Study on Enterprise Strategies for the Evaluation of Quality and Efficacy Consistency of Generic Drugs※

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Abstract: China is a big country of imitation, nearly ninety-seven of the drugs are made of imitation, but the quality of imitation drugs is uneven, causing widespread concern in China. The state, in order to regulate the safety of generic drugs, has steadily promoted the work since the publication of the opinions of the general office of the state Council on the quality and efficacy of generic drugs. But the products of enterprises sometimes as many as a dozen or more, this article from the perspective of pharmaceutical economics to help enterprises scientifically in many products to determine the priority of quality and efficacy consistency evaluation of products, save their capital costs, time costs, so that enterprises better deal with consistency evaluation policy, for the product to obtain a better development prospect.

1. Introduction

China is a large country of generic drugs, generic drugs have the advantages of small cost, short cycle, quick effect and low price. However, the quality of generic drugs is uneven, making Chinese people have little confidence in generic drugs. There are more than 5,000 pharmaceutical enterprises in China. Under the policy of consistency evaluation, how to select the drugs to be evaluated first among various varieties is of great importance for pharmaceutical enterprises. The analysis of strategy selection, countermeasures and future trends of the drugs to be evaluated by consistency evaluation is of great importance for pharmaceutical enterprises. By means of pharmacoeconomic evaluation, priority drugs are selected from a variety of different products of enterprises to obtain industry competitive advantages, control investment capital, analyze risks and influence surveys, and achieve maximum benefits under the requirement of consistent evaluation under the guidance of policies. Ensuring the health of the masses also makes generic drugs internationally competitive.

2. Generic drug quality and efficacy consistency evaluation

Since the issuance of the opinions of the general office of the state council on the evaluation of the quality and efficacy consistency of generic drugs (guo ban fa [2016] no. 8), the evaluation of the quality and efficacy consistency of generic drugs has been steadily advancing. Internationally, many countries have evaluated the quality and efficacy of domestic generic drugs, such as the United States, Britain and Japan. This is the country economy develops certain level to undertake policy adjustment, further stimulative economy grows outwards strategy.

China stipulates that generic drugs and original developed drugs should be consistent in five aspects, such as active ingredients, routes of administration, dosage forms, specifications and therapeutic effects. At present, the consistency evaluation of generic drugs is mostly in the preparatory stage. The generic quality consistency and curative effect evaluation is the independent corporate registration, group or panel method of review the administrative action to establish reference preparations, the specific evaluation method of dissolution in vitro rather than the

international consensus on bioequivalence in order to develop, consistency evaluation of enterprises within the industry is less, the cost of a variety of consistency evaluation according to unofficial statistics need to around 5 million, large than small enterprises have more financial strength advantages. At present, the industry input consistency evaluation is less, the policy implementation of the early detection, the food and drug administration has not defined the original research drug. Enterprises should evaluate and review the produced drugs, and carry out consistent evaluation selectively in advance, so as to keep up with the reform trend, cope with challenges and improve their product chain. Only in this way can they occupy a dominant position in the new round of industry "shuffle".

3. Influence of quality consistency of generic drugs on enterprises

Many companies have dozens or more products, many of which are of varying importance to the business. However, the capital cost, time cost and opportunity cost needed for a drug consistency evaluation make it impossible for enterprises to take into account many varieties at the same time. How to select the products with priority of consistency evaluation among many products, and select them from the following two methods.

3.1 product importance analysis

The importance of the product to the enterprise, including the impact of the profit of the product on the income of the enterprise, the importance of the product in the whole product chain, the contribution of the product awareness to the enterprise brand and the market share of the product in similar competitive products.

3.2 product life cycle analysis

Product life cycle refers to the life cycle of a product from its entry into the market to its final exit from the market. The typical product life cycle can be generally divided into four stages, namely the investment stage, growth stage, maturity stage and decline stage.

1. Investment period. When a new product is put into the market, customers' awareness of the product is low, and only a few customers who are willing to try it will buy it, resulting in low sales. At this stage, the production of products is not perfect and mature, the cost is high, the sales growth is slow, and the enterprise can not get profits, but may lose money. The product also needs to be further improved. The products at this stage are not suitable for quality consistency evaluation.

2. Growth stage. During this period, the products had a certain customer base in the market, and a large number of new customers were added to buy the products every year, and the product market gradually expanded. Enterprises began to mass production, relatively lower costs, sales rose rapidly, and profit margins are growing. During the same period of competition to see profitable, will have to join the competition, similar products gradually increase, in order to obtain the competition to gain profits, manufacturers subsequently price, enterprise profit space is becoming smaller and smaller. At this time, generic drug quality consistency evaluation can increase the competitiveness of the product, but also consider the time cost and capital cost of investment consistency evaluation, careful choice.

3. Maturity. Market demand is relatively saturated, there are few potential customers, and the sales volume grows slowly or even does not grow, which indicates that the product has entered the mature stage. At this stage, the product brings low profit to the enterprise, but still retains some popularity in the market, which is a sunset product. At this time, the consistency evaluation may increase the burden on the enterprise.

4. Decline phase. With the development of science and technology, the emergence of new products or customers' new demands will gradually change customers' consumption habits, and the sales and profit of products will decline rapidly. Then, the product entered decline phase again. The products at this stage are not suitable for quality consistency evaluation.

4. Selection strategy of enterprise consistency evaluation

After referring to the product life cycle analysis and product importance analysis, the enterprise considers the product importance in combination with the time factor, and USES the time-product rectangle diagram to divide the enterprise's products into four types of analysis:

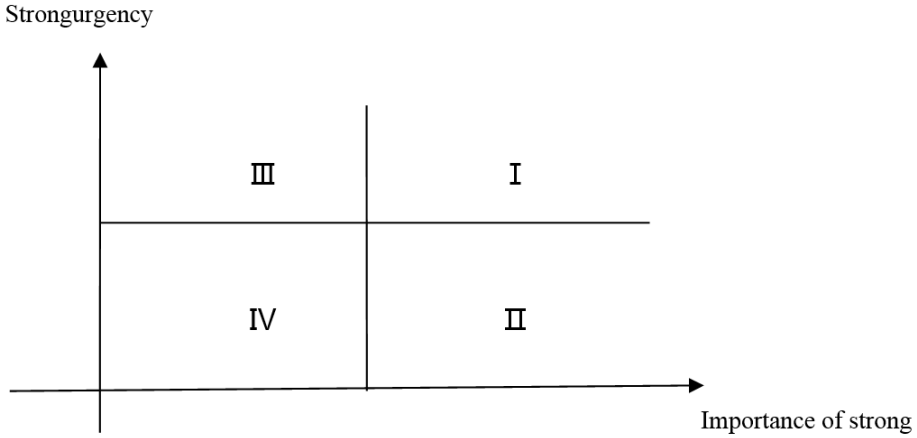

Figure 1. The time-product rectangle diagram

The figure shows that the high importance and timeliness of I area consistency evaluation of the drug product is the enterprise priority products: based on the good market foundation, high visibility and reputation, and occupies the important position in the enterprise product "stars" of the product, evaluate the consistency, is expected to further expand market share and obtain the similar competitive advantage, and monopoly, etc. In the short time, high degree of importance of the product, in the enterprise generally for the new development of the product. This product because II area, can consider to consider in evaluating area product, enterprises will further analysis of product innovation and competitive potential in this area to consider whether further invested capital. III area is an important level is not high but time is long the old products, they often have a good market reputation, but less on corporate profits, to give up these products and is especially bad, enterprises need these product reputation popularity and drive the other series of new products, after the consistency evaluation is expected to improve market share and profitability, can be placed in complementary consideration scope. IV areas of product time is short, the importance is not high, enterprises generally do not consider in the absence of any special additional capital in the breed easily, in this not be considered.

Companies cope with several products I area key consideration, analyzes its status in the industry market and the possible risk, pharmacoeconomics evaluation, choose the most suitable for priority consistency evaluation of products.

5. Application of pharmacoeconomic evaluation

5.1 Several basic evaluation methods of pharmacoeconomics

Pharmacoeconomic evaluation is an applied science that applies the principles and methods of economics to the evaluation of clinical drug treatment process, [9] and aims to guide clinicians to formulate reasonable cost-effectiveness prescriptions. With the in-depth development of the discipline, pharmacoeconomics from the perspective of society to carry out research, become a rationalization of the medical and health undertakings of a comprehensive discipline. [6] Here, we use the method of pharmacoeconomics to provide decision-making basis for the quality consistency evaluation of generic drugs of enterprises. The following are some basic methods of pharmacoeconomic evaluation.

5.1.1 Minimum cost analysis

Minimum cost analysis is usually first used in pharmacoeconomic research. To be specific, compare the difference in cost between two or more plans with the same result. In the two schemes with the same benefits, the scheme with the lowest cost is the first choice. However, in practical application, the result of the scheme is generally different, proving that the same result of the scheme is not easy, so the application of the minimum cost analysis method is limited to a certain extent. This method is suitable for simple and efficient, but it is often not comprehensive and objective.

5.1.2 cost-benefit analysis

Cost-benefit analysis is a method in which costs and effects are assessed in monetary units, converted into a comparison of the value of health resources consumed and the results produced. The present value of all the expected benefits and all the estimated costs of each alternative is compared to evaluate these alternatives, so as to serve as the basis for decision makers to make decisions and references.

To investigate whether the benefits of initiating a drug conformance assessment exceed the opportunity cost of their resource consumption. Only if the benefit is not lower than the opportunity cost is feasible. The cost includes the direct cost of the conformity evaluation (such as the cost of consulting experts and the cost of inspection), the indirect cost (the opportunity cost of the occupied labor resources) derived from the conformity evaluation, and the hidden cost. Efficiency is the greatest desire generated by the implementation of a program in monetary terms. Benefit includes direct benefit, indirect benefit, and invisible benefit.

Direct benefit refers to the foreseeable preferential treatment in pricing, medical insurance and centralized procurement after the implementation of a consistency evaluation scheme, while indirect benefit refers to the loss or gain in other aspects reduced after the implementation of consistency evaluation scheme. Such as more market share. Invisible income refers to the company, brand reputation, reputation and other aspects of the promotion of intangible assets.

Cost-effectiveness is usually evaluated by the following three outcome indicators:

(1) Net benefit value method: the total benefit minus the total cost is the net benefit (b-c), so it is also called the net residual value method. The net benefit value is positive, indicating that the benefit of the program is greater than the cost, indicating that the program is beneficial, and vice versa. The greater the net benefit, the better the scheme.

(2) Cost-effectiveness ratio method: namely, the efficiency and cost ratio method. The method is to compare the ratio of benefit and cost. When the benefit/cost is >1, it means that the benefit is greater than the cost and can benefit. When benefit/cost =1, it means that the benefit is greater than the cost. When the benefit/cost is less than 1, it means that the benefit is less than the cost, and this scheme has no economic benefit. When comparing these schemes, the one with the highest ratio is the best.

(3) Return on investment method: that is, the net benefit/cost, marked percentage [(b-c)/cx100%], the greater the percentage, the more beneficial the program.

5.1.3 Cost-effect analysis

In the cost-effectiveness analysis method, the effect here refers specifically to the clinical outcome of the drug treatment effect. Effect refers to useful results, which are composed of various values and have the properties of satisfying people's various needs.

This method is suitable for the comparison of clinical effects of drugs with different therapeutic functions. It is convenient for enterprises to evaluate this imitation. The difference between the quality level of the pharmaceutical and the original drug is an important tool to analyze the safety, quality degree and economy of each alternative.

Cost-effectiveness usually USES the cost-effectiveness ratio method:

Cost-effectiveness ratio: the cost of a drug is compared with its clinical effect in monetary terms. The smaller the cost/effect value, the higher the feasibility and benefit of the consistency evaluation of the drug.

5.1.4 Cost-effectiveness analysis

In economics, utility refers to the ability or satisfaction of a product to meet people's needs. In pharmacoeconomics, utility refers to the degree to which people's satisfaction with a particular health condition in a drug treatment or service is subject to certain subjective evaluation. Cost-effectiveness analysis is to pay more attention to the analysis of people's life and health quality level. Cost-utility analysis is to evaluate and compare the relative costs of improving the quality of life to describe the degree of satisfaction that people can obtain for each cost of physical and mental health. [7]

Utility measurement methods mainly include evaluation scale method, ratio measurement method, standard balance method, etc. In the study of pharmacoeconomics, the applicable method should be determined according to the purpose and direction of the study.

In cost-utility analysis, the calculation method of a single scheme can refer to the calculation of marginal cost in the cost-benefit analysis method, that is, the cost required for each quality adjustment life year, so as to measure whether the investment has been satisfied. The evaluation method of cost-effectiveness analysis among multiple schemes can refer to the cost-effectiveness analysis and only change the evaluation result into the quality-adjusted life year. The general formula for cost-effectiveness analysis is CUA= (C1+C2-B1-B2) /U, where C1, C2, B1 and B2 are the same as in the cost-effectiveness analysis formula.

5.2 combined use and sensitivity analysis of multiple drug economic evaluation methods

Since the time in the future natural state cannot be completely determined, when making decisions with the application of pharmacoeconomics, the probability of occurrence should also be estimated with the estimated risk, which is a kind of risk decision and uncertain decision. The four evaluation methods of pharmacoeconomics share the same theoretical basis for cost utility and cost-effect analysis, and improve and upgrade the cost-effect analysis of cost-benefit analysis [8]. However, the emphasis of each method is different. Based on the comprehensive and objective analysis, we often use several economic evaluation methods to jointly choose. Cost-utility analysis is combined with cost-benefit analysis. Cost-effectiveness analysis and cost-effectiveness analysis, minimum cost analysis and cost-effectiveness analysis, minimum cost analysis and cost-effectiveness analysis.

Sensitivity analysis is a process method to evaluate the reliability of economic models. By changing several uncertain factors or parameters, the degree of their sensitivity to decision making was investigated. Some factors are economic variables, some are humanistic variables, and some are clinical variables. Sensitivity analysis is a method used to evaluate whether the stability of results or conclusions will be affected by changing estimates within a certain range. Sensitivity analysis methods include simple method, threshold method, extreme analysis method, probability analysis method, etc.

6. Summary

Generic quality consistency evaluation is the inevitable trend in the process of economic development of medicine, enterprises face the future changes in product market the best strategy is to start as early as possible consistency evaluation of planning, in order to more quickly in the industry in a policy on AIDS, and to expand market share, competition in the same products. The method of pharmacoeconomics can not only help enterprises to make decisions, but also cooperate with the evaluation of post-marketing pharmacoeconomics to strive for better development prospects for products.

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