

# Research on the Innovation and Future Development of China's Medical Insurance Negotiation Mechanism

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**Abstract.** In recent years, China's medical insurance negotiations have achieved remarkable results but still have shortcomings. China's medical insurance reform is currently in the exploratory stage. This article looks at the characteristics of the dual role played by the Chinese government in medical insurance negotiations, and analyzes the advantages and drawbacks of enterprises accessing or not accessing medical insurance. The article argues that China cannot replicate foreign medical insurance mechanisms but must establish its own innovative mechanisms. This paper describes the progress and current status of medical insurance negotiations in China and elaborates on the five stages of medical insurance negotiations including preparation, declaration, expert evaluation, negotiation, and announcement. The article highlights some essential points and misconceptions of the negotiation stage. By investigating the medical insurance negotiation mechanisms in the United States, Canada, and Germany, this paper summarizes the practical experiences of developed countries in the control of drug prices and the use of negotiation mechanisms. The article reveals the existing problems of China's medical insurance mechanism and proposes pragmatic and feasible suggestions. It has important theoretical and practical significance for improving the medical insurance mechanism and promoting the healthy development of the drug industry.

**Keywords:** Medical insurance negotiation; NHSA; Negotiation mechanism.

## 1. Introduction

Based on real cases, the movie *dying to survive* said, there is only one illness in the world—poverty. When medical insurance was not widespread, the treatment of a serious illness may deplete the family's entire savings. And drug companies strongly refused to reduce prices to make profits. Ordinary people either spend all their savings to buy overpriced drugs or have to languish in their hospital beds. To stop this tragedy from happening constantly, the country started to promote medical insurance vigorously. And on behalf of the people to negotiate with drug companies to lower the cost of exorbitantly expensive drugs. Medical insurance negotiations are a process in which the NHSA's experts negotiate with drug companies, taking into account drug costs, demand, and competition to negotiate drug prices, resulting in lower drug prices and less financial stress for patients. To promote the establishment of China's medical insurance negotiation mechanism, many specialists have conducted extensive research. Hong Li made constructive suggestions regarding pricing negotiations on innovative medicines[1]. Francesca Barigozzi has shown that efficiency and prices are higher when basic research is integrated into drug companies compared to independent basic research[2]. Yi Liu examined the effects of the policies on the providers' drug selection and pricing behaviors[3]. This article intends to analyze China's drugs pricing negotiations from the aspects of background of negotiation roles, progress, characteristics of foreign medical insurance, and improvements.

## 2. Negotiation Role Analysis

The principle of the medical insurance negotiation mechanism is the adjustment of the government-business relationship. In national drug negotiations, the government enters the public domain in a different role and switches through the identity of regulator and buyer. Companies weigh the advantages and disadvantages of entering medical insurance or not. Both sides strike a balance that ultimately leads to the achievement of their goals.

## 2.1 Dual Role of Government

**Regulator:** The government is the main body that holds the public power of the nation and is the representative that exercises the public power of the nation [4].

**Buyer:** Universal Medical Insurance establishes capital advantage for the government [5], and adequate health care information provides informed access to drug prices.

The government has to share the dual role of regulator and buyer, and there is a conflicting relationship between the two, which puts the government in an awkward position: from the buyer's point of view, the government needs to purchase low-priced drugs and provide affordable services to patients; from the regulator's point of view, as the representative of the country, the government has administrative power beyond the market, but the government cannot replace the market. This is due to the fact that China no longer implements a planned economy, and as a result, the government is required to maintain the market's independence, adhere to market logic, and refrain from interfering with the drug market's smooth operation by imposing administrative power. What's more, simply lowering drug prices will not only fail to guarantee the availability of high-quality drugs, but will directly stifle the innovative spirit of drug companies, as no one is willing to invest huge costs in the research and development of new drugs [6]. Then, the only remaining low-efficacy drugs on the market will eventually make patients lose confidence and trust in the healthcare system, thus leaving the government in a passive position.

## 2.2 Drug Companies Enter the Medical Insurance

Drug companies can benefit in multiple ways by sacrificing the high pricing of their drugs to enter medical insurance. First of all, entering medical insurance means drug companies can save more marketing and promotion costs, while hospitals across China will purchase drugs that are included in medical insurance, which can rapidly increase sales. In 2018, Sintilimab Injection of Innovent Biologics entered the 2019 version of the medical insurance catalog with a price reduction of up to 63.73%. According to the annual report released by Innovent Biologics, as the first PD-1 inhibitor to enter the national medical insurance catalog, sales of Sintilimab Injection were ¥1.016 billion in 2019, ¥2.289 billion in 2020 and ¥2.801 billion in 2021, easily achieving rapid sales growth.

Moreover, entering medical insurance means that the drug companies have consistent sales channels and cash flow. Therefore, investors feel optimistic about the prospect of the enterprises, thus pulling up the share price of the enterprises. After Hengrui Pharmaceutical's Camrelizumab for Injection was announced to be included in the medical insurance system in 2020, its stock, which had been trading sideways for a while, continued to grow and the share price reached a record high with a market capitalization of ¥57 billion [7].

## 2.3 Drug Companies do not Enter the Medical Insurance

Drug companies abandoning access to medical insurance and maintaining high pricing will constrain patient penetration. The lengthy process of drug bidding and procurement into hospitals, along with the fact that the drugs are not covered by medical insurance, will obstruct the advertising of drugs in hospitals, which will have a passive impact on sales volume and revenues. Nevertheless, the drug industry is made up of many different segments, and a drug company's decision to leave one of those segments—the medical insurance drug market—due to profit pressure does not always suggest that they will leave the others. Drug companies can choose other nations as long as they maintain their competitiveness because China is not the only drug market in the world. Some drug company executives also told 21CBR that "if your innovative drug has high clinical value, even if you don't participate in health insurance negotiations, there are other mechanisms such as commercial insurance".

In 2022, China stated that it will continue to support commercial insurance institutions to develop commercial health insurance products that interface with basic medical insurance to better cover costs that are not covered by basic medical insurance [8]. This further demonstrates that medical insurance

is not the only option for companies, such as the \$1.2 million CAR-T (Chimeric Antigen Receptor T-Cell Immunotherapy) for cancer that goes into commercial insurance rather than medical insurance. This approach has the advantage of ensuring that the price of the drug in China will not be substantially lower than in other overseas markets, helping to maintain price stability and thus increasing the payback speed of the developed drug.

However, for patients, the best outcome must be to have access to drugs with good therapeutic effects and cheap prices, so building a proper negotiation mechanism is quite important for both the government and drug companies. An excellent negotiation mechanism can help build a harmonious and interdependent government-business relationship. Drug companies can get the necessary profit from a vast market and promote innovation. The government can prioritize the appropriate drugs from the abundant drug market and make the most beneficial decisions for patients, thus enriching the medical supplies system with limited finances. However, the specificity of the Chinese government's dual identity determines that it cannot just duplicate the drug negotiation mechanisms of other countries, but rather draw inspiration from them and build an innovative medical insurance negotiation mechanism of its own.

### **3. Negotiation Mechanism**

The negotiation follows the processes including preparation, declaration, expert evaluation, negotiation, and announcement [9].

#### **3.1 Preparation**

The preparation stage is for consultants and experts from the NHSA (National Healthcare Security Administration) to study and formulate a work plan, determine the principles, scope, and procedures for the adjustment of the NRDL (National Reimbursement Drug List), and consult widely with all sectors before officially releasing it [10]. Develop rules for competitive bidding of non-exclusive drugs and revise and improve rules for renewal of negotiated drugs, etc. Optimize and enhance the information system for enterprise declaration, expert evaluation, and negotiation data filling.

#### **3.2 Declaration**

The declaration stage is mainly to organize and guide enterprises to submit the necessary drug information to the NHSA, assemble a team of specialists to review the information submitted by enterprises and publicize the drugs and related information that have passed the official examination. The final list of drugs that pass the formal examination will be announced and feedback will be given to relevant enterprises through the declaration system.

#### **3.3 Expert Evaluation**

The expert evaluation stage mainly organizes experts in clinical medicine, pharmacology, pharmacoeconomics, medical insurance management, etc. to evaluate the declared successful drugs in five dimensions: safety, effectiveness, economy, innovation, and equity [11]. Only drugs that pass the comprehensive evaluation are eligible for further submission of relevant materials, thus determining the list of drugs to be moved out of the NRDL or included in the negotiation.

#### **3.4 Negotiation**

The negotiations consist of four stages. The first is to determine the intention to negotiate. The NHSA affirms that drug companies intend to engage in negotiations and instructs those who are willing to negotiate to submit relevant information. The second is to carry out price measurement and assessment. The NHSA organizes pharmacoeconomics and medical insurance measurement experts to conduct an evaluation by reviewing materials, and evidence and using fund measurement and pharmacoeconomics methods [12]. Reasonably calculate the negotiated base price of each drug, that is, the highest price that the medical insurance fund can afford. Third, communicate with enterprises.

Face-to-face interactions with enterprises can help them establish fair expectations for the ultimate pricing by discussing the concepts and priorities of drug measurement and evaluation. Fourth, carry out on-site negotiations. According to the pertinent rules and procedures, the NHSA unifies the negotiation standards and organizes experts to negotiate with enterprises on-site [13]. Encourage enterprises to offer prices that fall under the medical insurance base price. And strive for the most favorable price for the people within the range acceptable to the enterprises.

### **3.5 Announcement**

Signing agreements with successful negotiated companies, announcing successful negotiated drugs to be included in the NRDL (National Reimbursement Drug List), and publishing a new version of the drug list.

## **4. Highlights of the Negotiation Stage**

### **4.1 Principle of Estimating the Base Price**

The NHSA selects leading experts in pharmacoeconomics and medical insurance administration from across the country to form a pharmacoeconomics group and a fund measurement group. Pharmacoeconomists take into account clinical demand, drug value, medical insurance fund affordability, and corporate interests. The fund measurement experts estimate the impact on the medical insurance fund if the drug is successfully negotiated into the medical insurance. These two groups are measured in parallel without knowing each other's base prices. Finally, according to pre-defined rules, the results of the two parallel groups form the final base price for the medical insurance [14]. However, before the final base price is determined, each measurement group will communicate with the representatives of each drug company separately on how the drug price will be measured, to allay the concerns of the companies. After feedback from both sides, the NHSA then integrates all the content to obtain the final negotiated price for each drug.

### **4.2 Enterprise Offering Rules**

Firstly, the drug company will offer the price and have two chances to confirm the price. The company may adjust the price prior to confirmation in accordance with the NHSA's recommendations. If the company's price after the second confirmation exceeds 115% of the NHSA's negotiation base price, the negotiation fails. If the company's second confirmed price is not higher than 115% of NHSA's negotiated base price, negotiation between the two sides will proceed [15]. The final price cannot be higher than the NHSA base price. In other words, the success of the negotiations depends on the intersection of the NHSA and the drug company's base price.

### **4.3 Misconceptions about Negotiated Drug Prices**

For a long time, many people had a cognitive misconception about medical insurance negotiations - the lower the price of a drug, the better. In fact, reaching a consensus during medical insurance talks is more important. There are three major negotiation skills, according to Leigh Thompson's book *The Mind and Heart of the Negotiator*: creating value, claiming value, and building trust [16]. Negotiation is not a win-or-lose endeavor, but rather a win-win collaboration. In the case of medical insurance negotiations, the three negotiation skills correspond to win-win cooperation, maintaining profitability, and long-term cooperation. Without a doubt, from the patient's perspective, a drug's price should be as cheap as possible. However, the development, procurement, and sale of drugs are driven by unique economic factors. Medical insurance negotiation is only to reduce the unreasonable premium in these stages. If low prices break the healthy balance between drug companies, the NHSA, and patients, it will end up in a multi-loss situation [17].

#### **4.4 Lowering Drug Prices is not the Only Goal**

Lowering drug prices is an important goal in negotiations, but not the only one. In addition to lowering medicine prices directly, other methods, such as medical support, can help lower prices indirectly [18]. For example, work out a deal with pharmaceutical corporations to take a portion of the funds for patients to carry out health education, health management, and other public welfare activities. Additionally, the range of discussions will cover drug quality, sales volume, distribution strategies, etc.

### **5. Foreign Drug Negotiation Mechanism**

#### **5.1 America**

The U.S. healthcare system is based on commercial insurance, supplemented by public medical insurance for vulnerable populations [19][21]. The extent of disease coverage and insurance costs are directly correlated. Drug prices in the U.S. are determined through negotiations between healthcare providers and medical insurance companies. The U.S. government neither creates nor implements specific policies to regulate prices. The advantage of U.S. medical insurance is that it ensures an efficient supply of medical services and prevents providers from offering excessive services. But this mechanism ignores fairness because the wealthy receive far more benefits than the average person. Meanwhile, the price of medical services in the U.S. is usually much higher than in other countries due to insufficient market competition and weak government price regulation.

#### **5.2 Canada**

Canada implements a national medical insurance system. All citizens have access to free basic health care after individuals pay a certain percentage of the public health care tax. The government directly determines the usage and pricing of drugs [22][23]. The benefits include that it is sufficient to rectify the failures of the private insurance market and to provide maximum protection to all segments of the population while avoiding unreasonably large increases in insurance premiums. The disadvantage is that the shortage of labor resources and the long period of physician cultivation can exacerbate the oversupply of medical services.

#### **5.3 Germany**

Germany adopts a social medical insurance system [24][27]. Medical insurance is based on mandatory statutory health insurance, supplemented by voluntary private health insurance. Individuals enjoy comprehensive basic health insurance services after paying a certain percentage of their income in premiums. The government does not intervene in the operation of the market, but only performs the necessary regulation, coordination, and supervision. The advantage is that the fairness of the health insurance system is guaranteed since the health care services available to the participants are not differentiated by the amount of the premium. The drawback is that the aging of the German population makes it difficult to finance statutory health insurance while the costs are increasing.

### **6. Existing deficiencies and suggestion**

#### **6.1 Lack of Third-Party Evaluation Institutions**

Non-governmental third-party professional institutions exist in countries such as Korea, the UK, Germany, and Australia as listed below[28].

Korea: Health Insurance Review and Assessment, HIRA

United Kingdom: National Institute for Health and Care Excellence, NICE

Germany: Institute for Quality and Efficiency in Health Care, IQWiG

Australia: Pharmaceutical Benefits Advisory Committee, PBAC

These organizations independently evaluate the clinical effectiveness and economic value of drugs. They use systematic evaluation criteria to improve the scientific and public nature of medical insurance assessment. In China, however, the NHSA is both a decision-maker in the negotiation of rules and a participant in the expert evaluation and on-site negotiations. As a result, there is a lack of a non-governmental third-party institution to coordinate the domestic negotiations and to ensure that both sides have an equal voice in the negotiations.

The country should financially support academic institutions and industry-related organizations to spontaneously establish third-party institutions to provide advice on drug evaluation and base price estimation for medical insurance negotiations[29].

## **6.2 Clarify Pricing Guidelines for Drug Price Negotiations and Subsequent Adjustments**

The evaluation index weights and drug pricing criteria in China's medical insurance negotiations are both in need of clarification[30]. Negotiated drug price proposals are operated by the relevant national departments and are not announced to the public. Although the government promptly announces the final medical insurance prices of negotiated drugs, the assessment of drugs is basically undisclosed. Meanwhile, there is no standardized, long-term dynamic adjustment mechanism for the prices of drugs in the NRDL, resulting in long-term unchanged prices for certain drugs, while manufacturing costs may have dropped significantly.

Therefore, China should establish explicit drug pricing rules and make public detailed indicators for assessing the effectiveness of innovative drugs. At the same time, the prices of drugs in the NRDL should be adjusted periodically based on the collection of dynamic price information in the medical insurance drug market and changes in the size of the drug market, so as to form a sound, stable, and long-lasting medical insurance price adjustment mechanism[31].

## **6.3 Improve Supervision Mechanism and Reinforce Anti-Corruption Efforts**

In recent years, many criminals have been collecting medical insurance information from citizens under the pretense of providing hospitalization subsidies and low-cost medical treatment. They fabricate citizens' medical and hospitalization information and substitute expensive medications for low-priced ones when recording medical insurance data to defraud the medical insurance fund, which seriously undermines the healthy and sustainable development of the medical insurance system.

In July 2020, the General Office of the State Council issued the "Guidance on Advancing the Reform of the Medical Security Fund Supervision System", which clearly proposed to crack down on fraudulent insurance practices and establish a sound mechanism to eliminate fraudulent insurance behavior. In addition, the supervision agency should thoroughly understand the stages of corruption and their shifting patterns, concentrate on the most urgent issues, and resolutely eradicate systemic corruption.

## **7. Conclusions**

In 2021, there are already 1,362.97 million people enrolled in the national basic medical insurance, and the participation rate is stable at over 95%. The 221 negotiated drugs were reimbursed 140 million times during the drug agreement period. Through the negotiation of price reduction and medical insurance reimbursement, the total expenditure for patients was reduced by 149.49 billion yuan during the year. The results of medical insurance negotiations can be found to be increasingly successful. However, the improvement of the negotiation mechanism is not over yet. China still needs to learn from the practical experience of foreign countries to form a triple-win situation for the government, enterprises, and patients.

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