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THOUGHT LEADERSHIP BRIEF

The Chinese Pharmaceutical System under the "New Normal": Policy Environment and Prospect

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KEY POINTS

- China is the world's second-largest pharmaceutical market where the demand for large quantity of supply and product innovation are increasing rapidly.
- In 2009, a landmark national healthcare reform vowed to achieve universal and affordable healthcare by centralizing pharmaceutical procurement.
- Ongoing regulatory reforms have given rise to a "new normal" in the pharmaceutical system. Cost containment has become a key policy priority. However, there are concerns regarding the potential innovation-stifling effects and long-term industry growth.

ISSUE

Since 2017, China has overtaken Japan to become the world's second-largest pharmaceutical market, holding about 11% of the global market share in 2022. Given the rapidly aging population and increasing demand for quality healthcare, the Chinese market is set to witness even faster growth of up to US$345 billion in 2024. China's drug expenditure surged from US$93 billion in 2013 to US$166 billion in 2022. In 2022, original drugs constituted 28% of the total drug expenditures while the share for non-original branded products was 31%. However, expenditures of this segment of the market have been experiencing slower growth due to strict cost control measures stipulated by the government.

Pharmaceuticals represent a deep-seated problem in China's healthcare system. Total drug expenditures increased 17 times from 1990 to 2009 at an annual growth rate of 15.2%. These expenditures used to form close to 50% of China's total expenditures on health, which is significantly higher than the average level in OECD countries. A dysfunctional drug procurement system was partly responsible, whereby a 15% price markup was allowed in public hospitals. The use of drug commissions in hospitals became commonplace, creating perverse incentives for doctors to overprescribe medication. This resulted in the medical impoverishment of grassroots patients due to high drug costs. This issue sat in sharp contrast to large volumes of sales made at pharmaceutical companies, which in turn were to benefit a few corrupt government officials and hospital administrators, ultimately leading to significant public discontent.

ASSESSMENT

In 2009 a landmark national healthcare reform vowed to achieve universal and affordable healthcare. The controversial 15% price mark-up on drugs was abolished, and the National Essential Medicines System was implemented to regulate the procurement and use of basic drugs in public medical facilities. In order to promote affordable pharmaceuticals, a two-invoices policy and a centralized procurement system were put in place.

THE TWO-INVOICE SYSTEM

The Chinese government stipulated regulatory control by centralizing pharmaceutical procurement to the provincial level, through which public hospitals acquired the bulk of their supplies. Unfortunately, there was little evidence that provincial competitive bidding had either increased competition among suppliers or controlled price increases. Too many intermediaries were involved in the supply chain, exacerbating cost inflation. The actual factory exit price barely accounted for 10% to 50% of the retail price on average. Sales-related expenses including kickbacks and commissions offered to doctors, intermediary agencies, hospitals, and sales representatives used to account for 30% to 70% in the cost structure of pharmaceutical companies that in turn created disincentives for innovation.

Building "an appropriate pharmaceutical supply system" was envisioned as a key policy objective in the national healthcare reform. Inspired by a local experiment in Fujian, the State Council officially adopted the "two-invoices" system in 2016. This system, designed to streamline the distribution chain, allows only two invoices to be issued in the procurement process: one by the pharmaceutical manufacturer and another by the distributor. By cutting out many of the previous intermediary agents, the cost of drugs fell rapidly. This policy led to a new ecology for the pharmaceutical supply chain in China. Fujian Province was the first to implement the two-invoices system and witnessed a significant decrease in the number of pharmaceutical wholesale enterprises from 375 in September 2014 to 272 by the end of 2015. Large enterprises started to hold even larger market shares. Retail sales for the top 10 pharmaceutical enterprises in Fujian surged to 86.5% in the wholesale market following the introduction of the two-invoices system.

NATIONAL VOLUME-BASED PROCUREMENT SYSTEM

The launch of the national volume-based procurement system in 2018 by the newly established National Healthcare Security Administration (NHSA) aimed to streamline pharmaceutical procurement at the national level and seek substantial price reduction through centralized bargaining with pharmaceutical manufacturers. The vast quantity of national-level procurement gave the NHSA enormous bargaining power while companies were able to secure significant sales volume. Both original branded drugs and generic ones were included in the procurement program, and price was considered the most critical factor in purchase decisions. By the end of 2023, the NHSA had completed 9 rounds of procurement exercises for 374 types of drugs, saving over 500 billion yuan for health insurance funds. Table 1 below exhibits the details of the exercises, while their effects on drug prices are shown in Figure 2. Notably, 96% of the products procured are generic drugs.

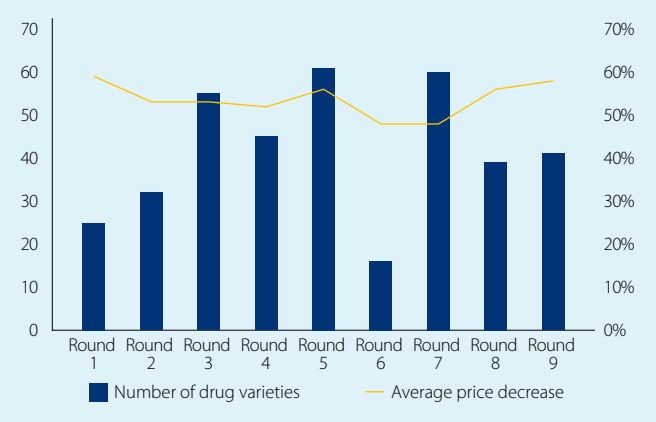
Table 1. Details of the National Volume-Based Pharmaceutical Procurement System

	No. of drug type	No. of bid-winning drugs	No. of bid-winning companies	Bid-winning ratio	Type of bid-winning companies	Average price reduction	No. of original drugs
Round #1 (2019)	25	25	45	/	7 foreign 38 domestic	59%	6
Round #2 (2020)	32	100	77	63%	4 foreign 73 domestic	53%	5
Round #3 (2020)	55	191	125	/	3 foreign 122 domestic	53%	3
Round #4 (2021)	45	158	118	77.6%	5 foreign 113 domestic	52%	2
Round #5 (2021)	61	251	148	73.6%	10 foreign 138 domestic	56%	10
Round #6 (2021)	16	42	11	/	4 foreign 7 domestic	48%	17
Round #7 (2022)	60	327	217	73%	6 foreign 211 domestic	48%	4
Round #8 (2023)	39	252	174	70%	5 foreign 169 domestic	56%	2
Round #9 (2023)	41	266	205	78%	5 foreign 200 domestic	58%	1

Source: NHSA, compiled by the authors

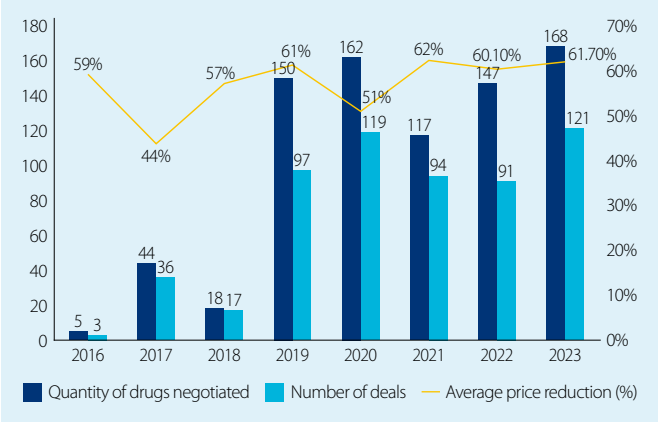
While the volume-based procurement system has been successful in managing generic drugs, the Chinese government has implemented national drug price negotiations to manage patented drugs. Characterized by clinical need but high costs due to a small volume of purchases, foreign patented drugs often become a cause of medical impoverishment for underprivileged patients, particularly those suffering from rare diseases. The NHSA and pharmaceutical companies negotiate under the condition that these drugs are included in the social health insurance catalogue. This inclusion is strategically important because it guarantees a relatively large volume of clinical use in public hospitals. The NHSA can therefore use *de facto* market access control as leverage for bargain prices. A typical negotiation exercise begins with an expert review to shortlist eligible patented drugs, followed by a one-on-one negotiation between the NHSA and the company. The NHSA sets the highest price that social health insurance funds can bear as a confidential threshold. Companies are given two opportunities to quote their prices and final negotiation will only proceed when the quotation falls within 115% of the threshold. Results from several rounds of negotiation exercises indicate a significant reduction of drug prices, averaging at 60% (Figure 3). In the meantime, there has been a notable increase in the total quantity of drugs procured and the actual volume of drug use. This significant increase in procurement spending can be attributed to the expanded accessibility of patented drugs.

Figure 2. Number of Drug Varieties and Average Price Decrease in Various Rounds of Volume-Based Procurement Exercises



Source: NHSA, compiled by the authors

Figure 3. Details of the Various Rounds of Drug Price Negotiation Exercises



Source: NHSA, compiled by the authors

CONCLUSION

Cost containment has become a key policy priority for the NHSA. These measures have not only earned public recognition but have also increased accessibility to medicine. However, this strict regulatory environment has reduced profit margins for the pharmaceutical industry. Losing a bid under centralized procurement can create far-reaching consequences for pharmaceutical companies. Losses in this market would force them to rely on alternative markets or private sector sales, which would still not compensate for the loss of public sector volume. Companies' market share and competitive standing in the industry are at stake. This profit decrease may deter them from investing in research and development, particularly innovative drugs. There are, therefore, increasing concerns regarding the potential innovation-stifling effects and long-term industry growth. The "winner takes all" logic of volume-based procurement may inadvertently lead to market monopolization. Public skepticism is also about the efficacy and safety of low-price generic drugs.

The Chinese health financing system is heavily reliant on social health insurance. However, rapid population aging and economic downtown are mounting financial pressure on its health insurance programs. Despite the increased financial accessibility of patented drugs, their clinical use still faces considerable hurdles due to stringent reimbursement conditions set by social health insurance agencies. As a result, hospitals are often reluctant to introduce these drugs into clinical use, thus limiting the policy's intended benefits to patients.

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