL.

In the 2023 NRDL, 57 drugs were approved for market authorization and included in the NRDL within the same year, and the drugs approved within the past five years constituted 97.6% of the newly added drugs in the 2023 NRDL, much higher than 32%, the 2019 figure.

d) <u>Introduce price confidentiality mechanism to support global expansion of domestic innovative products</u>. Domestic innovative pharmaceutical companies have voiced concerns that subsequent to NRDL negotiations their products hit global low prices, and the disclosure of such prices is detrimental to their global expansion efforts. This is particularly true for domestic companies with innovative drug portfolios that typically launch their products in China before going to

market in other countries.

To address this concern, the NHSA factored potential international impact into its practice and implemented a price confidentiality measure for certain drugs in the 2023 NRDL revision. The measure allows the final negotiated drug price to be omitted and replaced with an asterisk, as mentioned in Section 2.

In the 2023 NRDL, a total of 229 drugs were subject to price confidentiality.

4. Multinational companies' high-priced products struggle for NRDL inclusion.

Although the 2023 NRDL revision highlights Chinese policy makers' determination to promote innovation in China, certain innovative drug products, especially those manufactured by multinational pharmaceutical companies, still face challenges, such as in the areas of CAR-T, ADC, and PD-1 products.

a) <u>Highly priced CAR-T products continue to be excluded from the NRDL</u>. Despite its efficacy in cancer treatment, CAR-T therapy's prohibitively high cost (approximately 1 million RMB per injection or more) remains the primary obstacle to its inclusion in the NRDL.

Every year since 2021, CAR-T cell therapy has sought inclusion in NRDL. In 2021, for instance, Fosun Kite's Axicabtagene Ciloleucel Injection ultimately failed to secure a place in the NRDL despite passing the preliminary review, while JW Therapeutics' Relmacabtagene Autoleucel Injection missed the application deadline due to its late approval. By 2022, Fosun Kite decided not to submit an application for its CAR-T product, while JW Therapeutics' CAR-T product participated in the NRDL application process for the first time, passing the preliminary review but failing to advance to the negotiation stage. In the 2023 NRDL revision, both of the aforementioned CAR-T products passed the preliminary review. However, neither participated in the 2023 negotiation, perhaps because the cost of cell therapy has not been reduced to an affordable level within the annual budget of the health insurance fund.

b) <u>Antibody-drug conjugate (ADC) products from multinational companies still face barriers to</u> <u>NRDL inclusion</u>. As a prominent area in cancer treatment in recent years, ADC products garnered significant attention in the 2023 negotiation. Among the seven ADC products currently approved for market authorization in China, three products are already included in the NRDL—Roche's Trastuzumab Emtansine, Seagen/Takeda's Brentuximab Vedotin, and RemeGen's Disitamab Vedotin—and the remaining four products also appeared in the preliminary review list for 2023 NRDL negotiation.

These four products are Pfizer's Inotuzumab Ozogamicin, Roche's Polatuzumab Vedotin, Gilead/ Everest Medicines's Sacituzumab Govitecan, and AstraZeneca/Daiichi Sankyo's Trastuzumab Deruxtecan (DS-8201). Most of these products did not progress to the negotiation stage, and none were included in the 2023 NRDL.

Among them, AstraZeneca/Daiichi Sankyo's HER2-targeted drug DS-8201 was approved for market authorization in China in February 2023. It is currently the only ADC product in the field of breast cancer treatment that has been both certified as a breakthrough therapy by China's Center for Drug Evaluation (CDE) and prioritized for review and approval, with the dual advantages of efficacy and safety. The unit price of DS-8201 is currently RMB 8,860 per unit, with an annual treatment cost ranging from RMB 300,000 to 500,000. However, despite these attributes, the product failed to enter the 2023 NRDL, possibly due to the inability to reach a consensus on pricing with the NHSA. Other ADC drugs unwilling to make concessions in their prices faced the same results.

Roche's Trastuzumab Emtansine was approved in China in January 2020. Its initial listed price was as high as RMB 19,282 for the 100mg specification and RMB 27,632.04 for the 160mg specification. However, after undergoing two price reductions and being included in the 2022 NRDL, the unit price of the 100mg specification was reduced to RMB 3,580, while the unit price of the 160mg specification was reduced to RMB 5,130. This translates to a substantial price cut of about 80%, and the annual treatment cost is reduced to approximately RMB 180,000.

Similarly, the unit price of Seagen/Takeda's Brentuximab Vedotin, which was also included in the 2022 NRDL, saw a reduction from RMB 18,680/50mg to RMB 7,202/50mg, a 54% price cut.

On the other hand, products from domestic companies, such as RemeGen's Disitamab Vedotin, may have a smoother path to NRDL than their foreign peers. Disitamab Vedotin was included in the medical insurance catalog in 2021, the year of its market launch, experiencing a 71.85% price reduction and a remarkable 1513.23% increase in sales. In the same year, RemeGen paved the way for the global expansion of its ADC product by securing a global exclusive licensing agreement with Seagen, including a USD 200 million down payment and milestone payments totaling USD 2.4 billion.

c) <u>Competition in the PD-(L)1 market presents hurdles for latecomers</u>. In the PD-(L)1 sector, domestic pharmaceutical firms maintain their stronghold, with Junshi Biosciences, Innovent Biologics, BeiGene, and Jiangsu Hengrui Pharmaceuticals successfully securing the renewal or addition of indications in the 2023 NRDL. BeiGene's Tislelizumab Injection expanded its indications by two, Junshi's Toripalimab by three, Innovent Biologics' Sintilimab by one, and Hengrui's Camrelizumab by one.

Conversely, latecomers continued to encounter barriers to the NRDL. For instance, the Sugemalimab developed by CStone Pharmaceuticals and Pfizer obtained approval for a large indication of non-small cell lung cancer by the end of 2021. However, despite being eligible for the 2022 NRDL negotiation, it voluntarily relinquished its eligibility. Although Sugemalimab reappeared on the application list of the 2023 NRDL adjustment and passed the preliminary review, it still failed to be included in the final list. According to public information, the annual treatment cost of the drug is as high as RMB 446,000, and the annual treatment cost after charitable assistance is 99,000 yuan, which is still much higher than other PD-1 products that have been included in the NRDL.

Overall, the inclusion of high-priced drugs in the NRDL mainly depends on two main considerations. First, if there are already competing products in the NRDL, the price of these products will generally serve as the main reference. If the price gap is too large, the newcomers' products typically will not be taken into consideration. Second, if there are no competing products, the NHSA will consider the international market average price, the medical insurance fund's own affordability, and possible sales volume when determining the price.

5. Reference pricing system for negotiated drugs and non-exclusive drugs' bidding.

a) <u>Reference pricing system for negotiated drugs</u>. Some say a negotiated drug will be included in the final NRDL if the pharmaceutical company's quotation is lower than 115% of the "envelope price," i.e., the expected reimbursed price set by the NHSA.

According to relevant news, the "envelope price" is independently calculated by groups of experts from the pharmacoeconomics team and health care insurance fund team. The pharmacoeconomics experts propose a drug's expected reimbursed price based on its economic value, assessed through an evaluation of its safety, efficacy, and cost-effectiveness. This evaluation is based on (i) the lowest winning bid price of the product in China's local centralized procurements (if applicable), (ii) the global lowest price in key countries and regions¹ where such product is listed, and (iii) the prices of competing products with similar indication(s) and efficacy. The fund team experts propose another price that aligns with the priorities of the health care insurance fund. This proposed price considers factors such as the drug's potential burden on patients, its clinical needs, clinical value, level of innovation, and competing products' prices. The NHSA determines a final "envelope price" based on the two proposed prices.

However, the standards for the reference pricing system for negotiated drugs are not officially disclosed in the NHSA's publicly available documents released alongside the 2023 NRDL revision.

b) <u>Bidding of non-exclusive drugs</u>. On the other hand, the NSHA introduced the *Non-Exclusive Drug Bidding Rules* ("Bidding Rules") in the 2022 NRDL revision, allowing non-exclusive drugs, i.e., drugs with the same generic name manufactured by different companies, to apply for inclusion in the NRDL through bidding. The Bidding Rules and the bidding mechanism were maintained in 2023.

According to the **Bidding Rules**, the NRDL experts propose an expected price for the bidding products, for which the calculation standard is not disclosed. In the bidding process, as long as at least one company's quotation does not exceed the proposed price, its generic drug can be included in the Category B medical insurance directory. The reimbursed price for the selected products will not be lower than 70% of the proposed price. However, the company's quotation must not exceed the lowest winning bid price valid in provincial centralized procurements within two years, as well as the market retail price submitted at the time of application.

For instance, if a certain generic drug is produced by two companies, A and B, and the NHSA's expected reimbursed price is RMB 100:

- (i) If both Company A and Company B quote prices higher than RMB 100, neither of their products will be included in the NRDL;
- (ii) If at least one company quotes a price lower than RMB 100, this generic drug will be included in the NRDL, and the payment standard will be determined by the lower of the two quoted prices.

¹ Although the list of such key countries and regions is not officially disclosed, it is reported that pharmaceutical companies were asked to submit their drug prices in 12 "recommended countries or regions," including Japan, France, Germany, Italy, Spain, the United Kingdom, Canada, South Korea, the United States, Australia, Turkey, and Taiwan in previous years.

- (iii) However, if any company quotes a price lower than RMB 70, the payment standard for the drug will be set at RMB 70.
- 6. Revision of simple renewal rules protects applicable products from substantial price cuts.

In 2022, the NHSA introduced a simple renewal mechanism for the first time. Under this mechanism, the NHSA can calculate the price cut range for drugs subject to NRDL reimbursement renewal according to certain price adjustment rules and determine new payment standards. Pharmaceutical companies can complete the renewal directly in writing if they accept the new payment standards instead of participating in negotiation again (for more details, please see our previous issue).

On July 21, 2023, the NHSA published the revised Negotiated Drug Renewal Rules (the New Rules), which further build upon the simple renewal mechanism of 2022 with the following changes:

a) <u>Introduction of new price adjustment rules applicable to the drug throughout its lifecycle</u>: The New Rules propose the following price adjustment for negotiated drugs that have been continuously listed in the NRDL for a certain number of years:

Number of years continuously listed in the NRDL	Price adjustment mechanism
Fewer than four years	The price cut rate ranges from 0% to 25% according to the 2022 mechanism.
Between four and eight years	The price cut will be halved based on the above standard (for example, if a drug's price is reduced by 10% in the third year of inclusion in the NRDL and the drug is renewed in the fourth year, the price will be reduced by 5% in the fourth year).
Eight years or more	Entry into the regular catalog of the NRDL (i.e., no further price cuts).

The NHSA explains, "The peak sales period for drugs from the market launching to sales is about 8-10 years. Based on this, the New Rules proposed to include negotiated drugs continuously listed in the NRDL into the regular catalog." Previously high-priced drugs such as Tenofovir, Gefitinib, and Imatinib are now included in the regular catalog and the centralized procurement. The above "eight years" rule is based on considerations for future inclusion of negotiated drugs into the NRDL's regular catalog.

The policy to halve the price cut rate for drugs listed in the NRDL for between four and eight years signals that the NHSA will not unreasonably slash drug prices, thus providing a more predictable market access environment for innovative drug makers in the future.

b) <u>Application of a more modest discount rate on NRDL-listed drugs with new indications</u>: The New Rules stipulate that if a listed drug added indication(s) the previous year and is eligible to renew its agreement in the current NRDL revision, the previous year's price cut rate for the addition of indication(s) will be deducted when calculating the new renewal price cut rate, until such rate reaches zero.

Before the New Rules were issued, pharmaceutical companies faced a dilemma: the better a drug sold (under the 2022 simple renewal rules, meaning the actual expenditure exceeded the budgeted expenditure for the drug), and the more indications it had, the greater the price cut it faced in NRDL negotiations. The New Rules address this concern and incentivize companies to actively pursue the development of new indications for their products.

c) <u>Revised calculation method for health care insurance fund expenditures with a relaxed threshold</u> <u>for price reduction gradients</u>: In previous years, the health care insurance fund expenditure was calculated based on the actual product sale. However, this method may not accurately reflect the significant out-of-pocket payment amount caused by extensive off-label use, and there are huge variations in the implementation insurance policies for drugs subject to NRDL negotiation across different regions and health care institutions. Using actual product sale as the calculation basis would inflate the health care insurance fund expenditures. Under the New Rules, starting in 2025, renewals will no longer be based on "health care insurance fund expenditure" but will instead utilize "drug expense reimbursed under the actual payment scope" for the actual calculation.

As a result, a drug with high sales will not automatically receive a large price cut. Under the New Rules, if a drug has multiple approved indications but a smaller NRDL reimbursed scope, the price cut will be smaller than in previous years.

Furthermore, the threshold for the simple renewal price reduction gradient has been relaxed by approximately 1.5 times, with the maximum threshold increased from RMB 40 billion to RMB 60 billion. This rule signals an increase in health care insurance funds' willingness to cover the payment. Innovative pharmaceutical companies previously facing pressure to reduce drug prices due to actual expenditures far exceeding budgeted expenditures will now have more leeway.

d) <u>Avoiding unnecessary consequences of statutory price reduction in the simple renewal system by</u> <u>offering another renegotiation option</u>: For Class 1 chemical drugs, Class 1 therapeutic biological agents, and Class 1 and Class 3 proprietary Chinese drugs approved under China's current drug registration regulations, if the simple renewal triggers a price reduction mechanism, the NHSA now grants the pharmaceutical company the option to choose between simple renewal or renegotiation. This means that if a pharmaceutical company is unsatisfied with the price cut offered in the simple renewal mechanism, it can enter into a renegotiation process, where the price cut rate could be decreased.

It is worth noting, however, the New Rules also explicitly state that "if negotiations fail, the products will be removed from the NRDL." Pharmaceutical companies must also consider this potential risk.

Under the New Rules, among the 100 drugs successfully renewed through NRDL negotiations in 2023, 70% of them were renewed at the original price. Thirty-one drugs needed to reduce their prices due to exceeding the initial sale forecast, but the average price cut was 6.7%. The New Rules provide pharmaceutical companies with more stable sales expectations.

7. Conclusion

Since the establishment of the NHSA in 2018, the NRDL has undergone revision for six consecutive years. A total of 744 drugs have been added to the NRDL, while a number of drugs were removed for their uncertain effectiveness, tendency for clinical abuse, or unfavorable profile. This has reshaped the

landscape of the Chinese pharmaceutical market. Through negotiation for price reductions and medical insurance reimbursement, the cumulative financial relief to patients has exceeded RMB 600 billion.

The 2023 NRDL revision has provided further support for the innovative drug industry, especially helping domestic companies, which rely primarily on the local market, preserve resources in support of their overseas expansion. On the contrary, imported drugs included in the NRDL are generally offered at the lowest global prices. Additionally, measures such as price confidentiality are also beneficial for the global expansion of domestic innovative drugs. According to relevant statistics, there were nearly 70 license-out transactions for China's innovative drugs in 2023, nearly double the 2022 figures (44 transactions). The total disclosed deal amount for 2023 out-licensed transactions exceeds USD 46.5 billion, a 69% increase over 2022.

Based on the revision of NRDL policies, opportunities for cross-border transactions in the pharmaceutical sector may continue to increase in the future, given China's rapidly advancing scientific research and clinical practice, as well as the government's commitment to supporting global pharma players in China. The Chinese government's ambition to promote Chinese innovation around the world has been realized due to dedicated investment and strategic policymaking in several areas, including pricing.

Finally, we find Chinese policy makers also become mindful of the downside of stringent reimbursement practice against the attraction of the domestic market. While we remain cautious about the actual positive contribution by the latest self-assessment of innovative products ², it is possible the initial price of certain innovative products can increase in the next NRDL negotiation at the earliest. Additionally, the number of eligible drugs may not be as expansive as pharmaceutical companies have hoped for many years.

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² In a public speech in November 2023, Mr. Weng Linjia, the Deputy Director of the Pharmaceutical Pricing and Tender Procurement Department of the NHSA, stated that the NSHA was adjusting the pricing mechanism for innovative drugs and adopting a relatively lenient approach to the pricing of innovative drugs in the early stages of marketing. Notably, in early February 2024, the NHSA released the draft version of the *Notice on Establishing a Mechanism for the Initial Pricing of Newly Marketed Chemical Drugs to Encourage High-Quality Innovation* (《关于建立新上市化学药品首发价格形成机制 鼓励高质量创新的通知(征

求意见稿)》, the "Notice"), which was sent to relevant industry groups for soliciting comments. Although the full text of the Notice is not available to the public yet, the Notice is said to introduce more favorable policies for innovative drugs in provincial centralized procurements, according to relevant news. It is said that the drug makers will be required to run a self-assessment over the "innovation level" of their products. Products with a higher level of innovation (e.g., those with new biological targets or mechanisms of action) will be granted more flexibility in determining the initial marketing price and will benefit from additional supportive measures such as expedited or simplified listing on centralized procurement platforms. If officially promogulated, the Notice would have a significant effect on the NRDL negotiation, renewal, hospital purchase, and centralized procurement of innovation drugs. Drugs with higher levels of innovation may receive more favorable policies during NRDL negotiation, as explained by Professor Jin Chunlin from Shanghai Health Development Research Center in an interview by the *21st Century Business Herald*.

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