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Research on Quality Indictor of New Drug Based on Customer Perspective

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Abstract

The single evaluation indictor of new drug quality hinders the market and customers' cognition of new drug quality, which is not conducive to the rapid launch of new drugs. Based on the market, this research establishes a comprehensive evaluation indictor system of new drug quality from the perspective of customer demand. To improve the quality of new drugs, as soon as possible to provide scientific basis for the market.

Keywords

New drug quality; Quality evaluation; Quality management.

1. INTRODUCTION

In China, new drugs are defined as drugs that are not marketed globally (CFDA, 2007). In the United States, which accounts for 50 percent of the global market for new drugs each year, a new drug is defined as a drug not marketed within the jurisdiction of the FDA. Therefore, most new drugs refer to those that are seeking to be marketed and are actively undergoing clinical trials (Mehul, 2017).

However, the evaluation indictor of new drugs in China is relatively single. According to the quality control code for drug clinical trials issued by the state food and drug administration, there are mainly three indictors for the certification of new drugs: efficacy, safety and quality controllability (Mai, 2017). Among them, quality controllability is an indicator in the production process, and there are only two simple indicators of efficacy and safety in the pre-marketing clinical trials of drugs. There are too few indicators to meet the market understanding needs, especially the customers' understanding of the advantages and disadvantages of new drugs. If the quality evaluation of new drugs cannot reflect its own characteristics, it will lack market competitiveness, which is not conducive to the smooth launch of new drugs.

The purpose of this study is to develop a comprehensive evaluation indictor for the quality of new drugs, to provide scientific basis for improving the quality of new drugs, so as to enhance the market acceptance and recognition of new drugs and improve the market competitiveness.

2. RESEARCH METHODS

2.1. Research Objects and Sample Size

Population Size for Qualitative Research. Glaser and Strauss (1967) recommend the concept of saturation for achieving an appropriate sample size in qualitative studies. Morse (1994) suggested approximately 30-50 participants. For grounded theory, Morse (1994) suggested 30-50 interviews, while Creswell (1998) suggested only 20-30. For phenomenological studies, and Morse (1994) suggests at least six. These recommendations can help a researcher estimate how many participants they will need, but ultimately, the required number of participants should depend on when saturation is reached. Therefore, referring to the above literature, the sample size of experts in this study is: n = 30

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The new drug's customers are concentrated in hospitals. Doctors, nurses, pharmacists, hospital administrators. But the end customer is usually the patient. Therefore, the 30 customers all include the above customers. Among the 30 customers, 21 are male, 9 are female, 13 are doctors, 3 are pharmacists, 5 are nurses and 9 are patients. See the table1.

Table 1. Customer composition

Group	n	Percentage
Gender		
Male	21	70.00%
Female	9	30.00%
Age		
20-30	6	20.10%
30-40	13	43.30%
40-50	10	33.30%
>50	1	3.30%
Profession		
Doctor	13	43.30%
Pharmacist	3	10.00%
Nurse	5	16.70%
Patients	9	30.00%
Education		
Undergraduate	16	53.30%
Master	12	40.00%
Dr.	2	6.70%

2.2. Sources of New Drug Quality Indicators

According to the relevant national laws and policies on drug supervision, reviewing academic literature, consulting experts, etc., a total of 34 subordinate indicators in 6 dimensions of new drugs were preliminarily formulated. Specifically, 6 major quality indicators were available, including Efficacy, Safety, Appearance, Ease of use, Price, Taste, Smell and Shelf life.

2.3. Questionnaire Design

This study use Likert ten rating scale for measuring (Likert, 1932). A score of 10 means best, and a score of 1 means worst. Where 1, 2 and 3 represent very poor performance; 4, 5, 6, 7, said the medium level, 8, 9, 10, mean excellent.

Table 2. The scales of the ten level

Level judgment method									
1	2	3	4	5	6	7	8	9	10
Very Poor			Medium				Excellent		

2.4. Statistical Analysis Methods

SPSS25.0 software and EXCEL were used for processing and descriptive statistical analysis. The reliability test of the questionnaire shows that the reliability of >0.70 is acceptable. The results were expressed as Mean±S.

3. RESULT ANALYSIS

3.1. Questionnaire Reliability Analysis

The reliability coefficient of the total scale is better than 0.8, and between 0.7 ~ 0.8 is acceptable. The reliability coefficient of the subscale should be above 0.7, 0.6 t~ 0.7 is

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questionable, need to modify. If Cronbach's alpha coefficient is less than 0.6.a new questionnaire should be considered (Cronbach,1951). Cronbach's score of the questionnaire =0.938 >0.08, indicating that the reliability of the questionnaire is acceptable. See the table 3

Table 3. Reliability analysis of questionnaire

	Cronbach's α	Cronbach's Alpha Based on Standardized Items	Number
Quality	.938	.935	34

Table 4. New drug quality indictor score

Dimension	Mean	S.D	Level
Efficacy	8.92	0.72	Excellent
1 Curative rate	9.03	0.81	Excellent
2 Improvement rate	9.00	0.74	Excellent
3 Starting speed	8.97	0.67	Excellent
4 compared old drug	8.70	0.65	Excellent
Safety	8.57	0.67	Excellent
5 Body feeling	8.67	0.71	Excellent
6 Psychological feeling	8.50	0.63	Excellent
7 Adverse reactions	8.53	0.62	Excellent
8 Addiction	8.57	0.73	Excellent
Appearance	8.43	0.57	Excellent
9 Size	8.53	0.57	Excellent
10 Color	8.27	0.52	Excellent
11 Shape	8.40	0.56	Excellent
12 Design	8.53	0.62	Excellent
Ease of use	8.71	0.61	Excellent
13 Easy to carry	8.67	0.71	Excellent
14 Easy to take	8.83	0.53	Excellent
15 Easy to store	8.70	0.60	Excellent
16 Softness	8.83	0.57	Excellent
17 Easy to distinguish	8.53	0.62	Excellent
Price	8.42	0.58	Excellent
18 Cost	8.60	0.62	Excellent
19 Price	8.23	0.50	Excellent
20 Social Reimburse	8.33	0.55	Excellent
21 Discount	8.50	0.63	Excellent
Taste	8.58	0.63	Excellent
22 Tasteless	8.52	0.56	Excellent
23 sweet and sour	8.57	0.62	Excellent
24 Fruit Flavors	8.60	0.72	Excellent
25 Sugar-like taste	8.63	0.61	Excellent
Smell	8.60	0.66	Excellent
26 No odor	8.46	0.67	Excellent
27 Food-like	8.57	0.61	Excellent
28 Perfumes	8.62	0.62	Excellent
29 Herbal Flavor	8.77	0.73	Excellent
Shelf life	8.63	0.65	Excellent
30 Shelf life	8.64	0.70	Excellent
31 After opening	8.58	0.67	Excellent
32 Temperature	8.67	0.59	Excellent
33 Humidity	8.74	0.62	Excellent
34 Light	8.56	0.67	Excellent

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3.2. Score of New Drug Quality Indictor

The scores of the eight major dimensions of quality reached the excellent level. Among them, the first indicator Efficacy Mean=8.92, S.D=0.72, the second indicator Safety Mean=8.57, S.D=0.67, the third indicator Appearance Mean=8.43, S.D=0.57, the fourth indicator Ease of use Mean=8.71, S.D=0.61, the fifth indicator Price (Mean=8.42 S.D=0.58), the sixth indicators Taste Mean=8.58, S.D=0.63, The seventh indicators Smell Mean=8.60 S. D=0.66, the eighth indicator Shelf life Mean=8.63, S. D=0.65. As shown in table 4.

4. DISCUSSION

Previous researches on the quality of new drugs mainly focus on the two dimensions of efficacy and safety, which are further developed in this study. Effectiveness of the extended the Curative rate, Improvement rate, Starting speed, compared old drug4 a lower index. Security developed Body feeling, Psychological feeling, Adverse reaction, Addiction4 sub-indicators. Further explained the connotation and meaning of the traditional indicators, so that more conducive to customer understanding and acceptance. In addition, this study developed six new dimensions for quality evaluation of new drugs, including Appearance, Ease of use, Price, Taste, Smell and Shelf life. Its subordinate index accumulates to 26 subordinate indexes. These indicators can explain the quality characteristics of new drugs in detail and fully demonstrate the characteristics of new drugs. In the survey, 34 new drug quality indicators in the above 8 dimensions were all evaluated with excellent level, indicating that both old and new indicators were fully recognized.

At present, clinical trials of new drugs only evaluate and accept the efficacy and safety of new drugs. Limited indicators are clearly not conducive to market understanding and acceptance. The lack of a customer perspective can affect the speed and volume of its launch. Combined with the evaluation from the perspective of patients and customers, it can fully demonstrate more characteristics of the quality of new drugs, grasp the importance of quality characteristics of patients and customers and the market, help to improve the quality of drug products, and promote the new drugs to be put into the market as soon as possible to obtain a satisfactory market response.

This study will also well enrich the management system of drug clinical trial base, make the evaluation indictor of new drug quality no longer single, make the evaluation result more comprehensive, more functional, and more meet the actual needs of the market and customers. Therefore, the quality evaluation level of China's new drug clinical trial bases can be improved.

5. SUGGESTION

First, there are more angles for customers to evaluate new drugs. In addition to the efficacy and safety of new drugs, customers want to know about other quality characteristics of new drugs. For example, Appearance, Ease of use, Price, Taste, Smell, Shelf life. Only to meet the needs of customers to understand the product, the new drug is easy to be accepted by customers, the formation of market competitiveness.

Second, there are plenty of ways to improve the quality of new drugs. A single evaluation criterion limits the improvement of the quality of new drugs. Under the condition that the efficacy and safety of new drugs are basically satisfied, the quality of new drugs can also be improved from Appearance, Ease of use, Price, Taste, Smell, Shelf life and other channels. It also suggests that when there are some deficiencies in new drugs, they can maximize the quality of other aspects and improve the overall quality of new drugs. And the improvement of the quality of new drugs means the improvement of their market competitiveness.

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Third, the evaluation of new drugs by customers is diversified. In this study, the quality dimensions of new drugs were developed into 8, reflecting the diversification of customer perspectives. It also suggests that new drug developers, the current market environment is complex, a product must have more advantages, to adapt to the brutal market competition.

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