

The Dilemma of Drug Price Regulation and Countermeasures in China

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Abstract: From an international comparative angle, this paper investigates the cause, pattern and failure reasons of China's drug price regulation, and finds that it is the government inappropriate regulation pattern rather than the combination of prescribing and dispensing that made the drug price control unsuccessful. Owing to the complexity and uncertainty of the reform of separation of prescribing and dispensing, authors think that the more appropriate approach to improve government interventions on drug price is to take the fixed reference-pricing reimbursement, one new regulation form with an incentive to make medical facilities to prescribe cheap drugs, and to control evasive behaviors of stake-holders by completing some relevant arrangements.

Keywords: Drug price regulation, Combination of prescribing and dispensing, Fixed reference-pricing reimbursement

1 Introduction

The Chinese drug price regulation pattern has fallen into a dilemma. On the one hand, from 1998 to 2005, the government has for 17 times cut prices of the drugs included in the formulary of the Basic Health Insurance (BHI); however, consumers seemed not to be benefited from these price reductions, for prices of drugs prescribed and dispensed in hospitals were still maintaining on a very high level. On the other hand, pharmaceutical manufacturers have suffered greatly from these price-cut measures. For example, in the latest price reduction in 2005, 24 medical industry associations, including the Association of China Chemical Drug Manufacture, voiced together against the government's price-cut plan, and eventually forced it to be modified.

Nowadays, there are two popular policy suggestions about how to improve drug price regulation in China. One of them emphasizes that it is the combination of prescribing and dispensing rather than the price regulation pattern that makes drug price control unsuccessful. Therefore, only after separating prescribing from dispensing can the existing regulation pattern obtain its objectives^[1-3]. The other is also for the separation of prescribing and dispensing, but definitely against drug price regulation. It believed that the best way to control prices of drugs is to let them to be determined by the free competitive market. It argues that regulation would do nothing but distort the resources allocation of pharmaceutical industry^[4].

No doubt, separation of prescribing and dispensing would have positive impact on keeping drug price reasonable. However, separation reform is a very sticky business and full of uncertainties, for this reform needs to change the existing state of interest distribution radically. Besides, in a separation healthcare system, every pharmacy must have at least one pharmacist with strict professional pharmacology training in order to prevent drug misuse, but this requirement can hardly put into practice in current China because of the under-supply of the qualified pharmacists. It is, therefore, not optimistic to rely on the separation reform of China's healthcare system to solve the problem of drug price regulation quickly. On the other hand, it is also not appropriate to employ market competition mechanism for the drug price control under the current healthcare system, for the reason why government re-regulate prices of partial drugs price in late 1990s is that the previous deregulation led to the rapid increasing of drug price. Is there a third way, that is, only by reforming the price regulation pattern under the condition that the traditional healthcare system maintains unchanged, to control the price level of drugs effectively?

This paper will discuss this third way. It is organized as follows: Section 2 analyzes the motive difference of drug price regulation between developed nations and China from the viewpoint of relative institutional background. On this basis, by comparing to the drug price control performances in Japan and Korea, Section 3 demonstrates the reason for the failure of the existing regulation pattern. Section 4 put forward several suggestions for how to improve drug price regulation. And Section 5 concludes with the principal findings and some issues to be research further.

2 Motives for drug price regulation

2.1 Motives for drug price regulation in developed nations

Around developed nations, except the US, almost all other nations adopt some kind of drug price regulation. For these nations, whether governments regulate drug price is closely related to their systems of health insurance. If a nation's health insurance scheme covers its entire population, this nation's government will control drug prices; if not, drug prices will probably be determined by the free market. For example, there is no universal social health insurance scheme for the whole people in the US, so its drug price is not regulated too. While in the nations which has established a health insurance system for the entire population, their governments all adopt a certain direct or indirect regulating

method to intervene drug price^[5]. The corresponding relationships between these two institutional arrangements mean that, under universal social health insurance, the government has become the third party to actually offer medical expenditure. Under these circumstances, neither the patient nor the medical service providers has the incentive to control expenditure. Especially, when medical service is totally cost-free to a patient, to maximize his own utility, the patient will consume the medical service until his marginal utility equals zero^[6]. Obviously, if there is no corresponding controlling method, medical service would inevitably be over expended. On the other hand, in order to restrain medical service provider's moral hazard, the third party insurers than individual consumers have more advantages in controlling the prices of medical services and drugs because of their strong monopolistic powers^[7]. Therefore, most of governments would control the prices of drugs if their expenditure is reimbursed by public health insurance scheme. Similarly, it is also easily understood that why the US government did not regulate drug prices itself but leave it to private managed care organizations (MCOs) or pharmaceutical benefit management corporations (PBMs)^[8]. Besides, drug price regulation is less politically sensitive than other cost containment methods^[9].

Moral hazard under the third party reimbursement means the range of drug price regulation by government should be limited to the drugs which can be reimbursed by social health insurance. In fact, many evidences from the developed nations have already verified that the scope of drugs which prices are under the government control is limited to those reimbursed by social health insurance scheme.

Therefore, according to above analysis, we can conclude that in developed nations, the excessive drug expenditure caused by universal health insurance is the direct motive for drug price regulation.

2.2 Motives for drug price regulation in China

Chinese government started to re-regulate drug price since the late 1990s. At that time, the rural cooperative medical system established in the period of planned economy had almost collapsed; while in urban areas, the traditional health security system had also shown its conflicts with market economy. As a result, from 1980 to 2000, the ratio of health expenditure shared by individuals had increased from 21.2% to 59.0% while decreased from 78.8% to 41.0% for the part shared by individuals and nongovernmental organizations. In addition to that, after more than 10 years' hospital reform and the deregulation of drug price between late 1980s and early 1990s, medical market has fallen into a chaotic state. From 1988 to 1997, drug price had increased by 116.5%, and the average expenditure on drugs by outpatient and inpatient had respectively increased by 419.5% and 471.7%.

There are several reasons for the high drug price in China, which has not established universal health insurance yet.

(1) Asymmetric information.

Disease treatment is a highly professionalized occupation. It is physician who diagnoses what disease the patients get and what medicine they should take. Patients usually do not know how to cure their diseases. This kind of asymmetric information means that prescription drugs are mainly sold to physicians although the real users of drugs are patients. This characteristic of medical service enabled physicians to conduct their moral hazard behaviors easily.

(2) For-profit public hospitals under combination of prescribing and dispensing

Unlike most developed nations, in China, physicians both prescribe and dispense drugs in hospitals, and hospitals are permitted to earn revenue from drug sales. Under this background, with the deepening of hospital system reform and the reduction of government financial support, non-profit public hospital gradually degenerated to for-profit ones. However, because public hospitals do not have definite residual claimant as private ones, they often encounter more serious agent problem when they begin to seek profit. As a result, physicians' profit-seeking behaviors are connived to be normal and compatible with the hospital's economic interest.

(3) Lack of multi-level medical service system. In developed nations, medical service system can generally be divided into two levels. One is primary medical service provided by general practitioners or family doctors in their own clinic. The other is hospital service provided by special and synthetic hospitals. Under this obvious layered medical service system, general practitioners and patients often form a relatively stable relationship. This kind of doctor-patient relationship requires the doctors to maintain his reputation, so that the moral hazard of "inducing demand" can be voluntarily restrained to some extent. However, there is no such kind of medical service system in China. Usually patients go to hospitals directly, and in most cases, the service provided by doctors in hospitals is a one shot trade. Therefore, the "reputation" is not so important for a doctor to restrict his moral hazard behavior for the patients' interests.

(4) Kickback in drug sale. In the beginning of 1990s, foreign-investment pharmaceutical manufactures started to sell drugs by medicine representatives. In developed nations, it is a typical pattern to propaganda and market new drugs. However, this pattern evolved into a "kickback" competition for marketing drugs into hospitals in China, because more kickback is, more easily drugs sale. In such a drug market, high pricing naturally became an optimistic choice for pharmaceutical manufacturers. In fact, this kind of pricing strategy is actually the simplest way for pharmaceutical manufacturers to save transaction cost.

Thus, the motive for drug price regulation in China is different from developed nations'. It aims at cutting the high margin between drug's wholesale and retail price instead of controlling medical resources over-employment induced by

third party reimbursement. Chinese government take drug price regulation as an important tool for solve alleviating individuals' medical expenditure burden.

Tab.1 Retail and wholesale drug price ratio in several European nations and China*

Nations	UK	Sweden	Netherlands	Italy	France	Spanish	Denmark	Germany	China
Price ratio	1.24	1.25	1.27	1.29	1.38	1.39	1.41	1.46	2.5-10.0

Resource: Taylor, Mrazek and Mossialos (2004) and Luo zhongwei (2005)

*: In European nations the price ratio is retail price in drug store: wholesale price. In China, the price ratio is retail price in hospital: wholesale price

3 Analysis of drug price regulation failure

3.1 Current drug price regulation pattern

There are two methods of drug price regulation in China. One is direct price control; the other is competitive tendering. The former's characteristics are: first, the government directly set the price for every drug included in the formulary. Second, it allows the pharmaceutical manufacture to apply to government for individual pricing specifically, that is, if certain manufacture can prove that its drug's therapeutic effectiveness and safety are obviously superior to the other drugs of the same kind, it can apply for a higher price than the existed official price for other drugs.

Competitive tendering was tried out in 1999 and expanded universally in 2000. One of its outstanding characteristic is that the retail prices of drugs are made based on the wholesale price plus a constant rate. The rational return for hospitals is set with a constant percent of bidding price by provincial price administration departments.

Table 1 compares the retail and wholesale drug price ratio in several European nations and China. From these data, it can be seen that although drug price has been regulated by the above two means, relative to developed nations, the markup between retail and wholesale price in Chinese hospital market is much bigger than that in European nations.

3.2 Experience of drug price regulation in Japan and Korea

It is generally believed that the failure of these two price regulation methods roots from the combination of prescribing and dispensing. From the experiences in Japan and Korea, however, this viewpoint is not true. In Japan, physicians could also dispense the drugs that they prescribed; however, under governmental price regulation, drug price decreases continuously^[10]. While in Korea, despite the government implemented the reform of mandatory issuing of prescription in 2000, that is, from that year physicians would not dispense the drugs that they prescribed, the drug expenditure in social health insurance sharply went up.

The reason of Japan's effective drug price reduction is that it adopts a price regulation pattern appropriate to its healthcare system combined prescribing with dispensing. This pattern's outstanding characteristics are: first, the scope of drug regulation is very wide and covers all the prescription drugs. Except for that, for the drugs that are not included in National Health Insurance (NHI), the patients should not only pay for the drugs prescribes to them but also all the other relevant medical expenditure^[11]. Second, The medical facilities in Japan are reimbursed 100% of a drug's NHI price regardless of the cost price to that facility. This has given physicians the incentive to prescribe high priced reimbursed drugs at a low selling price to generate profits. Third, the reimbursement price is adjusted every two years. New reimbursement price would be promulgated for the drugs when the difference between weighted average of their real price and the reimbursement price exceeds rational range.

So, under this situation, pharmaceutical manufactures have strong incentives to price their products as low as possible, for the lower drugs' prices, the bigger demand for them. Eventually, the result of governmental regulation is continuous drug price reduction. Conversely, Korea had also adopted this similar regulation method before its reform, but the drug expenditure went up sharply after separating drug prescribing and dispensing. The reason is that hospitals and physicians no longer have the incentive to prescribe cheap drugs after the interest linkage between physicians, hospitals and drug revenue was cut off^[12].

3.3 Flaws in existing regulation pattern

The experience in Japan and Korea has shown that separating prescribing and dispensing is not necessary for controlling effectively drug price, and concrete regulation methods also play an important role. For China, since its healthcare system is similar to that of Japan and its regulation of drug price aims at cutting the margin between the retail price and the wholesale price, an effective regulation pattern should at least have the following two functions: one is to reduce as much as possible the opportunities which can be taken by stake-holders to avoid government regulation; the other is to stimulate physicians to prescribe low price drugs. Obviously, the existing regulation pattern have no such functions because of its flaws existed in the following aspect.

(1)Regulation range. Only part of drug price is regulated by the government, that is, drugs which are not included

in the formulary are priced by the manufacturers independently. Obviously, this partly regulating method leaves spaces for hospitals and manufacturers to avoid governmental regulation.

(2)New drug application. In this aspect, both the definition of new drugs and their evaluation and approval are too loose. Illustrated by data in 2004, the SFDA of China accepted 10009 kinds of new drug applications, while the FDA of the USA only accepted 148 kinds. This difference shows the fact that pharmaceutical manufactures in China have a lot of alternatives, such as changing dosage, specification, and package or adding a little irrelative component so as to transform the cheapened drug to so called “new drugs”, to avoid the government regulation.

(3)Brand name prescription. In China, the pharmaceutical manufacturers prefer to applying brand names to their drugs. The reason is that the brand names could enable it easier for physicians and medical facilities to make profits by substituting expensive drugs for cheap ones with the similar therapy, since drugs with brand names could strengthen further the existing asymmetric information about drug usages between physicians and patients. Thus, in China, brand name has become a tool for pharmaceutical manufacturers and medical facilities to avoid government regulation.

(4)Individual pricing. In order to encourage pharmaceutical manufactures to improve the safety and therapeutic effectiveness of the drugs, the rule of individual pricing was promulgated in Nov. 2000. However, in practice, this rule’s function equals to splitting a crack on the governmental price control net, and giving more opportunities for pharmaceutical manufactures to avoid governmental regulations.

(5)Price markup method. Under the combination of prescribing and dispensing, the price markup added with a fixed rate in compulsory competitive tendering provides the incentive for hospitals to give priority to the drugs with higher price or more kickback among the same kind which have win the bid. In order to eliminate the negative effect of price markup, the State Development and Reform Commission have ordered recently all the provincial price administrations to implement price markup with differentiated fixed rates for drugs with different price levels. From the differentiated rates implemented, however, this new directive is not enough to change hospitals’ preferences to buying drugs with higher prices.

4 Suggestions for improving drug price regulation pattern

Based on above analysis, we think that the current regulation pattern should be improved from the following three aspects.

4.1 Encouraging low price drugs usage by fixed reference-pricing reimbursement

Fixed reference-pricing reimbursement includes two parts: one is reference pricing, the other is the reimbursement method in Japan. Reference pricing is firstly adopted by Germany in 1989^[13]. Recently, it has been adopted by Netherlands, Spain, New Zealand and the British Columbia in Canada ^[14]. With this method, drugs are clustered according to their active component, equivalent or similar therapeutic effectiveness, and then charged a single price (reference price) that can be reimbursed by health insurance for all the drugs in one cluster. When real price exceeds reimbursement price, patients pay for the difference themselves. When real price is below reimbursement price, it is reimbursed according to real price.

The advantages of this price regulation method are, first, it can intensify price competition among drugs in the same cluster because the patients with health insurance would try their best to ask physicians not to prescribe the drugs whose prices exceed reference price. Second, the subjectivity rooted from the traditional cost-plus pricing can be avoided because manufacturers are free to charge prices on their products. However, in the context of the separation of prescribing and dispensing, reference pricing may reduce competition below the reference price since physicians can not obtain profits from drug’s sale.

The difference between fixed reference-pricing reimbursement and reference pricing is their reimbursement methods. That is, the former one follows the Japanese fixed price reimbursement way. The drug expenditure is reimbursed according to reference price instead of real price so as to provide the incentive for medical facilities to use cheap drugs.

Obviously, compared to the current price regulation, fixed reference-pricing reimbursement is more appropriate for China’s drug price control. But in order to conduct this method more effectively, we have to solve the following two problems well.

(1)Relationship between hospitals and patients: first, hospitals must list publicly the real tendering price and reference price of all their prescription drugs. And the price should be publicized in reference clusters so that patients can easily know drug alternatives. Second, the makeup added by fixed rate should be abolished. For patients with BHI, the drug expenditure can be reimbursed with reference price; while patients without BHI could pay the real price. This rule can protect patients without BHI, since most people in China has not be included in BHI now. Third, charging for prescriptions so as to offset hospitals’ revenue loss caused by eliminating markup added by fixed rate. Further, this rule can set a basis for separating prescribing and dispensing in the future. Fourth, empowering patients to ask for cheaper drug in the same cluster. If not suitable, physicians must explain the reason to patients. From German experience, this rule is helpful to restrain physicians from prescribing the drugs whose real price exceeds reference price, for

explanation occupies physicians' time and reduces their income from prescription^[15].

(2) Determination of reference price. First, to avoid the impact of local government protection, the reference price should be set by national administration uniformly. The level of reference price can be determined according to certain cheap drugs in the cluster. However, the reference price could not be too low so as to ensure hospitals have enough incentives to use cheap drugs. Second, to encourage manufactures to develop innovative new drugs (generally with compound patent) and restrain imitated development (such as adding some irrelative components and changing dosage), the imitated drugs should be grouped with generics, and be reimbursed by fixed reference price. Only for the real original ones, single pricing is promulgated. Third, price adjustment must be made on a constant time basis so as to encourage manufactures to improve efficiency and reduce cost under stable expectations.

4.2 Reducing the possibility of avoiding price regulation by stake-holders

(1) Expanding the range of drug price regulation. That is, all the prescription drugs should be brought into the formulary and OTC drugs should be kept out. The reasons for this adjustment is as follows: First, since consumers can directly buy OTC drugs in drug stores where existed price competition, it is unnecessary for the government to regulate their price; second, regulation for all the prescription drugs can effectively restrain pharmaceutical manufacturers from avoiding governmental regulation by switching to the drugs excluded in the formulary.

(2) Strengthening new drug application and brand name registration supervision. A stricter procedure should be implemented for evaluating and approving new drugs. Besides, to prevent local government's intervention on new drug evaluation and approval and drug production, provincial drug administrations should be put under the supervision of the State administration.

(3) Regulating physician's prescribing behavior. Except for real new drugs (such as new chemical entities), physicians should prescribe with generic names. If the imitated drug is really different from the same cluster's generics, the brand name could be marked additionally. However, because of the particularity of drugs, this exception should be eliminated as quickly as possible by reinforcing the supervision of GMP, for example, the FDA in the USA orders that drug's therapy and side effect must be the same for both brand and imitated^[16].

4.3 Improving compulsory competitive tendering

Competitive tendering should be improved from the following aspects: first, tendering area. It is suggested that tendering area be partitioned according to provinces so as to save cost for pharmaceutical manufacturers; Second, the principal of bid invitation. It is suggested that health insurance organizations (including commercial insurance companies) initiate the bid invitation, select and engage relative experts such as physicians and pharmacists to set up the bid invitation organization and answer for bid invitation issues; Third, range of tendered drugs. All the prescription drugs should be included into the tendering range. And it should be regulated that hospital purchase all the prescription drugs through tendering and mandatory issue OTC drugs; Fourth, purchasing contract. It is suggested that bid invitation initiators supervise the subscription of drug purchasing contract by hospitals and bid-winning manufactures or agents. Purchasing contract should specify the time and the amount of purchased drugs, and empower the initiators to inspect the implementation of contracts; Fifth, publicizing bidding procedure as much as possible, such as, promulgating the product and quote of all the tender submission manufacturers, so that consumers and media can conveniently supervise them.

5 Conclusion

By analyzing the motives, pattern and failure of drug price regulation in China through international comparison, this paper reaches the following three conclusions:

(1) In Chinese medical environment, an unregulated drug market has an abnormal characteristic, that is, demand for a drug would increase when drug's price gets higher. Thus, different from developed nations, drug price regulation in China aims at restraining the reasonable markup between retail-wholesale price instead of controlling the over-consumption of drugs caused by third party reimbursement. Undoubtedly, in such a market, the policy that allows drug price to be determined by the free market is not feasible.

(2) From drug price regulation practice in Japan and Korea, the direct reason for the failure of current Chinese regulation pattern is that it can neither provide incentives for physicians to prescribe cheap drug nor effectively restrain the stake-holders to avoid government regulation.

(3) Therefore, since healthcare system reform is a very sticky business and cannot be accomplished in a few years, only for regulating drug price, taking the new regulation pattern of fixed reference-pricing reimbursement accompanied by changing some relevant institutional arrangements for restraining the stake-holders' evasive behavior is a more realistic way to get out of the dilemma of current drug price regulation.

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