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Progress on drug pricing negotiations in China

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Summary **On November 28th, 2019, the National Healthcare Security Administration (NHSA) and the Ministry of Human Resources and Social Security (MOHRSS) of China announced the results of drug pricing negotiations. Seventy first-negotiated drugs with 60.7% average price decrease and twenty-seven re-negotiated medicines with 26.4% average price fall, involving 11 disease categories, were successfully incorporated into National Reimbursement Drug List (NRDL). Medicines that successfully get accessed to NRDL are mostly new listings with high clinical value, and more than half of them are manufactured by Chinese enterprises. Compared to the negotiated drug list of 2017, the biggest increase in western medicines is the alimentary tract and metabolism (10 drugs added), and the traditional Chinese medicine is internal medicine (17 drugs added). The negotiation follows the process including preparation, examination, negotiation, and announcement. There are several innovations in the procedure, such as the parallel calculation of the floor price, the introduction of competitive negotiations, allowing companies to apply for price confidentiality, and increasing government-enterprise communication before negotiations. Incorporating patented drugs into NRDL by negotiation not only helps patients reduce the economic burden, but also encourages pharmaceutical companies to innovate.**

Keywords: National Reimbursement Drug List, pricing negotiation, negotiation process

1. Introduction

On November 28th, 2019, the National Healthcare Security Administration (NHSA) and the Ministry of Human Resources and Social Security (MOHRSS) of China officially issued the results of the drug pricing negotiations. Seventy first-negotiated and twenty-seven re-negotiated medicines, involving 11 disease categories, were successfully incorporated in National Reimbursement Drug List (NRDL). The average price decrease of the first-negotiated and re-negotiated drugs are 60.7% and 26.4%, and the price of drugs for hepatitis C that has received much attention fell by an average of more than 85% (*1*). Incorporating drugs into NRDL through negotiation, which is a major innovation in China's reimbursement drugs list adjustment in recent years, can significantly improve the availability and affordability of patent drugs for patients, and can make the NRDL structure more optimal (*2*).

This article intends to analyze China's drugs pricing negotiations in 2019 from the aspects of the policy background, progress, similarities and differences with conventional access, and potential impact.

2. Policy background for drug pricing negotiations

Patented drugs, as an inadequately competitive commodity in the pharmaceutical market, have both clinical value and high price (*3*). In order to introduce patented drugs into the Chinese market at a price acceptable to all three parties who are pharmaceutical companies, medicare payers, and patients, in February

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2015, the State Council of China issued *the Guidelines on Improving the Centralized Procurement of Drugs for Public Hospital*, and proposed establishing an open and transparent price negotiation mechanism for some patented and exclusively manufactured drugs (*4*). In the same year, the former National Health and Family Planning Commission (NHFPC), National Development and Reform Commission (NDRC) and the MOHRSS initiated the first round of national-level drug pricing negotiations and announced the results on May 20th, 2016. The price of three drugs, Iressa, Kemena and Werder's, have dropped significantly after negotiations, with an average reduction of 58.6% (*5*). In 2017, the MOHRSS introduced pharmacoeconomic evaluation as a negotiation tool for the first time, and successfully incorporated 36 drugs, with an average reduction of 44% (*6*), which are used to cure cancer or major diseases. In 2018, The NHSA included another 17 anti-cancer drugs, and proposed that medical institutions whose actual cost exceeded controlled index of total amount due to policy reasons (*e.g.* negotiated drugs were incorporated in list) should be appropriately reimbursed when it was time for year-end clearing, thereby guaranteeing the initiative of supplying and using negotiated drugs (*7*).

Apart from national level drug negotiations, in some areas such as Qingdao, Jiangsu, Jiangxi, Zhejiang, *etc*. also actively explored the mechanism of drug pricing negotiations (*8*). Drug pricing negotiations at the local level mainly included some drugs, with accurate and effective effects but are expensive, which are essential for the treatment of severe and catastrophic diseases. Local level negotiations are preceded by the national negotiation, which offered referential experience and lessons for the national negotiation. Nevertheless, with the release of 2019 NRDL, provincial governments do not have authorization to adjust Type B NRDL.

Explorations at the national and local levels have actively promoted construction of the drug pricing negotiations access mechanism in China. However, since China's drug pricing negotiations started late, there are deficiencies in actual work, such as fewer drugs were negotiated resulting in less patient benefit, and the negotiation mechanism is still incomplete leading to misjudgment of relevant information by enterprises. In this context, taking the opportunity of the overall adjustment of the NRDL in 2019, China has launched the fourth drugs pricing negotiation.

3. Progress on Drug Pricing Negotiations in China

3.1. *Basic situation and characteristics of negotiated drugs*

The drugs to be negotiated in 2019 are for exclusive drugs that entered the Chinese market before December 31, 2018 (*9*). Among all the exclusive medicines, 119 medicines were selected for negotiation after expert review and voting, and enterprises confirming. In addition, there are 31 medicines that were negotiated in 2017 that need to be re-negotiated to determine whether the contract can be renewed. The two parts add up to a total of 150 (*1*). Compared with previous years, the number of successfully negotiated drugs has reached a record. Although the negotiation success rate has declined, the price decline of successfully negotiated drugs is still steady (Figure 1).

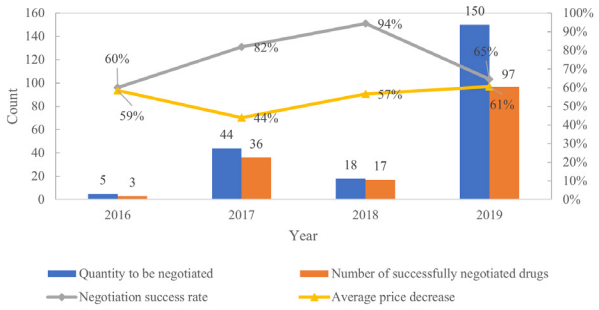

Figure 1. Status of medicines negotiated in China NRDL from 2016 to 2019. *Data source*: The information of drug price negotiations is collected from the NHSA, MOHRSS and the former NHFPC of China from 2016 to 2019 (*4-6*). MOHRSS, Ministry of Human Resources and Social Security; NHFPC, National Health and Family Planning Commission; NHSA, National Healthcare Security Administration.

Most drugs successfully negotiated in 2019 are new to the Chinese market in recent years and have high clinical value. These drugs cover 11 clinical treatment categories including cancer, rare diseases, hepatitis, diabetes, multi-drug resistant tuberculosis, rheumatic immunity, cardiovascular and cerebrovascular diseases, and digestion, *etc*. of which respiratory medicine is a new treatment category. Compared with the number of negotiated medicines in 2017, the number in all categories has increased. The largest increase in western medicine is for digestive and metabolic drugs (10 drugs added), and Chinese medicine is for internal medicine (17 drugs added), which reflects China's focus on proprietary Chinese medicines (Table 1).

In the context of the innovation capabilities of foreign companies far exceeding those of domestic companies, more than half of the drugs successfully negotiated at this time were those produced by Chinese companies (Figure 2). It is estimated that prices of drugs produced by Chinese companies have fallen less than those of foreign companies, which is conducive to improving the innovation capabilities of Chinese pharmaceutical companies.

3.2. *The procedure of drug pricing negotiations*

The negotiation follows the processes including preparation, evaluation, negotiation, and announcement (Figure 3) (*10,11*).

i) Preparation. A total of three tasks are performed during the preparation phase. First, drawing up a work

Table 1. Distribution of treatment categories of drugs negotiated successfully from 2016 to 2019 in China NRDL

Categories	2019		2018		2017		2016		Total	
	N	%	N	%	N	%	N	%	N	%
Total	**97**	**100.00**	**17**	**100.00**	**36**	**100.00**	**3**	**100.00**	**153**	**100.00**
Western medicine	**74**	**76.29**	**17**	**100.00**	**31**	**86.11**	**3**	**100.00**	**125**	**81.70**
Antineoplastic agent	22	22.68	16	94.12	16	44.44	2	66.67	56	36.60
Antiinfectives for systemic use	11	11.34	0	0.00	2	5.56	1	33.33	14	9.15
Alimentary tract and metabolism	11	11.34	0	0.00	1	2.77	0	0.00	12	7.85
Blood and blood forming organs	8	8.25	0	0.00	3	8.33	0	0.00	11	7.19
Cardiovascular system	6	6.19	0	0.00	3	8.33	0	0.00	9	5.88
Sensory organs	5	5.16	0	0.00	2	5.56	0	0.00	7	4.57
Nervous system	4	4.12	0	0.00	2	5.56	0	0.00	6	3.92
Various	4	4.12	0	0.00	2	5.56	0	0.00	6	3.92
Respiratory system	3	3.09	0	0.00	0	0.00	0	0.00	3	1.96
Systemic hormone preparations, excl. sex hormones and insulins	0	0.00	1	5.88	0	0.00	0	0.00	1	0.66
Chinese patent medicine	**23**	**23.71**	**0**	**0.00**	**5**	**13.89**	**0**	**0.00**	**28**	**18.30**
Internal medicine	19	19.59	0	0.00	2	5.56	0	0.00	21	13.73
Antitumor medicine	4	4.12	0	0.00	3	8.33	0	0.00	7	4.57

Data source: The data comes from the negotiating materials published by the former NHFPC, the MOHRSS, the NHSA and other related departments of China from 2016 to 2019 (*11*). MOHRSS, Ministry of Human Resources and Social Security; NHFPC, National Health and Family Planning Commission; NHSA, National Healthcare Security Administration; NRDL, National Reimbursement Drug List.

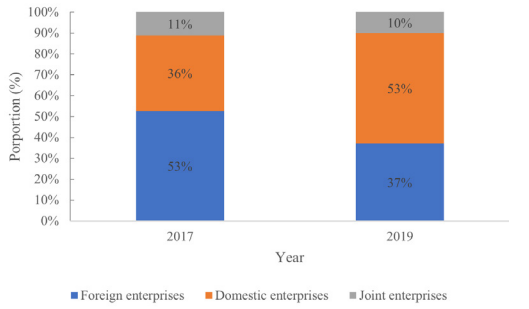

Figure 2. Category change of drug company negotiated successfully in China NRDL. *Data resource*: According to the negotiation information published by the NHSA of China (*9*). NHSA, National Healthcare Security Administration; NRDL, National Reimbursement Drug List.

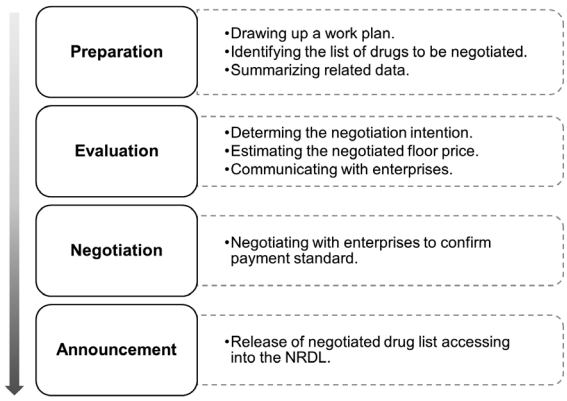

Figure 3. Drug pricing negotiation process of China NRDL. NRDL, National Reimbursement Drug List.

plan. The NHSA works with relevant departments to formulate the *2019 Work Plan for Drugs Pricing Negotiation to the NRDL*. Second, identifying the list of drugs to be negotiated. NHSA with related departments organize consultants (around 300, recommended by academic associations and industry associations) and experts (around 25,000, most of them are experts in clinical medicine or medical insurance management, recommended by local academic and industry associations in various provinces) to determine the list of drugs to be negotiated by evaluating and bidding. Third, summarizing related data. The relevant data of the drugs, which laid a solid foundation for the negotiation, are collected through multiple stakeholders, such as local medical insurance departments, enterprises, and drug recruitment platforms.

ii) Evaluation. The evaluation stage consists of three parts. The first is to determine the negotiation intention. The NHSA confirms the negotiation intentions of relevant companies, and organizes the companies that have willingness to negotiate to provide materials on the basis of prescribed format and time limit. The second is to estimate the negotiated floor price. Authoritative experts on pharmacoeconomics and medical insurance management are selected nationwide, and the pharmacoeconomics measurement group and fund measurement group are established respectively. Two groups make parallel calculations according to the technical points, and finally generate the floor price. The third is to communicate with enterprises. The NHSA organizes a centralized communication meeting to introduce the negotiation work arrangements, price calculation considerations, and negotiation rules to the companies to lead them to form reasonable expectations. In addition, NHSA also listens to the opinions of enterprises, and responds in time, and organizes experts to demonstrate to them if necessary.

iii) Negotiation. First, according to the negotiation

rules and procedures, the NHSA unified the caliber and standard of negotiations. Then the negotiators, composed of representatives from the national or local medical insurance agency, conduct on-site negotiations with the enterprises based on the evaluation opinions. After the negotiation, the negotiators announce the results on the spot and sign a confirmation contract with the enterprises. Finally, NHSA signs formal agreements with the enterprises one by one based on the results of the negotiations.

iv) Announcement. Release of negotiated drug list accessing into the NRDL.

3.3. *Highlights of the negotiation mechanism*

Compared with previous years' drugs pricing negotiations, there are several following highlights in this negotiations. First, calculating the floor price parallelly. In this negotiation, the pharmacoeconomics measurement team and the fund measurement team calculate the floor price separately according to the technical points, and convert the measured price of the two groups into the final price according to the prescribed method, which guarantee fairness and confidentiality of the measurement results. Second, introducing competitive negotiations. Because the six hepatitis C medications are generally effective and the cost of each treatment is more than 50,000 yuan, it is difficult to guide companies to reduce the price into a reasonable range based on pharmacoeconomic calculations and conventional access negotiations. Therefore, the method of competitive negotiation was creatively introduced, only two drugs with the lowest full-course cost could be allowed to enter the catalogue within 2 years, to guide enterprises to fully compete. Third, enabling companies to apply for price confidentiality. The rule of pricing negotiation allows companies to ask for confidentiality of the transaction price, in order to induce companies to reduce prices significantly. Fourth, strengthening communication between government and enterprises. This negotiation has added a communication meeting with the enterprise in the evaluation stage. The purpose of communication is to reach a consensus with the enterprise on basic information and materials, to prevent the failure of negotiations due to misunderstanding of information.

4. Similarities and differences with conventional admission

Due to the limited time and manpower of the management department, the adjustment of the NRDL was divided into conventional admission and negotiation admission based on the characteristics of new drugs. Conventional admission is a quick way for most new drugs to be incorporated into NRDL. First, the management department delineates the scope of candidate drugs based on registration information from the China Food and Drug Administration (CFDA) to ensure legality. Second, clinical medicine and pharmacy experts conduct secondary selection to ensure the candidate medicines meet clinical need. Among these candidate drugs, if the price is not higher than similar products in the NRDL, they can be directly accepted.

Negotiation admission is a process for a few highly innovative but expensive medicines. As with conventional access, these new drugs also need to be legally compliant, safe, effective, and meet clinical need. However, different from conventional admission, the management department will refer to the multi-dimensional price information, which plays a decisive role in the negotiations, including the international price, self-pay price, gift items, medical insurance budget impact, cost-effectiveness, *etc*. and invite experts to screen and evaluate this information. Based on this information, the final negotiated floor price is formed (*12,13*).

5. Potential impact

5.1. *Reduce patient's financial burden*

In this negotiation, the price of the newly added 70 drugs has decreased by 60.7%. If the actual reimbursement ratio is 50%, the patient's out-of-pocket ratio will be reduced to less than 20%, and even some drugs will be reduced to 5%. It is foreseeable that with the substantial decline in personal out-of-pocket costs, patients' affordability and availability of patented drugs will increase simultaneously.

5.2. *Encourage pharmaceutical companies to innovate*

Adjusting NRDL by negotiating will promote innovation in pharmaceutical companies. Most of the successfully negotiated drugs are new listings in recent years and are quickly included in the catalog, which releases a clear signal to support innovation. At the same time, drastic price reductions of drugs also put forward higher requirements for the company's R & D and pricing. It is required that companies could not simply consider costs and benefits of the company or price elasticity of the market when pricing the products, but also need to think about how to benefit multiple parties at the same time, such as meeting patients' medication needs and maintaining medical insurance funds sustainability (*14*).

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