Impact Assessment of National Centralized Drug Procurement Pilot Policy (the “VBP”) & Study on VBP Impact and Procurement Guideline

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April 2020
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In November 2018, the Joint Procurement Office issued the “4+7” Cities Centralized Drug Procurement Document. On 6th December 2018, the bidding results of “4+7” VBP policy were publicized, and the average bid price was decreased by 52%.

In January 2019, the General Office of the State Council issued the Pilot Plan for National Centralized Drug Procurement and Use (issued by GOSC [2019] No. 2) (the “Plan”), the aim of which, through Centralized Drug Procurement, is to: (i) significantly reduce drug prices; (ii) vacate the cage to substitute birds; (iii) support the reforms in public hospitals; (iv) reduce the transaction costs for companies; (v) clean up the environment for drug distribution; and (vi) explore market-led mechanisms for drug price formation. In this context, the Central Committee of Biotechnology and Pharmacy of Chinese Peasants and Workers Democratic Party, has formed a joint research team to conduct a study on the impact evaluation of national centralized drug procurement pilot policy (the “Pilot Policy”) and on the design of procurement system. Policy suggestions on the reform of drug procurement system have been made based on the research results. The main results of the study are as follows:

1. Overview and Key Practices of the Pilot Policy

1. Implementation scope

11 cities (4 municipalities: Beijing, Tianjin, Shanghai, Chongqing; 7 major cities: Shenyang, Dalian, Xi’an, Guangzhou, Shenzhen, Chengdu, Xi’an) are selected in the Plan to start the pilot drug volume-based procurement (VBP). The significance of the VBP Policy is that it has determined the contractual relationship between price and volume, and achieved “volume-based price”, “price reduction for more market size” and “price reduction for volume guarantee”.

2. Administration

The basic ideas of the VBP pilot policy are: (i) the state formulates basic policies and determines the scope and requirements; (ii) 11 pilot cities form a procurement alliance; (iii) public medical institutions in 11 cities are buyers in VBP; (iv) the total purchase volume is 60% - 70% of the aggregated annual VBP drug consumption of all public medical institutions in pilot regions. The Pilot work is undertaken by the pilot workgroup and its office, together with Joint Procurement Office whose daily operation and the work toward policy implementation is undertaken by Shanghai Medical Procurement Administrative Agency. The organizational framework of VBP is shown in Figure 1 below.

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1. The key members of the collaborative study workgroup include: Shanghai Health Development Research Center, IQVIA, Chinese Pharmaceutical Enterprises Association, and China Association of Enterprises with Foreign Investment, the R&D-based Pharmaceutical Association Committee; on-site survey supporters: Peking University, Xi’an Jiaotong University, Sun Yat-sen University, and Shenyang Pharmaceutical University.
3. Drug Selection and the Results

The “4 + 7” VBP molecules are selected from the drugs with large sales volume in CVD, anti-cancer, antibiotic, psychiatric diseases and other common & frequently occurring diseases. Drugs that pass the Generic Quality Consistency Evaluation (GQCE) and the reference preparation of VBP molecules can participate in the bidding. 25 drugs are selected through VBP bidding, including 22 GQCE generic drugs (88%) and 3 originators (22%). Only 1 company selected for each molecule in 12-month procurement period. If procurement of pre-agreed volume is completed in advance in the procurement period, the selected price will still be applicable to the excess of purchase volume until the end of procurement period.

II. Preliminary Effectiveness of the Pilot Policy Implementation

1. VBP pilot policy lead to significant price reduction and multi-dimensional reform effects have begun to appear

The implementation of VBP policy has led to a significant reduction in drug prices. Compared with the lowest purchase price of in the 11 pilot cities in 2017, the prices of the 25 winning drugs have dropped by an average of 52% with the highest drop of 96%. The originators of gefitinib tablets and fosinopril sodium tablets have dropped by 76% and 68% respectively. The originator of flurbiprofen axetil injection made in China has dropped by 44%. VBP policy of “price reduction for more market size” has begun to take effect. Such significant drug price reduction affect the prices of non-selected drugs, which has boosted the effects of price reduction. In consequence, patient’s burden of drug expense has effectively alleviated. The results of the VBP Policy was effective on April 1, 2019. Up to the end of August 2019, the procurement volume of 25 winning drugs in the “4 + 7” cities was 1.7 billion tablets. The progress of VBP policy pilot exceeded expectations, and the purchase volume of the winning drugs accounted for 78% of 25 VBP molecule procure volume. The effects of pilot work have begun to appear.

The VBP Policy has: (i) specified drug prices and the purchase volume; (ii) changed the model of drug distribution through agreements; (iii) compressed the shady benefit chain of drug distribution; (iv) regulated the behaviors of delivery and purchase; and (v) reduced the costs in sales and transactions of pharmaceutical companies. In addition, the reduction in drug prices has also helped achieve the target of hospitals’ cost control. VBP policy of “volume-based price” has made good sense in the building of professional ethos of medical personnel. Healthcare security administrations may “vacate the cage to substitute birds” through the VBP and invest medical insurance fund in more valuable medical resource.

2. Expansion of VBP policy has benefited greater population

In order to boost the effects of the VBP Policy, China’s 25 provinces and Xinjiang Production and Construction Corps have formed a new cross-regional procurement alliance in September 2019 and started the VBP of the 25 winning drugs, except the “4 + 7” pilot cities and provinces including Fujian, Hebei & Taiwan, as well as Special Administrative Regions of Hong Kong & Macao, based on the valuable experience gained in the previous pilot work and under the guidance of the National Healthcare Security Administration (NHSA) and other agencies. The Pilot Policy has expanded to the whole country. The alliance has successfully completed the procurement of all the 25 VBP molecules. There are 45 proposed companies and 60 products winning VBP expansion bid, with an average reduction of 59% in the bidding prices compared with the lowest procurement prices in allied regions in 2018 and a reduction of 25% in average compared with “4 + 7” VBP price cities. In this round of VBP, the VBP Policy has started applying to following institutions: military medical institutions in expanded pilot regions, medical insurance designated social medical institutions & medical insurance designated retail pharmacies by voluntary participation. VBP expansion has solved the issue of large price difference of pilot drugs between “4 + 7” pilot cities and other relevant regions and has benefited more people.

III. Main Research Findings and Issues

During the implementation of the VBP policy, all parties concerned about the potential risks in the supply security, clinical use and drug quality of the winning drugs. Therefore, in this survey, a total of about 60 representatives of management and academic experts in medical insurance, medicine and from hospitals were invited to participate symposiums. From August to September 2019, five Symposia were held respectively in five cities —— Beijing, Shanghai, Guangzhou, Xi’an and Shenyang. A questionnaire survey was conducted among about 500 doctor representatives and 500 patient representatives from primary medical institutions, secondary and tertiary hospitals in representative cities; in addition, three company seminars were held in Beijing, Nanjing and Shanghai, with a total of 59 participating companies (including 7 bidding winners, 15 participating bidders, and 37 non-participating bidders) to collect information on issues and suggestions of VBP policy, and discuss the actual impact of the VBP policy on the drug accessibility for patients, doctors’ prescription rights, hospital management, drug quality, manufacturing and supply, procurement and medication.
1. Doctors tend to prescribe VBP winning drugs; different perceptions exist between doctors and patients

72.10% of interviewed doctors accept the VBP policy. Region and level of the interviewed doctor’s institution are the influence factors of acceptance degree; southern regions (i.e., Guangzhou and Shanghai) have lower degree of acceptance than northern regions (i.e., Beijing, Shenyang and Xi’an); the lower level of the medical institutions the interviewed doctor at, the higher degree of acceptance. The top three reasons for interviewed doctors partially rejecting VBP policy: inconvenient daily diagnosis and treatment, low efficacy of diagnosis and treatment, negative feedback from patients. 79.21% of interviewed doctors stated the increase in use rate of VBP winning drugs after VBP policy implementation; 58.95% of interviewed doctors believe the implementation of VBP Policy has certain effects on doctors’ prescription.

66.41% of interviewed doctors are familiar VBP policy. The higher professional titles of doctors, the more familiar he is with VBP policy. Doctors with intermediate and lower professional titles are less familiar with VBP policy. Interviewed doctors in Class II hospitals are less familiar with VBP policy than those in Class III hospitals and community health service centers. The interviewed doctors were mainly familiar with the overall Policy objectives, drug selection methods, bidding procurement methods and requirements for clinical use, etc. However, they had less knowledge of supporting measures for VBP policy and information on VBP winning drug. 59.44% of interviewed patients did not know VBP policy. Educational level, level of hospital they visit and region are relevant factors of patients’ knowledge of VBP policy as patients in Beijing and Guangzhou know VBP policy better than those in other regions, and for patients, the higher level of hospital they visit, the less knowledge of VBP policy they have, and the higher educational level, the more knowledge of VBP policy.

2. Positive feedback from patients on VBP winning drugs, despite regional differences in acceptability of drug substitution

According to patients’ feedback collected from interviewed doctors, most of feedback are positive (45.6%). Negative feedbacks (13.03%) mainly are “less choices of drugs” and “low efficacy of VBP winning drugs”; 77.11% of interviewed patients used drugs produced in China; 93.77% said that the drugs prescribed could satisfy their needs.

47.75% of interviewed doctors have encountered patient refusing VBP winning drugs. Patients in Beijing, Shanghai, and Guangzhou refuse VBP winning drugs more frequently than the other two cities. During the implementation of VBP policy, 39.74% of interviewed doctors said their patients had experienced switch back [i.e., VBP winning drugs were switched back to originators], with higher rates of switching back in Shanghai and Guangzhou compared with other regions. At the symposiums, some doctor representatives also mentioned that there is a quality gap between the VBP winning generics and originators in terms of efficacy. For example, the same clinical effect as originators can only be achieved by increasing the dosage of generics, and allergic symptoms occur at higher frequency in some VBP winning generics; During the treatment with antihypertensive drugs, patients occasionally experienced side effects such as large fluctuation of blood pressure, pruritus or gastrointestinal reactions, and the patients require to switch back to original drugs. In sensitive areas such as antihypertensive therapy, psychosis and post-cardiovascular surgery, physicians still prefer originators.

Only about 30% of patients are willing to switch drugs. 90.16% of the interviewed patients accepted doctors’ advice to change to VBP winning drugs, but the feedback from patients varies from regions. The acceptability of patients in Shenyang and Xi’an was higher than that in Beijing, Shanghai and Guangzhou. In addition, there remains difficulty in changing drugs for some patients, e.g., it is difficult to change the medication habits of patients with chronic diseases due to their high compliance with specific brands.

3. Hospitals place focus on monitoring use of VBP winning drugs and partially restrict doctor-patient medication options, the refined level of management needs to be improved

After implementation of VBP policy, medical institutions concern the management of VBP winning drug consumption, some regions adopt more mandatory regulations, e.g., apply fixed consumption ratio to VBP winning drugs; stop originators supply in certain hospitals due to policy pressure. These regulations partially resulted in constraints on doctors’ prescription rights and patients’ choices for drugs. In some regions, as the drug reimburse standard is gradually adjusted based on VBP prices, the reimbursement proportion for originators will be gradually decreased, causing dissatisfaction among some patients.

Policy publicity related work increased the workload of physicians. Influx of patients from non-pilot regions to pilot cities in a short time also increases medical staffs’ workload. Regular monthly completion and report of procurements in “4 + 7” cities after VBP policy implementation increased workload of frontline medical staffs and hospitals in pilot regions. During the interview, it was learned that the balance retained amount has not yet been liquidated and supporting incentives are unclear, since the implementation of VBP policy has not been completed for one year. Although workload of medical personnel increases, they lack remuneration for their work, leading to insufficient motivation among them. Before the “two allowances” salary system for medical personnel in pilot regions is substantially implemented, there will be greater resistance to the further promotion of the VBP Policy.
4. Because of only one winner in each molecule, some bidding winners face pressure of supply and quality control, leading to increase in drug quality risks

The "4 + 7" VBP policy allows only one bidding winner in each molecule. Successful bidders shall independently undertake the supply of contract purchases within the procurement cycle. This caused pressure of supply and quality control to some successful bidders.

In the short term, the historical production volume of some bidding winners is far lower than the bidding volume (Figure 2); the drug prices in pilot regions are significantly lower, leading to the "price depression effect"; some provinces follow up VBP Policy, increasing demand for selected drugs (Figure 3). Under the influence of comprehensive factors, the bidding winners are facing significant supply pressure. In order to meet the supply demand, the bidding winners are required to improve production capacity in a short period of time, which will increase the difficulty in quality control, causing a tough challenge to manufacturers. Therefore, it is necessary to pay close attention to the drug quality risks exacerbated by the accumulation of supply pressure.

![Figure 2 Ratio of drug bidding volume and bidding winner's output in 2017](image)

![Figure 3 Ratio of predicted yearly demands for winning drugs and the bidding volumes in pilot regions](image)

Additionally, ICH Q10 guidance for the quality monitoring throughout the product lifecycle requires to "facilitate continual improvement (of process performance and product quality) across all stages including reverse engineering/technology transfer, drug manufacturing, drug distribution, post-market surveillance using four pharmaceutical quality system elements and corresponding supporting systems (Figure 4). At present, the generic drug industry in China is at a critical stage of developing life-cycle quality management capability, and the quality control systems and quality control capabilities still need to be further improved. Specifically, some generic companies have limited attention to the construction of quality system, resulting in many weaknesses in the quality management throughout the product lifecycle, including: lack of quality culture, insufficient quality control personnel, limited personnel training; ineffective implementation of quality system; lower level of technology transfer and reverse engineering; insufficient raw material quality control in commercial manufacturing. Meanwhile, implementation of GSP requirements in distribution need to be accelerated; post-market surveillance and pharmacovigilance system need to be improved. After the implementation of VBP policy, potential risks in drug manufacturing and distribution have been further increased (Table 1) due to the intensified supply pressure, making it significantly more difficult to control the quality risks for some bidding winners.
Impact Assessment of National Centralized Drug Procurement Pilot Policy (the “VBP”) & Study on Procurement System Design

Table 1 ICH Q10 Framework of Quality Management Throughout the Product Lifecycle

<table>
<thead>
<tr>
<th>Link</th>
<th>Quality measurements</th>
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<tbody>
<tr>
<td>Manufacturing</td>
<td>Lack of professional skills and experience in drug manufacturing and quality control</td>
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<tr>
<td></td>
<td>Unreasonable proportion of drug quality testing personnel</td>
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<tr>
<td></td>
<td>Unsatisfactory quality control of APIs</td>
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<tr>
<td></td>
<td>Unsatisfactory quality control of excipients, and packaging materials</td>
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<tr>
<td></td>
<td>Unsatisfactory implementation of maintenance and validation of manufacturing environment</td>
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<tr>
<td></td>
<td>Ineffective implementation of Quality Risk Management (QRM) System</td>
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<td></td>
<td>Unsatisfactory implementation of terms in quality agreements</td>
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<tr>
<td></td>
<td>Inadequate monitoring of key quality indexes by carriers and transit distributors</td>
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<td></td>
<td>Inadequate assessment of shipment routes and risks by distributors</td>
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<tr>
<td></td>
<td>Inadequate temperature monitoring and tracking records during transportation and storage</td>
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<td></td>
<td>Lack of strict implementation of rules for drug traceability code</td>
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<td></td>
<td>Non-standardized destruction procedure during drug monitoring</td>
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<td>Delay in the follow-up of adverse reactions and labeling updates</td>
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Take the corrective action and preventive action (CAPA) system in the quality system as an example, ideally, CAPA system operates effectively to identify deviations and the causes in advance, and implement corrective actions in time, to continuously improve manufacturing process. However, it is difficult for generic companies to achieve such ideal CAPA execution level. In some cases of non-effective operation, it is impossible to identify abnormalities in advance and to find the direct and root causes of the problem for companies, hence the improvement measures cannot solve the basic problem and the potential risks continue to exist. In conclusion, it is necessary for companies to have an efficient CAPA system under the pressure of VBP to identify and correct quality risks in advance in order to prevent quality risks from spreading to pilot regions. The potential risks of raw materials and manufacturing might break out with rapidly increasing supply pressure if the bidding winner companies’ CAPA system, which causes obvious potential risk of VBP drug quality.

Change management in the quality system will also become a prominent risk under VBP pressure. In response to the price reduction and supply pressure caused by VBP, some bidding winners have implemented change, including but not limited to: expanding the production line/capacity greatly beyond the GQCE approval volume; initiation of new production lines for drug manufacturing; changing APIs, excipients, and packaging materials, and applying cost-saving manufacturing process, etc. Due to supply pressure or weak awareness of quality control, some companies may lack enough validation of process changes, or insufficient compliance of the change procedures, which lead to the problems such as failure to identify change requests, insufficient change assessment, non-standardized change implementation, non-compliance of change procedures, lack of change assessment, etc. Take the drug capacity expansion for example, the potential quality risks will be increased accordingly if the change management is not qualified. Therefore, the interviewed experts and companies generally emphasized that it is necessary to pay close attention to the standardization of change management implemented by bidding winners. In summary, the supply pressure caused by VBP may lead to quality risks if generic companies lack capabilities in quality control across the entire product lifecycle.

5. The rule that winning by the lowest bidding prices influences the operation of companies with low-profit, affecting continuous quality improvement

Drug marketing authorization holder (MAH) system is an important measure to deepen the reform of drug registration system in China. This system regards the drug MAH as the first person responsible for the quality system and requires the MAH to take primary responsibility for drug quality throughout the life cycle. Usually, the bidding winners, as the drug developer and manufacturer, act as the first person responsible for the quality system. However, the price pressure of VBP affect the continuous quality improvement by the bidding winner as the first person responsible for the quality system. On the one hand, some bidding winners may take cost-saving measures that affect quality, resulting in potential quality risks; on the other hand, when companies operate with low-profit, it will be more difficult to increase their investment in the sustainable construction of the quality system, and the drug quality risks will accumulate continuously.

The VBP led to price reduction pressure of the selected drugs. The average price reduction of 25 winning drugs is 65%. 8 winning drugs cut price by > 80%, and 4 winning drugs cut price by → 90%. The sharp price reduction of the winning drugs has aroused industry’s attention to the drug quality. According to the interviewed experts and companies, to relieve price pressure, some bidding winners may take cost-saving measures, including but not limited to: use low-price APIs, excipients, and packaging materials instead of high-price ones, have less quality requirements for APIs, excipients and packaging materials and reduce frequencies of maintenance...
and validation of manufacturing environment, etc. The questionnaire also showed that the most industry experts clearly agree that short-term price pressure will induce individual generic drug companies to take cost-saving measures, resulting in quality risks.

After the implementation of the VBP policy, the bidding winners are facing stricter quality standards. They urgently need to establish, upgrade and improve the quality management system to ensure drug quality. However, on the one hand, the sharp price reduction of drugs and profit shrinks caused by centralized procurement make bidding winners’ focus to ensuring supply and saving costs, and have less emphasis on life-cycle quality management; on the other hand, generic companies operating at low profit levels lack sufficient resources and capacity to invest in continuous improvement of life-cycle quality management. If situation goes on like this, generic companies would lack capacity to improve the quality system, reduce quality supervision, making the quality system to fail in risk identification and risk control.

6. Pharmaceutical industry cautiously promote GQCE while the attractiveness of industry invest decrease

Some companies reflected that after the implementation of VBP policy, they have become more cautious in the decision-making of GQCE, and fully considered the capital investment and anticipated market benefits required for GQCE to make GQCE decision. GQCE ask for consistency evaluation on product quality and company capital, hence not all companies have the technical and capital strength required by GQCE. GQCE will increase industry concentration in generic market. Therefore, before the implementation of VBP policy, the motivation for companies to carry out GQCE is to achieve monopoly premium and/or expand market share through GQCE.

However, companies with GQCE drugs did not obtain monopoly premium but experienced a sharp price reduction due to VBP. Small and medium-sized companies without sufficient large-scale capacities and cost advantages have withdrawn from most of the market (50%-70% of the market share taken by VBP bidding winners). For such companies, the initial willingness to expand the market share is also difficult to achieve. Meanwhile, when the drugs passed GQCE, companies are facing the possibility of being listed in VBP, and the motivation to participate in GQCE may be greatly reduced. In the absence of follow-up GQCE incentive policies, companies participating in GQCE would mainly be large companies with cost advantages. Moreover, as the overall return on investment of GQCE is expected to drop sharply, the scale of investment to GQCE will also drop sharply, and companies will be more cautious in choosing products for GQCE. Attitude changes of pharmaceutical companies towards GQCE can be verified by CDE’s GQCE data. From April 2018 to January 2019, the number of monthly acceptances of oral formulations’ GQCE application gradually increased. Subsequently, that acceptance number dropped significantly to 30 in April 2019. Except for July 2019, the monthly acceptance number from March to November 2019 was lower than the average volume during nearly 1.5 years.

IV. Major Policy Recommendations

1. Suggestions on optimization of the VBP Policy Expansion and supporting policies and measures

Based on the pilot experience in the early stage, the bid winning rules have been improved and adjusted in the VBP expansion. The number of bidding winners should be increased based on the number and quotation level of participating companies, and the bidding prices of different winning companies can be different for guiding companies to compete orderly. The increased number of bidding winners also avoids the risk of shortage supply and monopoly caused by exclusive winner, and ensures the long-term and stable implementation of the national drug centralized procurement policy. However, continuous attention is needed in the aspects of supply security, quality monitoring, policy publicity, supporting incentives, rational use and industrial development etc.

(1) Continue to promote the interpretation and publicity of the VBP Policy

Hospitals and public media should strengthen the publicity of the VBP Policy and improve public awareness, so as to further increase public recognition of the Policy. In particular, the publicity should be aimed at patients using winning drugs, that is, more patients can know the sharp price reduction of drugs by the Pilot Policy, which is conducive to reducing the economic burden of patients’ medication. It can not only relieve the policy interpretation by clinical frontline medical personnel, but also facilitate the smooth progress of Policy and improve the acceptance and satisfaction of patients.

(2) Develop a refined usage management strategy for the winning drugs

Medical institutions are required to develop a more refined management strategy for the winning drugs, take rational use of drugs as the key point of drug management and guide doctors to gradually achieve the prescription quantity of winning drugs, rather than mandatory administrative regulations. At present, the incentive measures for medical staffs are still unclear, and the enthusiasm of medical staffs is poor. It is suggested to establish a positive incentive mechanism related to the implementation of VBP Policy through the formulation of medical insurance payment rules, and increase the enthusiasm of the medical staffs through a positive incentive mechanism, to ensure the smooth implementation of the VBP expansion policy.

(3) Strengthen the monitoring of the supply shortage of winning drugs

In the long run, the bid fails face the dual pressure of decreasing market demand volume and falling price. Companies lacking advantages in scale and cost will be excluded from the market. The market may become relative monopoly. If there are fluctuations in raw materials, production or distribution of companies in a comparative
monopoly position at this time, it will lead to a wide range of supply risks in the market. Therefore, it is suggested to continuously pay attention to the influencing factors of long-term stable supply and regional shortage of winning drugs.

(4) Continuously follow up the potential quality risks of the winning products

In 2016, after the NMPA further advanced the GQCE policy, the quality of generic drugs in China has been gradually improved, but the improvement of quality management in the industry is still an arduous task. At present, there are still many deficiencies in quality culture, quality management talents and quality system in generic companies, including lack of a solid quality culture, insufficient attention to quality management by leadership, lack of quality management talents, incompetent drug full life-cycle quality management system and pharmacovigilance and adverse reaction monitoring system. Long-term quality control mechanism should be implemented to pharmaceutical companies of drugs passing GQCE. Full life-cycle quality management should be conducted in the production, distribution and use of winning drugs. Regularly publish adverse reaction monitoring report of winning drugs, and ensure the quality of the winning drugs used nationwide.

Drug procurement is only one of many parts in the drug supply security system. The parallel progress of the relevant supporting reform measures should be considered if the policy target is to control the drug expenditure and achieve the goal of drug supply security system. Firstly, improve the system of centralized procurement and use of drugs, clarify its policy positioning in the medical reform, and use the centralized procurement as a breakthrough to further deepen co-movements. Secondly, accelerate the reform of medical insurance payments and explore and formulate drug payment standards as soon as possible. Thirdly, rely on clinical comprehensive evaluation of drugs to promote the selection and rational use of drugs with real world data. Fourthly, rationally adjust the structure of medical expenses, better reflect the labor value of medical staff, and promote the reform of public hospital performance and salary system. Fifthly, attach importance to the development trend of the generic drug industry, promote investment activities for the improvement of generic drug quality and process optimization, and vigorously promote the sustainable development of generic drug industry in China.

2. Policy Suggestions on Design of Future National Procurement System

Before 2000, China’s drug procurement was mainly based on decentralized procurement by medical institutions. Since 2000, China has experienced a variety of procurement modes, such as centralized bidding and procurement of drugs organized by prefecture-level municipalities, online centralized drug procurement by provinces, “double envelope” procurement of essential drugs, etc., and gradually formed drug classification procurement mode. In 2018, NHSA was established and launched “4+7” VBP policy, opening a new stage of medical insurance-led VBP and initiating the VBP policy led by medical insurance.

On the whole, the drug procurement system concerns China’s drug supply guarantee and drug safety. Therefore, the top-level design of the drug procurement system and the ownership of rights and responsibilities are very important. National Healthcare Security Administration is the core designer of the drug procurement system, who is responsible for the establishment of a unified procurement platform, the transparent release of procurement information, the implementation of centralized drug procurement supervision, and the design of the medical insurance payment system. National Medical Products Administration promotes the quality tracking of winning drugs and winning enterprises, which encourages the diversification of centralized medicine procurement entities and promotes the practice of multiple procurement modes such as regional centralized procurement or group procurement (GPO).

Considering the development experience of centralized drug procurement policy in China, with systematic summary of the experience of typical countries and regions implementing the centralized drug procurement policy led by the public agencies, represented by the European Union, Australia, Singapore, Hong Kong and Macau, the following development suggestions for the design of the national drug procurement system are proposed based on the strategic goal and operational principles of public agencies drug procurement in the "Operational Principles for Good Pharmaceutical Procurement" of WHO:

(1) Follow the basic drug market principles and insist on procurement pattern considering drugs’ classification

International procurement forms mainly include bidding procurement and negotiation procurement. Other procurement forms also include direct procurement, invitation-to-tender procurement and rebate procurement etc., which are flexibly used in different countries and regions. VBP is only one of them. The centralized drug procurement should be continuously adhered to implement an open and transparent procurement considering drugs’ classification (VBP, negotiation, online procurement, manufacture in designated site), and classify all kinds of purchased drugs according to the different characteristics of different classes of drugs. For example, VBP is applicable to drugs in heavy use with wide range of application, widely accepted generic drugs made in China with guaranteed quality, and drugs that can be supplied by many eligible companies. VBP should be held off for newly marketed generic drugs while originator drugs are still in the phase of expanding indications, generic drugs with great quality differences to the innovator drugs and generic drugs with higher replacement risks. VBP is not applicable to exclusive drugs, drugs in shortage with small procurement volume & narrow therapeutic window. Therefore, the future drug procurement should allow independent online procurement in pilot cities in addition
to actively promoting national VBP by drawing on the current international practices of drug procurement, in accordance with the general requirement that the market plays a decisive role in resources allocation and the government plays a better role. It should give full play to the role of provincial centralized drug procurement platform during the entire process of drug procurement to guarantee the quality and supply of drugs.

(2) Actively play the organizational role of government & promote diversification of purchasers

Government plays an important role in drug procurement from the perspective of current international centralized drug procurement policy: on the one hand, government performs functions of quality regulation and price control; on the other hand, it improves capability of drug bargaining taking advantages of large procurement volume based on drug demand in medical institutions. For the form of organizations, except central procurement led by the NHSA, it should encourage regional or group procurement led by provincial/municipal authorities or hospital alliances, or drug procurement conducted by group purchasing organizations (GPOs), to promote diversification of purchasers in centralized drug procurement.

(3) Improve principles of drug procurement to ensure controllable procurement risks

Drug procurement risks include procurement fund risks, drug quality risks, drug supply risks, corruption risks in organizations, industrial development risks, etc. Scientific & comprehensive operation principles should be established to control multidimensional procurement risks. Firstly, it should establish an efficient and transparent organizational management system, making full use of technical support from experts, taking the needs of different stakeholders into account; advance the system by written procedures and publicize relevant work standards; specify procurement plans and establish a performance monitoring system and an industry regulatory mechanism and a third-party assessment mechanism for procurement work. Secondly, in respect of drug selection and specification of procurement volume, priority should be given to the purchase of NEDL drugs and NRDL drugs, the procurement and bidding documents should use the molecular names of drugs, procurement volume should base on actual demand. Thirdly, in respect of financing and competition, it should ensure stable sources of financing for drug procurement & achieve volume-based prices with the principle of economies of scale. For drug procurement by public medical institutions, priority should be given to competitive bidding, and members of “group procurement” must purchase drugs from agreed suppliers. Fourthly, in respect of supplier selection and quality assurance, pre-assessment of supplier qualifications (product quality, service reliability, delivery time and financial stability, etc.) is needed, while using international standards to ensure quality of purchased drugs (i.e. drug defect reports).

(4) Introduce comprehensive evaluation of drug procurement to ensure standardized procurement processes

According to the drug procurement strategic goals of public agencies set by WHO, a multidimensional comprehensive evaluation system (focus on dimensions like economics, quality and efficiency) of a drug procurement process should be established to ensure the process standardization. In drug selection, the most cost-effective common (essential) drugs should be given priority in purchasing, with accurate calculation of the supply volume deliverable to reduce risks of inventory and shortage. The first choice would be the reliable high-quality drug suppliers with effective systems for quality regulation and monitoring. Procurement and delivery systems should be able to ensure timely and effective delivery of drugs at lowest total costs (including drug purchase prices; hidden costs due to poor drug quality, poor supplier performance or short shelf life; inventory costs at all levels of supply system; operation and management costs in procurement and delivery systems).

Conclusion: The collaborative project team carried out a 9-month study, visiting 5 cities including Beijing, Shanghai, Guangzhou, Xi’an and Shenyang, and investigating 500 doctors, 500 patients, 60 hospital administrators and 59 company representatives. Doctors and patients provided positive feedback on the impact of the pilot policy. The implementation of the pilot policy should be optimized, and potential risks are existing in supply and quality assurance. For this reason, the collaborative project team has shared the results of the study with the NHSA, NMPA and NHC as well as some local healthcare security administrations, medical products administrations and health departments through various ways. In view of the implementation of the “4+7” VBP Pilot Policy and the expansion of the VBP policy to 25 provinces, the collaborative project team has exchanged relevant improvement suggestions, some of which have been approved and adopted by relevant departments. The collaborative project team expresses its heartfelt thanks to the relevant leaders, experts, scholars and industry colleagues who care about and support the project.