Reflections on Innovative Drug Price Management

Kai WEI

Law School, China Jiliang University, Hangzhou, Zhejiang, China

1475963801@qq.com

Keywords: Marketization of Innovative Drugs, New Drug Pricing, Medical Insurance Directory, Centralized Purchasing.

Abstract. China's innovative drugs to the market limited by the government-related policies, facing new drug pricing, medical insurance directory, centralized purchasing three checkpoints, of which Development and Reform Commission is responsible for the pricing of new drugs, the Ministry of Health and Social Security is responsible for the directory and Centralized purchasing which determine whether new drugs can enter the hospital for sale. These three checkpoints are the three mountains that press on the drug companies, restricting and compressing the existence of innovative drugs. This has led to low market returns and even the loss of pharmaceutical companies, which have severely hit the enthusiasm of Chinese enterprises in developing innovative drugs. This article analyzes the status of innovative drugs in the market and analyzes the barriers to market based on the impact of new drug pricing, health insurance catalogs and centralized purchasing on the price formation mechanism of innovative drugs, then reflecting and putting forward corresponding suggestions.

Introduction

In recent years, the issue of drug prices in our country has drawn continuous attention. Innovative drugs from research and development to the last line of sale face the complicated relationship between the stakeholders, registration and review time is too long, the price negotiations are difficult, failed to regularly enter the medical insurance directory, bidding without cost advantage, the procurement cycle is too long, etc. Series of questions. Although the relevant ministries have conducted many reforms and taken a variety of control methods, they have not established a reasonable mechanism of price formation. Instead, they have made the people lose confidence in drug price reform and their social conflicts have deepened. The overall objective of the new round of drug price reform clearly pointed out that it is necessary to return the drug prices in our country to the market mechanism and give full play to the role of both the government and the market in the construction of a specific system. This requires the government to establish a scientific and reasonable drug prices to form a supporting system; pharmaceutical companies under the guidance of the policy to follow the market competition and pricing laws to determine drug prices. This disregards the chaos caused by artificial pricing and at the same time challenges the specific system how to build good governance in order to achieve price formation. Especially the price management of innovative drugs different from the price management of generic drugs in the management, should be supported by the policy and promoted the marketability of innovative.

Definition and Characteristics of Innovative Medicine

To explore the mechanism of price formation for innovative drugs and the barriers to the marketization of innovative drugs, we must first understand what is innovative medicine. The key point is to understand the difference between innovative drugs and generic drugs so that we can grasp the essence of the problem profoundly. In the international community, innovative drugs generally refer to new substances in new chemical entities or biological products. According to the law of our country, new drugs refer to drugs that have not been marketed in China, that is to say, change drug routes, add new indications, or listed in foreign countries but not in the domestic
market of drugs, all belong to the category of new drugs. Generics generally refer to medicines manufactured with new drugs that have passed the patent protection period. Generic drugs without their own intellectual property is just a simple imitation, the cost is low compare with new drugs.

Drug pricing need to consider the cost; just consider the cost of research and development of new drugs is much higher than the cost of generic drugs. According to incomplete statistics, a new drug took average 12 years from the initial laboratory study to the final display of medicine cabinet sales. Only 5 out of the 5,000 compounds in clinical trials will be able to enter the follow-up clinical trials, and one of them will be finalized for marketing approval. Innovative drug development cycle is long, and China's clinical testing standards are moving closer to international standards, virtually which increase the pharmaceutical companies’ risks and costs. At the same time, even if new drugs are approved for listing, they still need to face the restriction of pricing of new drugs, enter the medical insurance catalog, and centralized purchasing can not immediately enter the market. Sales of medical institutions also affect the return on investment of enterprises and the enthusiasm of innovation in pharmaceutical enterprises.

The Barriers to the Marketization of Innovative Drugs

**New Drug Pricing.** At present, there are mainly three types of mechanism for the formation of drug prices according to the different levels of the main body of the formulation. The drugs that enter the national medical insurance catalogs are set by the competent department of national drug prices. The drugs that enter the provincial medical insurance catalogs are set by the competent department of provincial drug prices, the remaining drugs are set by enterprises according to the laws of the market independently. Our government pricing is depend on the pharmaceutical market price research, expert demonstration, approved the cost of drug production, based on the prescribed rate to develop the maximum retail price of medicines.[1] The important basis for the development is the cost information reported by the enterprise, and the relevant departments shall set the corresponding price after add the reasonable profit. From which we can see that the main basis for the pricing of medicines is the cost information of the enterprises, the method of cost addition is adopted, and the distinction between innovative medicines and generic medicines is not made. China has always been to develop cost-oriented drug prices, based on the production costs and market supply and demand, but the factors that affect the pricing of innovative drugs more important is the cost of research and development costs, sales and marketing service costs. Therefore, the cost of drugs formulated by the method of cost-adding can not reflect the value of innovative drugs, which inevitably will lead to the deviation of price and value of innovative drugs and the phenomenon of price distortions. The price of medicine must reflect its due value, and the price of innovative medicine should fluctuate along the value. Otherwise, the formation mechanism of drug prices can not play an incentive role for innovative drugs. After the huge cost of R & D, the pharmaceutical enterprises can not obtain a reasonable profit return in the follow-up sales, which seriously hit the innovation enthusiasm of the pharmaceutical enterprises.

**Medical Insurance Directory.** In China's pharmaceutical sales market, the ability to access healthcare coverage has a major impact on drug sales. Pharmaceutical companies put huge cost into the research and development of innovative drugs, so the price of the innovative drug does not have a competitive advantage. If innovative drugs can enter the Medicare directory to offset part of the price by state finances or commercial insurance, it can be very beneficial for opening up the sales market and recovering huge R & D costs.

At present, the entry and exit mechanism of medical insurance catalog system in our country is not perfect, resulting in that medical insurance can not really play its due role. First of all, there is no scientific basis for our assessment. Currently a drug can enter the medical insurance directory is mainly based on the experience and discussion of reviewers rather than relying on the standard evaluation system, it has great subjectivity and uncertainty. This virtually increases the risk of pharmaceutical companies to develop innovative drugs, but also provides space for rent-seeking,
which is not conducive to innovative medicines enter the health insurance directory.[2] Second, the slow update of the medical insurance directory in our country can not reflect the ever-changing market changes and patient needs. Since the first medical insurance catalog was formulated in 2000, our country has not yet amended the medical insurance catalog since it was revised in 2004 and 2009 respectively. Innovative drugs are inaccessible to medical insurance catalog during the time of adjustment, thus losing the price advantage of competing with other drugs.

Centralized Purchasing. The centralized purchase system of medicine helps to improve the hospital operation efficiency, ensure the medical safety and reduce the medical cost. The bidding and purchasing policy explicitly required that the hospital should report the quantity, specifications and dosage forms of medicines needed to the institutions responsible for centralized purchasing, but because the specifications of the bidding medicines are too complicated due to too many kinds of medical institutions and medicines involved. The rules are hard to enforce. As a result, information asymmetry occurs between centralized purchasing agencies and medical institutions, and centralized purchasing of medicines becomes the mere pursuit of the lowest drug prices.[3] Pharmaceutical companies pay a huge cost to develop a drug, the government-led centralized purchasing system ignores the actual needs of medical institutions to pursue the price concessions, which suppressed the profit margins of innovative drugs and even pharmaceutical companies at no profit at all. For pharmaceutical companies centralized purchasing system is not a competition for survival of the fittest, but has completely become a tool that is used by government to control drug prices. The government will inevitably try its best to cut prices in order to save on medical expenses. However, innovative drugs do not have the advantage in terms of price, which ultimately results in the failure to enter the purchasing list of medical institutions. The centralized purchasing model of the current government monopoly is not conducive to market competition, nor is it conducive to improving the allocation efficiency of medical resources.

Advice on Innovative Drug Price Management

I believe that the new drugs pricing, medical insurance directory, centralized purchasing is not conducive to the management of drug prices, innovative drugs in such a management system can not form a reasonable price. I think we should improve the drug price management from the above three aspects.

Make the Price Based on the Value of the Drug. Drug pricing needs to reflect the law of value, but also need to respond to market supply and demand. At present, the pricing of medicines in our country basically still adopts the method of cost plus to determine the price of medicines, and formulates the prices of medicines with the cost as a guideline, so that the full cost of the pharmaceutical enterprises can not be fully reflected. In fact, a long time ago some scholars in our country have proposed that the drug value should be the guideline to determine the price of medicines, which is also the trend of drug pricing. The key is how to quantify the value of the drug objectively expressed, which requires the use of scientific evaluation system for the value of the drug evaluation and measurement. Pharmacoeconomic evaluation system can effectively reflect the value of drugs, and by comparing the evaluation results of similar drugs is conducive to guide the formulation of drug prices.[4] Specifically, the value of a drug can be evaluated by the method of pharmacoeconomics, and then the price can be determined based on the result of the evaluation. After that, the same kind of drug is priced based on the pharmacoeconomic evaluation result of the drug to form an organic price system. This will not only increase the profit margins of enterprises to encourage pharmaceutical companies innovative drug research and development, but also makes drug pricing tends to be reasonable.

Establish a Dynamic Adjustment Mechanism for Health Insurance Directory. At present, there is no scientific evaluation system for the value of medicine in our country. In this way, it is not
only impossible to scientifically formulate medicine price, but also lacks the basis for evaluation of the medical insurance catalog entry and exit. [5] Therefore, not only in the pricing of medicines, medical insurance catalogs in determining the basis for the assessment also need to use drug economics methods for objective evaluation of drugs. The evaluation results as a reference to whether to enter the medical insurance directory or withdraw from the medical insurance directory, and can not rely solely on the evaluation experience and discussion of medical insurance directory review experts.

At the same time, it is necessary to shorten the renewal period of the medical insurance catalog, consider the clinical needs, support innovative drugs and medical insurance affordability to establish a dynamic adjustment mechanism. The key is the medical insurance catalog should establish a set of access and exit evaluation system for the drugs, which meet the conditions of access to health insurance directory for drugs, which do not meet the conditions of access to timely withdrawal from the health insurance directory so that the health insurance directory based on drug evaluation the results are dynamically updated to reduce the time cost of bringing innovative drugs into the medical insurance catalog to encourage innovation in pharmaceutical companies.

**Medical Institutions as the Main Body of Centralized Purchasing.** In view of the unreasonable setting of the central purchasing authority in our country, we should take this drug price reform as an opportunity to fully mobilize the enthusiasm of medical institutions in the process of centralized purchasing and weaken the government's leading role in them. [6] In the process of centralized purchasing, the hospital can be the tenderer or entrust purchasing group to negotiate with the pharmaceutical enterprise on behalf of the tenderer. In this process, the government only takes the role of supervising, directing and supervising. In this way, the demand of medical enterprises can be reflected really and timely, and the enthusiasm of market competition can be fully mobilized by the invisible hand of the market so as to improve the efficiency of resource utilization. Get rid of the government one-sided pursuit of the wrong model of low prices, innovative drugs in the market demand will inevitably reflect his value. Under the adjustment of the market price mechanism, innovative drugs will also obtain reasonable prices in the competition and the enterprises will also obtain reasonable profits.

**Conclusion**

This article puts forward suggestions for the problems exposed in the process of innovative drug price management. In the new drug pricing phase change in the past only consider the explicit cost of practice, the value of drug-oriented pricing. At the stage of entering the medical insurance directory, the evaluation basis for entering and leaving the medical insurance catalog should be systematized and standardized, and the update cycle of the medical insurance catalog should be shortened. In the centralized procurement phase, changing the functions of government and medical institutions, and making medical institutions as the main body of centralized procurement to adjust the price of medicines by market competition mechanism. The listing of innovative drugs not only relates to the economic returns of the pharmaceutical enterprises, but also relates to the development of the government's health system and the health benefits of patients in our country. To formulate a scientific and rational pricing system for innovative medicines will not only give the pharmaceutical enterprises a return on investment that is conducive to stimulating the innovative spirit of pharmaceutical enterprises and enhancing the competitiveness of the pharmaceutical industry in our country. At the same time, for the broad masses of the people, innovative medicines can make the original incurable disease medicine. Therefore, improving the management of drug prices is of great significance in promoting the sound and healthy development of China's pharmaceutical market and in fulfilling the protection of people's lives and health.
References


