**Standardization for innovation: The adoption of drug entity identification in the pharmaceutical industry**

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**Abstract**

Whether the pharmaceutical factory has already performed in-plant drug entity identification, whether the newly-developed drug product has implemented drug entity identification, the government aspect of company cooperation with the Department of Health to subsidize pharmaceutical factories to implement drug entity identification, the government aspect of the Department of Health arranging project grants to encourage the pharmaceutical factories to implement drug entity identification, the government aspect of the government’s need to mandate regulations for drug entity identification, the government aspect of the government’s need to continue to provide subsidies to pharmaceutical factories to implement drug entity identification, the implementation aspect of drugs should implement entity identification, the implementation aspect of company belief that the implementation of drug entity identification is most needed by the public, the implementation aspect of company belief that the implementation of drug entity identification is most needed by medical institutions, the benefit aspect of company belief that the implementation of drug entity identification is most beneficial to medical institutions, and the cost aspect of company belief that the implementation of drug entity identification will increase the manufacturing costs of the pharmaceutical factories, have a significant impact on the willingness to cooperate. The site of the pharmaceutical factory had a significant impact on drug identification implementation, as shown by the Chi-square test. In addition, the proportion of domestic sales of pharmaceutical plants and the number of Western drug items had a significant impact on the ratio of drug entity identification, as found by the chi-square test.

**Keywords:** Standardization, Innovation, Drug Entity Identification

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**1 Introduction**

1.1 Research Motives

Medicine can not only cure disease, but also cause disease. Drugs can cure diseases, yet bad drugs or the wrong drugs can cause illness. Proper use of medicine can cure or control diseases, while the use of medicine with unknown origins, unclear or no identification are most likely to endanger people's health due to misuse. The main causes of drug abuse include drug knowledge deficits, patient information deficits, and faulty drug identity checking, etc. In recent years, misuse of drugs has become frequent in Taiwan. How to choose and determine the correct use of medicine? In addition to the doctors’ prescriptions or pharmacists’ correct dispensing prescriptions, how can people identify and judge the right or wrong medicine? Who is responsible for the safety of medication? The process from the manufacturing end of the drug to the consumer end, like the ecological food chain, is interlocked to form the drug safety chain. In recent years, to ensure people’s medication safety and improve the identification of drugs by the public and professionals, advanced countries have promulgated laws to standardize the labeling of the drugs or rewarded pharmaceutical factories for entity identification (such as the United States and Japan, etc.). Publicly-available medical books in advanced countries also include drug pictures and codes, which are used by the general public and professionals to ensure the safety of people's medication. To reduce the misuse of drugs and improve the safety of medications, prevention mechanisms must be added at all stages of the medication process. The entire medication protection chain should include the doctor’s prescription, dispensing by a pharmacist, delivery by a nurse, patient self-administration, medication follow-up, and drug store management, and so on. A safety management system should be added to each step. In a study by Bates et al. of Harvard Medical School, it was pointed out that in most of the avoidable adverse drug events, 49% of the errors occurred when the prescription was made, 26% occurred at the drug delivery, and 14% occurred in the dispensing process. The types of medication misuse include incorrect dosage, improper drug selection, neglect of allergy history, and forgetting administration, etc. To reduce the risks of the wrong injection or taking the wrong drugs, advanced countries use clear drug codes for drug labeling and encourage drug companies to implement drug identification or package labeling; however, Taiwan has not established any regulations for compulsory standardization. The identification of drugs is critical to people's medication safety. As a result, pharmaceutical manufacturers have become an important key to the safety of people's drug use. The Department of Health of Taiwan's Executive Yuan promotes the program of Building a National Drug Identification System - Promoting a Pharmaceutical Drug Identification System. However, not all pharmaceutical factories are willing to cooperate, and some of the pharmaceutical factories insist continuing to use their existing internal methods of identification. The main motivation for this study was to understand the relevant factors affecting the willingness of each pharmaceutical factory to implement the National Drug Identification System program under the manufacturing cost and various related impact factors, so as to make Taiwan pharmaceutical factories fully cooperate with the Pharmaceutical Drug Identification System and maintain the safety of people's drug use.

Innovation and standardization are two aspects of corporate competitiveness. In recent years, numerous studies have attempted to combine innovation and standardization [1]. Successful innovation depends on market acceptance, and many innovations face failure and unprofitability [2]. Featherston, Ho, Brévignon-Dodin and O’Sullivan[3] developed a theoretical framework to illustrate the standardized procedures required for innovation, including how innovation activities should be combined, coordinated, and prioritized in a certain period. Manders, de Vries and Blind [4] further explored how ISO 9001 can be applied to innovative quality management; De Vries and Verhagen [4] analyzed how the energy performance standards of the Dutch construction sector influence innovation; Wang, Zhang, Sun and Zhu[5] studied how innovation and standardization are integrated to facilitate customization. Tamura [6] analyzed the influence of Japan's electromechanical industry standardization on R&D activities. Future research directions include: the relationship between service industry innovation and standardization, the balance between innovative intellectual property rights and the general public's profitability through standardization, the systematic analysis of the impact of standardization at the initial stage of new scientific and technological innovations, how the government profits from standardization, and how companies coordinate hierarchy standardization and innovation. Karlsson [7] believed there are four main reasons for systematic innovation management. First, innovation does not happen by chance. As customer demand and competitive pressures increase, the company's operations become more and more streamlined, and accidental innovations will become fewer and fewer. Second, R&D alone is not enough. The 2012 Booz & Company survey found that among the top 1000 companies with large R&D investments, such investments were not significantly related to their performance. Third, innovation is becoming increasingly complex (driven by the market, the rise of emerging markets, the rise of opening up and collaboration trends, and the need to consider all stakeholders). Fourth, organizations are confused about innovation. What is innovation? What can innovation do? Does it need to be formally managed? In summary, the innovation system has the following benefits: (1) increasing the growth rate, revenue and profit brought by innovation; (2) bringing new ideas and new values to the organization; (3) getting higher value by understanding future market demands and possibilities; (4) helping define and mitigate risks; (5) developing an organization's overall creativity and ability; (6) gaining value through innovative collaboration with partners; and (7) encouraging employees to participate and nurture teamwork ability.

Wiegmann, de Vries & Blind [8] made a multi-mode summarization for standardization, which is divided into three categories: committee-based standardization [9–12] market-based standardization [13,14], and government-based standardization [15,16]. This study explored government-based standardization, which is performed mainly through the coordination of various aspects of the government mechanism to promote the implementation and practice of standardization. The government uses mandatory requirements to standardize or use a certain standardization in different industries [16–21]

Based on the above arguments, this study took the pharmaceutical industry as the research object and discussed how the pharmaceutical industry uses the standardization (drug identification system) approach to innovate the industry, discussed the determinant factors of the willingness to execute the drug identification system and conducted empirical research.

1.2 Research Objectives

The driving force for promoting standardization and product compatibility comes from the market. The reason is that the risk of misuse of standardized products is relatively small. The production cost is also necessarily lower. This is welcomed by consumers. Differentiated products have certain unique features and appearances, but for technology products that have a short life cycle and are used in work, consumers do not necessarily like differentiated technology products because of their uniqueness and incompatibility, which significantly increases the costs and risks of usage. Generally speaking, the earlier the standardization, the more obvious the market benefits from compatibility, and therefore the more favorable it is to the development of the overall industry. When markets compete with each other due to numerous specifications, each manufacturer will invest assets in developing its own specifications and forming market segments that are unique, and it will therefore become more difficult to form a consistent standard specification. For consumers, when market standard specifications are not established, they face greater uncertainty in their decision-making for procurement, so they will delay the purchase, which is unfavorable to the supply-side market growth.

Because of Taiwan’s heavy financial burden on national health insurance, the National Health Insurance Bureau regularly cuts the prices of drug products, resulting in a sustained decline in the gross profit margin of drugs and a squeeze on the profitability of Taiwanese pharmaceutical manufacturers. In case of decreasing profits, the promotion of the Pharmaceutical Drug Entity Identification System program by the Drug Administration Department of the Department of Health will certainly cause the increase in manufacturing costs for pharmaceutical manufacturers. However, the implementation of the Pharmaceutical Drug Entity Identification System involves the identification of drugs by physicians’ prescriptions or pharmacists' prescriptions, as well as people's safe medication. There is an innovation dilemma in this area, therefore this study attempted to explore the following two issues:

1. Understand the intention and current situation of each pharmaceutical factory to implement the Pharmaceutical Drug Entity Identification System through the questionnaire analysis results.

2. Explore the willingness of pharmaceutical manufacturers to implement the Pharmaceutical Drug Entity Identification System, as well as their relevance to the determinant factors through the questionnaire study and analysis results.

**2 Literature Review**

## 2.1 Identification of Drug Entities

Drug packaging and instructions for use can be used by doctors and patients. However, the problems caused by the difficulty in identifying drug bulk products have resulted in delays during emergencies when medical personnel are dispensing the medicine for patients, or people accidentally taking drugs and then being sent to the hospital for first aid where medical personnel cannot identify the medicines being used. Therefore, in order to ensure the safety of people's medications, it is necessary to establish a drug identification system. Drug packaging and instructions for use are available to doctors and patients to follow, but it is difficult to identify the product after bulk drug preparation. Therefore, the drug entity is used to identify characteristics such as size, color, nicks, and marks on solid dosage forms of the medication. Generally, the mark on the solid dosage form contains the manufacturer's code and product code. The format of the mark is divided into English words, numbers, and figures. The purpose of drug entity identification is mainly to: (1) increase the identification rate of solid dosage forms in Taiwan for obvious distinguishing; and (2) establish a drug identification system in Taiwan to ensure the safety of people's medications and to provide a reference to medical practitioners and patients in Taiwan for identification.

2.2 Origin of the Pharmaceutical Drug Entity Identification System

In order to tie in with the government’s promotion of R&D and industrial upgrading in the biotech and pharmaceutical industries, and to make the pharmaceutical industry one of the ten emerging industries, in response to the increasingly fierce competition in the global pharmaceutical industry and internationalized and liberalized global trading since Taiwan’s access to international organizations, the Department of Health of the Executive Yuan has actively cooperated with the spirit and standards of the International Association of Pharmaceutical Laws and Regulations to formulate internationally-recognized regulations relating to pharmaceuticals and establish an international brand image for pharmaceutical factories in Taiwan to expand the international market.

In order to facilitate the correct use of drugs by medical colleagues in the process of dispensing drugs to patients to treat or control diseases, and to prevent unclear or even unmarked drugs, the Department of Health has initiated a plan to promote the Pharmaceutical Drug Entity Identification System in recent years. Taiwan has a wide range of pharmaceutical products and there are different methods for drug labeling in domestic pharmaceutical factories in Taiwan. The scope of the program’s implementation is as follows:

1. Solid preparations (e.g., sugar-coated tablets, film-coated tablets, general tablets, hard-soft capsules, and other technically available dosage forms) are the object of implementation.

2. Mainly prescribed drugs and OTC drugs.

3. The main goal of the identification symbols is to clearly distinguish different manufacturing plants and products. Each pharmaceutical factory has its specific identification mark for differentiation.

4. According to the preliminary plan of the Department of Drug Administration of the Department of Health, starting from 2002, tablets and capsules newly registered for inspection must be printed with the identification code.

The proposed coding guidelines for solid preparations are as follows. The basic combination method is to use the manufacturer’s identification code (hereinafter referred to as the manufacturer code) and a product identification code (hereinafter referred to as the product code), in a different arrangement with single-sided printing or double-sided printing for identification purposes. The manufacturer's code is usually marked with an abbreviation code in English or the manufacturer's graphic logo. Placement depends on the area and shape of the solid preparations, and the product code is usually a serial number or a combination of English letters and serial numbers.

Renren: Duracrin  CBC: Beetomin Tablets

 

Century: Nadon Capsule Taiyu：Ton-Pass Capsule 250 mg

 

Figure 1 Entity Drug Identification Photos

**3 Research Design**

3.1 Research Framework

According to the research objectives, the results were reviewed and the research framework was organized to study the interrelationships among the various research variables. The perception of the drug entity's identification by the pharmaceutical factories will affect their willingness to cooperate. This study was divided into four items: the Scale of Pharmaceutical Factories, the Pharmaceutical Factory’s Product Structure, the Ratio of Pharmaceutical Factories Already Implementing Drug Entity Identification, and the Impacts of Implementing Drug Entity Identification, to discuss whether or not they had an impact on the pharmaceutical factories’ implementation of drug entity identification in the future. The Impact of Implementing Drug Entity Identification was further subdivided into four levels: government, implementation, benefit, and cost. Whether or not these items have an impact on the pharmaceutical factories’ implementation of drug entity identification in the future was also discussed. This study tried to understand the pharmaceutical factories’ recognition of the drug entity identification system to infer the willingness of pharmaceutical factories to identify drug entities, and a study was conducted to investigate the effects of various constructs and willingness to cooperate. From the above research constructs and hypotheses, the research structure of this study was developed, as presented in Figure 2.



Figure 2 Research Framework

3.2 Hypothesis Development

3.2.1 Scale of pharmaceutical factories vs. their willingness to cooperate in the identification of drug entities

Under the government's policy to promote the internationalization of drug quality, Taiwanese pharmaceutical manufacturers have continuously made large investments, and this has caused a drastic drop in the number of pharmaceutical manufacturers. There are such policy contents as the promotion of GMP, cGMP, the drug identification system, original bottle on-shelf, bar code labeling, and PIC/s, but new thrift policies of the Central Health Insurance Bureau have also been continuously introduced. If the pharmaceutical factory does not have a certain scale or advantage with better response capacity, it will be difficult to bear the continuous shrinking of the market and profits, and the ever-increasing operating costs. Through the willingness of pharmaceutical plants of different scales to carry out drug entity identification, this study discussed the relationship between the size of the pharmaceutical factory and its willingness to perform drug entity identification. Therefore, the following hypothesis was proposed in this study:

**H1: The size of the pharmaceutical factory has a positive effect on its willingness to cooperate in drug entity identification.**

3.2.2 Product Structure of Pharmaceutical Factories vs. their Willingness to Cooperate in Identification of Drug Entities

According to the Western Drug License Inquiry System of the Department of Health, dosage form is divided into raw materials, oral dosage form, injection type, topical dosage form, eye and ear nasal dosage form, vaginal/anal dosage form, test formulation, dental dosage form, traditional Chinese medicine type, and cosmetic dosage form. They can be further divided by color, appearance, size, nick, mark, odor, dosage form (bare tablet, enteric-coasted tablets, film coated tablets, slow release tablets, sugar-coated tablets, granules, capsules, liquid preparations, ointments, powders, and soft capsules) and type of preparation. This study mainly used solid preparations as the investigational dosage form for performing identification. Solid preparations generally refer to bare tablets, enteric-coated tablets, film-coated tablets, slow release tablets, sugar-coated tablets, and capsules.

Taiwan's pharmaceutical factories are mostly small and medium-sized, of which more than 90% supply Taiwanese market demands. However, due to the small size of the overall pharmaceutical market, the growth rate is not high. In response to environmental demands, pharmaceutical plants have applied for many long-term permits. In the past, the government lacked regulations on the identification of drug entities. In the face of promoting cGMP regulations and improving people's medication safety, the differences in the proportion of different types of product permits held by various pharmaceutical plants were further explored to see the relationship between the number of permits held by pharmaceutical factories for different dosage forms of the product with its implementation of the drug entity identification. Therefore, this study proposed the following assumption:

**H2: The product structure of the pharmaceutical factory has a positive effect on its willingness to cooperate in the identification of drug entities.**

3.2.3 Ratio of Pharmaceutical Factories Already Implementing Drug Entity Identification vs. their Willingness to Cooperate

While the government continues to promote GMP and cGMP to improve the quality of pharmaceuticals, at the present stage, the identification of drug entities, original bottle on shelf, bar code management, and packaging identification etc. promoted for the public health have all increased the operating costs of pharmaceutical factories. According to the results of the medium-term plan of the Drug Entity Identification System from the Department of Health from 2001 to 2005, before the plan was promoted, some pharmaceutical factories had already developed and implemented drug entity identification systems to meet the demand for business channels and the overall development plan of pharmaceutical companies. During the five-year project promotion period, more than 1,000 drug-related items were added to the Taiwan pharmaceutical factory's old drug items for drug entity identification to cooperate with the program. This study used this information to further understand the relationship between the proportions of old drug products that have already implemented drug entity identification in the pharmaceutical factories and their willingness to cooperate. Therefore, this study proposed the following assumption:

**H3: The percentage of pharmaceutical factories that have already performed drug entity identification at present has a positive impact on their willingness to cooperate.**

3.2.4 Impact of Implementing Drug Entity Identification vs. Willingness to Cooperate

The Department of Health of the Executive Yuan has pointed out that the wrong drugs were frequently used in the past. In order to improve people's drug safety and the effective identification of drugs by medical professionals, in addition to promoting the effective labeling of packaging and medicine bags, they are interested in promoting the identification of drug entities to make the medications have manufacturer and product identifiers. However, the rush toward implementation will lead to an increase in the cost of drug production. There is a fear that the pharmaceutical industry in Taiwan will rebound and it will not be possible to identify imported drugs. Therefore, the Department of Health of the Executive Yuan planned to establish a five-year medium range project promotion plan to entrust the Taiwan Pharmaceutical Industry Association to promote the advocacy and enforcement of drug entity identification. After the first year of comprehensive advocacy and grants for four consecutive years of funding, Taiwan pharmaceutical factories and medical clinics began to embrace the concepts and needs of drug entity identification.

This study examined the impact of drug entity identification on the government, the public, medical institutions, and pharmaceutical companies. Whether the promotion of drug entity identification has a positive impact was understood from the four perspectives of government, implementation, benefits, and cost.

1. The government made practical plans to improve the drug identification rate many years ago. Although there is no mandatory promotion method due to the concern that the increase in manufacturing costs will cause difficulties in promotion, the project plan was promoted over five years. With the cooperation of the project promotion instructions and the awarding of grants, there many manufacturers became willing to cooperate with the promotion of the project plan. Therefore, from the perspective of the government, this study discussed the relationship between the impact of the implementation of drug entity identification and the willingness to cooperate.

2. In the development of Taiwan's pharmaceutical industry, manufacturers continue to research and market new products, and numerous manufacturers apply to the Department of Health for drug permits every year. There are now more than 20,000 drug permits available, and if the government requires all manufacturers to place drug identifiers on the drug before a new product is sold, the manufacturers will not have to make additional efforts. Therefore, the second point of this study was to explore whether there is a positive relationship between the compulsory implementation of new products with drug entity identification.

3. Is a drug entity's identification beneficial to the public, the government, or the hospital? Drugs are provided to hospitals, clinics, pharmacies, and other medical institutions after production according to government regulations, followed by physicians’ prescriptions after the diagnosis, which are then transferred to the public on the basis of the prescription. Individuals take the medicine according to the instructions of the doctor, the pharmacist or the medicine bag. Possible errors in the circulation of the medicine will cause harm. This study investigated whether there is a positive relationship between the benefits and the willingness to perform drug identification.

4. Under the promotion of the government's policies to improve quality at various stages, such as the implementation of GMP, cGMP, PIC/S, and the promotion of the total amount payment system by the National Health Insurance Bureau due to the poor financial health of insurance, drug price surveys, balance payments, or other thrift policies, if a pharmaceutical factory does not have a certain scale or has a differentiation operating ability, it will be unable to bear the burden of ever increasing manufacturing costs. Therefore, from the perspective of cost, this study explored whether there is a positive correlation between costs and drug entity identification. Therefore, the following hypotheses were proposed in this study:

**H4: The impact of a pharmaceutical factory's implementation of drug entity identification has a positive impact on its willingness to cooperate.**

**H4-1: The impact of a pharmaceutical factory's implementation of drug entity identification, from the government aspect, has a positive impact on its willingness to cooperate.**

**H4-2: The impact of a pharmaceutical factory's implementation of drug entity identification, from the implementation aspect, has a positive impact on its willingness to cooperate.**

**H4-3: The impact of a pharmaceutical factory's implementation of drug entity identification, from the benefit aspect, has a positive impact on its willingness to cooperate.**

**H4-4: The impact of a pharmaceutical factory's implementation of drug entity identification, from the cost aspect, has a positive impact on its willingness to cooperate.**

3.2.5 Relationship between the size of the pharmaceutical factory and the ratio of implementing drug entity identification

The scale of a pharmaceutical factory can be seen in terms of its market penetration and market share. The size of a pharmaceutical factory will also affect its willingness and importance for brand building. The exclusive trademarks placed on the products will also increase public loyalty to the products. According to data from the National Health Insurance Bureau, hospitals under the total payment system account for more than 70% of the health insurance drug market. Large medical institutions generally exercise stricter and more prudent management of drugs, and they set clear requirements for drug packaging, identification, quality and processing, therefore the market of the larger pharmaceutical factories is focused on larger medical institutions, followed by clinics and pharmacy channels. Therefore, the relationship between the difference in size of the pharmaceutical plants, the ratio of their existing products with drug entity identification, and their willingness to implement drug entity identification is defined by the aforementioned scale of the pharmaceutical industry.

This study observed whether the percentage of each pharmaceutical factory's existing products with drug entity identification has a positive relationship with the scale of the pharmaceutical factory. Therefore, the following hypothesis was proposed in this study:

**H5: The size of the pharmaceutical factory has a positive impact on the proportion of drug entity identification.**

3.2.6 Relationship between the Product Structure of the Pharmaceutical Factory and the Proportion of Drug Entity Identification

In this study, solid preparations were mainly used as the formulation for identification. Solid preparations generally refer to naked tablets, enteric insoluble tablets, film coated tablets, slow release tablets, sugar-coated tablets, and capsule dosage forms. The product types and quantities of each pharmaceutical factory are affected by their channel properties and differences in business planning and equipment. According to the member properties of the Taiwan Pharmaceutical Industry Association, there are pharmaceutical factories that focus on the production of drip formulations, raw material formulations, oral formulations, injection formulations, topical formulations, eye, ear and nose formulations, vaginal/anal dosage forms, test formulations, dental dosage forms, traditional Chinese medicine types, cosmetic dosage forms, and other different dosage forms, and the main product structure of the pharmaceutical factory will affect the ratio of the actual products used for drug identification. Therefore, this study put forth the following hypothesis:

**H6: The product structure of the pharmaceutical factory has a positive effect on the proportion of implementation of drug entity identification.**

**4 Results Analysis**

The research object was western medicine factories. This study mainly discussed the following four constructs: the Scale of the Pharmaceutical Factory, the Pharmaceutical Factory’s Product Structure, the Ratio of Pharmaceutical Factories Already Implementing Drug Entity Identification, and Impact of Implementing Drug Entity Identification, to explore whether there is a willingness to cooperate in the future, that is, are the factories willing to use the drug entity identification system to assist their business. Therefore, a traditional paper questionnaire was adopted as the method of data collection, and western medicine factories were chosen as the sampling parent. To facilitate the sampling method, this study distributed a traditional paper questionnaire through the Taiwan Pharmaceutical Association to enable respondents to fill in the questionnaire.

4.1 Effect of Performing Drug Entity Identification Analysis

The results of the study indicated that the average mean of that government’s need to provide funding to support pharmaceutical factories in implementing drug entity identification was the highest (4.49).

Table 1 Statistical Table for Drug Identification Implemented in Pharmaceutical Factories

|  |  |  |  |
| --- | --- | --- | --- |
| No.  | Question contents  | Average mean | Standard deviation |
| 1 | You think that drugs should require the implementation of drug entity identification. | 4.32 | 0.68 |
| 2 | The company has the intention of coordinating with the project plan of the Department of Health to subsidize drug entity identification. | 4.30 | 0.67 |
| 3 | You know that the Department of Health has arranged project awards and grants to encourage pharmaceutical factories to implement drug entity identification. | 4.46 | 0.58 |
| 4 | You think that the government needs to enforce the norms of drug entity identification. | 3.55 | 0.98 |
| 5 | You think that the implementation of drug entity identification will increase pharmaceutical manufacturing costs. | 4.25 | 0.77 |
| 6 | You think that the implementation of old drug entity drug identification will increase the cost of each drug. | 4.23 | 0.84 |
| 7 | How much is the cost for old drugs to cooperate with the implementation of drug identification for each medicine? | 2.42 | 1.12 |
| 8 | The company’s attitude towards the compulsory requirement from medical institutions for drug entity identification. | 3.70 | 0.75 |
| 9 | You think that drug entity identification can help people with drug safety. | 4.07 | 0.67 |
| 10 | You think that the implementation of drug entity identification is most needed by the people.  | 3.62 | 0.77 |
| 11 | You think that the implementation of drug entity identification is most needed by the government.  | 3.48 | 0.83 |
| 12 | You think that the implementation of drug entity identification is most needed by medical institutions.  | 4.09 | 0.72 |
| 13 | You think that the implementation of drug entity identification is most needed by pharmaceutical factories.  | 3.64 | 0.89 |
| 14 | You think that the implementation of drug entity identification is most beneficial to the people.  | 3.99 | 0.72 |
| 15 | You think that the implementation of drug entity identification is most beneficial to the government.  | 3.43 | 0.87 |
| 16 | You think that the implementation of drug entity identification is most beneficial to medical institutions. | 3.99 | 0.76 |
| 17 | You think that the implementation of drug entity identification is most beneficial to pharmaceutical factories.  | 3.42 | 0.88 |
| 18 | You think that the government needs to provide funding to support pharmaceutical factories in implementing drug entity identification. | 4.49 | 0.66 |

4.2 Willingness to Cooperate

According to the results shown in Table 2, the overall average mean was 4.06, indicating that pharmaceutical manufacturers' perceptions of whether new drug products and imported drugs were undergoing drug identification tended to be high in the middle. Among which, the mean value of “Do you think that imported drugs need drug entity identification or not” was the highest (4.10), indicating that pharmaceutical factories consider imported drugs to be a model for drug entity identification. The mean value of "You believe that newly-marketed drugs should fully implement entity identification" was the lowest (4.01), indicating that pharmaceutical manufacturers do not believe it necessary for the full implementation of drug entity identification of all newly developed and marketed drugs. In addition, the standard deviation of “Do you think that imported drugs need drug entity identification or not” (1.09) was the highest, indicating that pharmaceutical factories include both state-owned and foreign-funded pharmaceutical factories, and they have different views on whether or not imported drugs are subject to drug entity identification. (Note: imported drugs are performed according to the rules of their country of origin, and whether Taiwan needs to promote the implementation of imported drug entity identification is subject to each factory). The standard deviation for “You believe that newly-marketed drugs should fully implement entity identification” was the lowest (0.83), indicating that there was consensus among the pharmaceutical factories that drug entity identification should be fully implemented on newly marketed drugs.

4.3 Reliability and validity analysis

Tables 3 and 4 show that the Cronbach's Alpha of the study constructs were all higher than 0.7, and the Item-Total Correlation was higher than 0.5 or close to 0.5. Therefore, the reliability and validity of this study both reached a certain level.

Table 2 Statistical Table of Willingness to Cooperate

|  |  |  |  |
| --- | --- | --- | --- |
| No.  | Question contents  | Average mean | Standard deviation |
| 1 | You believe that newly-marketed drugs should fully implement entity identification. | 4.01 | 0.83 |
| 2 | Do you think that imported drugs need drug entity identification or not?  | 4.10 | 1.09 |

Table 3 Reliability Analysis of Impact Scales for Performing Drug Entity Identification Analysis

|  |  |  |  |
| --- | --- | --- | --- |
| Scale Items  | Item-TotalCorrelation | Alpha If ItemDeleted | Coefficient Alpha |
| Government aspect |  |
| You think that the implementation of drug entity identification is most beneficial to the people.  | 0.3835 | 0.7698 | 0.7465 |
| You think that the implementation of drug entity identification is most beneficial to the government.  | 0.6595 | 0.6213 |
| You think that the implementation of drug entity identification is most beneficial to medical institutions. | 0.5969 | 0.6650 |
| You think that the implementation of drug entity identification is most beneficial to pharmaceutical factories.  | 0.5548 | 0.6875 |
| Implementation aspect |  |
| You think that drugs should require the implementation of drug entity identification. | 0.4843 | 0.7649 | 0.7865 |
| Your company’s attitude towards the compulsory requirements of medical institutions for drug entity identification.  | 0.6261 | 0.7310 |
| You think that the implementation of drug entity identification is most needed by the people.  | 0.4147 | 0.7811 |
| You think that the implementation of drug entity identification is most needed by the government.  | 0.4955 | 0.7636 |
| You think that the implementation of drug entity identification is most needed by medical institutions.  | 0.5858 | 0.7417 |
| You think that the implementation of drug entity identification is most needed by pharmaceutical factories.  | 0.6205 | 0.7305 |

|  |  |  |
| --- | --- | --- |
|

|  |
| --- |
| Benefit aspect |

 |  |
| Your company has the intention of coordinating with the project plan of the Department of Health to subsidize drug entity identification. | 0.5018 | 0.6680 | 0.7305 |
| You know that the Department of Health has arranged project awards and grants to encourage pharmaceutical factories to implement drug entity identification. | 0.5251 | 0.6660 |
| You think that the government needs to enforce the norms of drug entity identification. | 0.5694 | 0.6487 |
| You think that drug entity identification can help people with drug safety. | 0.4549 | 0.6850 |

Table 4 Reliability Analysis of Impact Scales for Performing Drug Entity Identification Analysis

|  |  |  |  |
| --- | --- | --- | --- |
| Scale Items | Item-TotalCorrelation | Alpha If ItemDeleted | Coefficient Alpha |
| You think that the government needs to provide funding to support pharmaceutical factories to implement drug entity identification | 0.4139 | 0.6995 |  ---- |
| Cost aspect |  |
| You think that the implementation of drug entity identification will increase pharmaceutical manufacturing costs. | 0.6771 | -- | 0.8075 |
| You think the use of old drugs in conjunction with the implementation of drug entity identification will increase the cost of each drug. | 0.6771 | -- |
| Impact of performing drug entity identification (17 items) | 0.8854 |

4.4 Chi-square Analysis

This study used Chi-square analysis to analyze the correlations and divided them into two groups: no significant impact and significant impact.

1. Detailed analysis of the results showing no significant effects

Table 5 Summary Tables of No Significant Effects

|  |  |  |  |
| --- | --- | --- | --- |
|  | Item | Chi-square test | Sig. |
|  | 1. Pharmaceutical factory site vs. willingness to cooperate  |  |  |
| 1 | Regions using newly-marketed drugs should fully implement entity identification.  | 9.232 a | 0.161 |
| 2 | Do regions using imported drugs need drug entity identification or not? | 10.895 a | 0.208 |
|  | 2. Capital amount vs. willingness to cooperate |  |  |
| 3 | Capital amount vs. newly-marketed drugs should fully implement entity identification. | 18.685 a | 0.096 |
| 4 | Capital amount vs. imported drugs need drug entity identification or not. | 22.675 a | 0.123 |
|  | 3. Annual total sales vs. willingness to cooperate |  |  |
| 5 | Annual total sales vs. newly-marketed drugs should fully implement entity identification. | 11.270 a | 0.258 |
| 6 | Annual total sales vs. imported drugs need drug entity identification or not. | 9.917 a | 0.623 |
|  | 4. Number of employees vs. willingness to cooperate |  |  |
| 7 | Number of employees vs. newly-marketed drugs should fully implement entity identification. | 14.132 a | 0.118 |
| 8 | Number of employees vs. imported drugs need drug entity identification or not. | 12.179 a | 0.431 |
|  | 5. Years since establishment vs. willingness to cooperate |  |  |
| 9 | Years since establishment vs. newly-marketed drugs should fully implement entity identification. | 4.213 a | 0.897 |
| 10 | Years since establishment vs. imported drugs need drug entity identification or not. | 14.906 a | 0.247 |
|  | 6. Proportion of domestic sales products in total annual turnover vs. willingness to cooperate |  |  |
| 11 | Proportion of domestic sales products in the total annual turnover vs. newly-marketed drugs should fully implement entity identification. | 8.910 a | 0.711 |
| 12 | Proportion of domestic sales products in the total annual turnover vs. imported drugs need drug entity identification or not. | 24.764 a | 0.074 |
|  | 7. Number of western drug preparations vs. willingness to cooperate |  |  |
| 13 | Number of western drug preparations vs. newly-marketed drugs should fully implement entity identification. | 9.578 a | 0.386 |
| 14 | Number of western drug preparations vs. imported drugs need drug entity identification or not. | 17.088 a | 0.146 |
|  | 8. Number of permits for tablets vs. willingness to cooperate |  |  |
| 15 | Number of permits for tablets vs. newly-marketed drugs should fully implement entity identification. | 5.709 a | 0.769 |
| 16 | Number of permits for tablets vs. imported drugs need drug entity identification or not. | 10.352 a | 0.585 |
|  | 9. Number of permits for oral capsules vs. willingness to cooperate |  |  |
| 17 | Number of permits for oral capsules vs. newly-marketed drugs should fully implement entity identification. | 3.901 a | 0.690 |
| 18 | Number of permits for oral capsules vs. imported drugs need drug entity identification or not. | 9.965 a | 0.268 |
|  | 10. Proportion of items with drug entity identification vs. willingness to cooperate |  |  |
| 19 | Proportion of items with drug entity identification vs. newly-marketed drugs should fully implement entity identification. | 18.120 a | 0.112 |
| 20 | Proportion of items with drug entity identification vs. imported drugs need drug entity identification or not. | 18.502 a | 0.295 |
|  | 11. Whether or not the compulsory requirements of medical institutions for drug entity identification are met vs. willingness to cooperate |  |  |
| 21 | Whether or not the compulsory requirements of medical institutions for drug entity identification are met vs. newly-marketed drugs should fully implement entity identification. | 1.260 a | 0.739 |
| 22 | Whether or not the compulsory requirements of medical institutions for drug entity identification are met vs. imported drugs need drug entity identification or not. | 7.017 a | 0.135 |
|  | 12. Implementation aspect - Company attitude towards the mandatory requirements of medical institutions for drug entity identification vs. willingness to cooperate |  |  |
| 23 | Implementation aspect - Company attitude towards the mandatory requirements of medical institutions for drug entity identification vs. newly-marketed drugs should fully implement entity identification. | 14.807 a | 0.096 |
| 24 | Implementation aspect - Company attitude towards the mandatory requirements of medical institutions for drug entity identification vs. imported drugs need drug entity identification or not. | 19.569 a | 0.076 |
|  | 13. Implementation aspect – Company belief that the implementation of drug entity identification is most needed by the government vs. willingness to cooperate |  |  |
| 25 | Implementation aspect – Company belief that the implementation of drug entity identification is most needed by the government vs. newly-marketed drugs should fully implement entity identification. | 9.319 a | 0.675 |
| 26 | Implementation aspect – Company belief that the implementation of drug entity identification is most needed by the government vs. imported drugs need drug entity identification or not. | 15.151 a | 0.514 |
|  | 14. Implementation aspect – Company believe that the implementation of drug entity identification is most needed by pharmaceutical factories vs. willingness to cooperate |  |  |
| 27 | Implementation aspect – Company belief that the implementation of drug entity identification is most needed by pharmaceutical factories vs. newly-marketed drugs should fully implement entity identification. | 9.072 a | 0.431 |
| 28 | Implementation aspect – Company belief that the implementation of drug entity identification is most needed by pharmaceutical factories vs. imported drugs need drug entity identification or not. | 8.538 a | 0.742 |
|  | 15. Benefit aspect – Company belief that drug entity identification can help people with drug safety vs. willingness to cooperate |  |  |
| 29 | Benefit aspect – Company belief that drug entity identification can help people with drug safety vs. newly-marketed drugs should fully implement entity identification. | 13.732 a | 0.132 |
| 30 | Benefit aspect – Company belief that drug entity identification can help people with drug safety vs. imported drugs need drug entity identification or not. | 11.861 a | 0.457 |
|  | 16. Benefit aspect – Company belief that the implementation of drug entity identification is most beneficial to the public vs. willingness to cooperate |  |  |
| 31 | Benefit aspect – Company belief that the implementation of drug entity identification is most beneficial to the public vs. newly-marketed drugs should fully implement entity identification. | 15.508 a | 0.078 |
| 32 | Benefit aspect – Company belief that the implementation of drug entity identification is most beneficial to the public vs. imported drugs need drug entity identification or not. | 20.421 a | 0.060 |
|  | 17. Benefit aspect – Company belief that the implementation of drug entity identification is most beneficial to the government vs. willingness to cooperate |  |  |
| 33 | Benefit aspect – Company belief that the implementation of drug entity identification is most beneficial to the government vs. newly-marketed drugs should fully implement entity identification. | 14.607 a | 0.264 |
| 34 | Benefit aspect – Company belief that the implementation of drug entity identification is most beneficial to the government vs. imported drugs need drug entity identification or not. | 18.507 a | 0.295 |
|  | 18. Benefit aspect – Company belief that the implementation of drug entity identification is most beneficial to pharmaceutical factories vs. willingness to cooperate |  |  |
| 35 | Benefit aspect – Company belief that the implementation of drug entity identification is most beneficial to pharmaceutical factories vs. newly-marketed drugs should fully implement entity identification. | 15.949 a | 0.068 |
| 36 | Benefit aspect – Company belief that the implementation of drug entity identification is most beneficial to pharmaceutical factories vs. imported drugs need drug entity identification or not. | 15.013 a | 0.241 |
|  | 19. Cost aspect - The company thinks that the implementation of old drug entity drug identification will increase the cost of each drug vs. willingness to cooperate |  |  |
| 37 | Cost aspect - The company thinks that the implementation of old drug entity drug identification will increase the cost of each drug vs. newly-marketed drugs should fully implement entity identification. | 12.462 a | 0.188 |
| 38 | Cost aspect - The company thinks that the implementation of old drug entity drug identification will increase the cost of each drug vs. imported drugs need drug entity identification or not. | 20.803 a | 0.053 |
|  | 20. Capital amount vs. pharmaceutical factory’s drug identification |  |  |
| 39 | Capital amount vs. whether the company has implemented in-plant drug entity identification specifications | 3.464 a | 0.483 |
| 40 | Capital amount vs. ratio of products that the company has performed drug entity identification on  | a21.360 | 0.165 |
| 41 | Capital amount vs. whether the company’s newly marketed products have drug entity identification | a5.576 | 0.233 |
| 42 | Capital amount vs. whether the company has been required by medical institutions for compulsory drug entity identification | a6.218 | 0.183 |
|  | 21. Total annual sales vs. pharmaceutical factory’s drug identification |  |  |
| 43 | Total annual sales vs. whether the company has implemented in-plant drug entity identification specifications | 0.456 a | 0.928 |
| 44 | Total annual sales vs. ratio of products that the company has performed drug entity identification on  | 12.259 a | 0.425 |
| 45 | Total annual sales vs. whether the company’s newly marketed products have drug entity identification | 2.599 a | 0.458 |
| 46 | Total annual sales vs. whether the company has been required by medical institutions to provide compulsory drug entity identification | 7.132 a | 0.068 |
|  | 22. Number of employees vs. pharmaceutical factory’s drug identification |  |  |
| 47 | Number of employees vs. whether the company has implemented in-plant drug entity identification specifications | 1.424 a | 0.700 |
| 48 | Number of employees vs. ratio of products that the company has performed drug entity identification on  | 9.666 a | 0.645 |
| 49 | Number of employees vs. whether the company’s newly marketed products have drug entity identification | 2.815 a | 0.421 |
| 50 | Number of employees vs. whether the company has been required by medical institutions to provide compulsory drug entity identification | 4.431 a | 0.219 |
|  | 23. Years since establishment vs. pharmaceutical factory’s drug identification |  |  |
| 51 | Years since establishment vs. whether the company has implemented in-plant drug entity identification specifications | 1.298 a | 0.730 |
| 52 | Years since establishment vs. ratio of products that the company has performed drug entity identification on | 4.932 a | 0.960 |
| 53 | Years since establishment vs. whether the company’s newly marketed products have drug entity identification | 2.627 a | 0.453 |
| 54 | Years since establishment vs. whether the company has been required by medical institutions to provide compulsory drug entity identification | 4.039 a | 0.257 |
|  | 24. Number of permits for oral tablets vs. ratio of implementing drug entity identification  |  |  |
| 55 | Number of permits for oral tablets vs. whether it has already implemented pharmaceutical drug identification | 2.603 a | 0.457 |
| 56 | Number of permits for oral tablets vs. ratio of items that have implemented identification  | 12.903 a | 0.376 |
| 57 | Number of permits for oral tablets vs. whether newly marketed drugs have implemented identification | 3.886 a | 0.274 |
| 58 | Number of permits for oral tablets vs. whether compulsory identification is required | 4.876 a | 0.181 |
|  | 25. Number of permits for oral capsules vs. ratio of implementing drug entity identification |  |  |
| 59 | Number of permits for oral capsules vs. whether it has already implemented pharmaceutical drug identification | 5.382 a | 0.068 |
| 60 | Number of permits for oral capsules vs. ratio of items that have implemented identification  | 10.597 a | 0.226 |
| 61 | Number of permits for oral capsules vs. whether newly marketed drugs have implemented identification | 11.210 a | 0.546 |
| 62 | Number of permits for oral tablets vs. whether compulsory identification is required | 3.648 a | 0.161 |

**P< 0.05 \* P< 0.01 \*\***

According to Table 5, the Chi-square test found that the site of the pharmaceutical factory, the amount of capital, the total annual turnover, the number of employees, the number of years since establishment, the ratio of domestic sales to total annual turnover, the number of Western medicine preparations, the number of permits for oral tablets, the number of permits for oral capsules, the proportion of items that have implemented drug entity identification, whether the medical institutions have required compulsory drug entity identification, the implementation aspect of the company’s attitude towards the mandatory requirements of medical institutions for drug entity identification, the implementation aspect of company belief that the implementation of drug entity identification is most needed by the government, the implementation aspect of company belief that the implementation of drug entity identification is most needed by the pharmaceutical factories, the benefit aspect of company belief that drug entity identification can help people with drug safety, the benefit aspect of company belief that the implementation of drug entity identification is most beneficial to the public, the benefit aspect of company belief that the implementation of drug entity identification is most beneficial to the government, the benefit aspect of company belief that the implementation of drug entity identification is most beneficial to the pharmaceutical factories, and the cost aspect of the company’s view that the implementation of old drug entity drug identification will increase the cost of each drug have no significant effect on the willingness to cooperate. Capital amount, total annual turnover, number of employees and number of years since establishment had no significant impact on the drug identification of the pharmaceutical factories as found by the Chi-square test. In addition, the number of permits for oral tablets and oral capsules had no significant impact on the drug identification of the pharmaceutical factories as found by the Chi-square test.

2. Detailed analysis results of significant effects

Table 6 Statistical Table of Significant Effects

|  |  |  |  |
| --- | --- | --- | --- |
|  | Item | Chi-square test | Sig. |
|  | 1. Whether in-plant drug entity identification has been implemented vs. willingness to cooperate |  |  |
| 1 | Whether in-plant drug entity identification has been implemented vs. newly-marketed drugs should fully implement entity identification | 9.691 a | 0.021\* |
| 2 | Whether in-plant drug entity identification has been implemented vs. imported drugs need drug entity identification or not | 6.699 a | 0.153 |
|  | 2. Whether newly-marketed drugs have implemented drug entity identification vs. willingness to cooperate  |  |  |
| 3 | Whether newly-marketed drugs have implemented drug entity identification vs. newly-marketed drugs should fully implement entity identification | 10.357 a | 0.016\* |
| 4 | Whether newly-marketed drugs have implemented drug entity identification vs. newly-marketed drugs should fully implement entity identification | 7.446 a | 0.114 |
|  | 3. Government aspect - The company cooperates with the Department of Health to subsidize pharmaceutical factories to implement drug entity identification vs. willingness to cooperate |  |  |
| 5 | Government aspect - The company cooperates with the Department of Health to subsidize pharmaceutical factories to implement drug entity identification vs. willingness to cooperate vs. newly-marketed drugs should fully implement entity identification | 13.776 a | 0.032\* |
| 6 | Government aspect - The company cooperates with the Department of Health to subsidize pharmaceutical factories to implement drug entity identification vs. willingness to cooperate vs. newly-marketed drugs should fully implement entity identification | 9.092 a | 0.335 |
|  | 4. Government aspect - The Department of Health arranges project grants to encourage the pharmaceutical factories to implement drug entity identification vs. willingness to cooperate |  |  |
| 7 | Government aspect - The Department of Health arranges project grants to encourage the pharmaceutical factories to implement drug entity identification vs. newly-marketed drugs should fully implement entity identification | 18.641 a | 0.005\*\* |
| 8 | Government aspect - The Department of Health arranges project grants to encourage the pharmaceutical factories to implement drug entity identification vs. newly-marketed drugs should fully implement entity identification | 19.455 a | 0.013\* |
|  | 5. Government aspect – The government needs to mandate regulations for drug entity identification vs. willingness to cooperate |  |  |
| 9 | Government aspect – The government needs to mandate regulations for drug entity identification vs. newly-marketed drugs should fully implement entity identification | 24.695 a | 0.003\*\* |
| 10 | Government aspect – The government needs to mandate regulations for drug entity identification vs. newly-marketed drugs should fully implement entity identification | 24.492 a | 0.017\* |
|  | 6. Government aspect – The government needs to continue to provide subsidies to pharmaceutical factories to implement drug entity identification vs. willingness to cooperate |  |  |
| 11 | Government aspect – The government needs to continue to provide subsidies to pharmaceutical factories to implement drug entity identification vs. newly-marketed drugs should fully implement entity identification | 14.550 a | 0.104 |
| 12 | Government aspect – The government needs to continue to provide subsidies to pharmaceutical factories to implement drug entity identification vs. newly-marketed drugs should fully implement entity identification | 36.018 a | 0.000\*\* |
|  | 7. Implementation aspect - Drugs should implement entity identification vs. willingness to cooperate |  |  |
| 13 | Implementation aspect - Drugs should implement entity identification vs. newly-marketed drugs should fully implement entity identification | 23.542 a | 0.001\*\* |
| 14 | Implementation aspect - Drugs should implement entity identification vs. newly-marketed drugs should fully implement entity identification | 4.586 a | 0.801 |
|  | 8. Implementation aspect – Company belief that the implementation of drug entity identification is most needed by the public vs. willingness to cooperate |  |  |
| 15 | Implementation aspect – Company belief that the implementation of drug entity identification is most needed by the public vs. newly-marketed drugs should fully implement entity identification | 18.892 a | 0.026\* |
| 16 | Implementation aspect – Company belief that the implementation of drug entity identification is most needed by the public vs. newly-marketed drugs should fully implement entity identification | 8.709 a | 0.728 |
|  | 9.Implementation aspect – Company belief that the implementation of drug entity identification is most needed by medical institutions vs. willingness to cooperate |  |  |
| 17 | Implementation aspect – Company belief that the implementation of drug entity identification is most needed by medical institutions vs. newly-marketed drugs should fully implement entity identification | 15.247 a | 0.084 |
| 18 | Implementation aspect – Company belief that the implementation of drug entity identification is most needed by medical institutions vs. newly-marketed drugs should fully implement entity identification | 34.263 a | 0.001\*\* |
|  | 10. Benefit aspect – Company belief that the implementation of drug entity identification is most beneficial to medical institutions vs. willingness to cooperate |  |  |
| 19 | Benefit aspect – Company belief that the implementation of drug entity identification is most beneficial to medical institutions vs. newly-marketed drugs should fully implement entity identification | 20.388 a | 0.016\* |
| 20 | Benefit aspect – Company belief that the implementation of drug entity identification is most beneficial to medical institutions vs. newly-marketed drugs should fully implement entity identification | 29.244 a | 0.004\*\* |
|  | 11. Cost aspect – Company belief that the implementation of drug entity identification will increase the manufacturing costs of pharmaceutical factories vs. willingness to cooperate |  |  |
| 21 | Cost aspect – Company belief that the implementation of drug entity identification will increase the manufacturing costs of pharmaceutical factories vs. newly-marketed drugs should fully implement entity identification | 14.000 a | 0.122 |
| 22 | Cost aspect – Company belief that the implementation of drug entity identification will increase the manufacturing costs of pharmaceutical factories vs. newly-marketed drugs should fully implement entity identification | 24.462 a | 0.018\* |
|  | 12. Site of pharmaceutical factory vs. existing implementation of drug identification in the pharmaceutical factory  |  |  |
| 23 | Region vs. whether the company has implemented in-plant drug entity identification specifications | 3.056 a | 0.217 |
| 24 | Region vs. proportion of company products that have drug entity identification of all drug products | 6.429 a | 0.599 |
| 25 | Region vs. whether the company's newly developed and marketed drugs already use drug entity identification  | 7.587 a | 0.023\* |
| 26 | Region vs. whether the company has been required by medical institutions to provide compulsory drug entity identification  | 0.421 a | 0.810 |
|  | 13. Proportion of domestic pharmaceutical factory sales vs. proportion of drug entity identification |  |  |
| 27 | Proportion of domestic pharmaceutical factory sales vs. whether or not the pharmaceutical factory has implemented drug identification | 17.161 a | 0.002\*\* |
| 28 | Proportion of domestic pharmaceutical factory sales vs. proportion of drugs already implementing drug identification  | 8.461 a | 0.934 |
| 29 | Proportion of domestic pharmaceutical factory sales vs. whether newly developed and marketed drugs have been identified  | 9.006 a | 0.061 |
| 30 | Proportion of domestic pharmaceutical factory sales vs. whether compulsory identification is required | 1.391 a | 0.846 |
|  | 14. Number of Western medicine product items vs. ratio of drug entity identification  |  |  |
| 31 | Number of Western medicine product items vs. whether or not the pharmaceutical factory has implemented drug identification | 6.221 a | 0.101 |
| 32 | Number of Western medicine product items vs. proportion of drugs already implementing drug identification  | 9.335 a | 0.674 |
| 33 | Number of Western medicine product items vs. whether newly developed and marketed drugs have been identified  | 7.449 a | 0.059 |
| 34 | Number of Western medicine product items vs. whether compulsory identification is required | 12.108 a | 0.007\*\* |

**P< 0.05 \* P< 0.01 \*\***

As shown in Table 6, whether the pharmaceutical factory has already performed in-plant drug entity identification, whether the newly-developed drug product has implemented drug entity identification, the government aspect of company cooperation with the Department of Health to subsidize pharmaceutical factories to implement drug entity identification, the government aspect of the Department of Health arranging project grants to encourage the pharmaceutical factories to implement drug entity identification, the government aspect of the government’s need to mandate regulations for drug entity identification, the government aspect of the government’s need to continue to provide subsidies to pharmaceutical factories to implement drug entity identification, the implementation aspect of drugs should implement entity identification, the implementation aspect of company belief that the implementation of drug entity identification is most needed by the public, the implementation aspect of company belief that the implementation of drug entity identification is most needed by medical institutions, the benefit aspect of company belief that the implementation of drug entity identification is most beneficial to medical institutions, and the cost aspect of company belief that the implementation of drug entity identification will increase the manufacturing costs of the pharmaceutical factories, have a significant impact on the willingness to cooperate. The site of the pharmaceutical factory had a significant impact on drug identification implementation, as shown by the Chi-square test. In addition, the proportion of domestic sales of pharmaceutical plants and the number of Western drug items had a significant impact on the ratio of drug entity identification, as found by the chi-square test.

**5 Conclusion and Suggestions**

5.1 Results and Discussion

The purpose of medical services is to relieve or reduce patient illness and improve quality of life. However, some patients are harmed during the doctor’s treatment process. The Taiwan pharmaceutical industry mainly focuses on the domestic market, which accounts for about 70% of the total market demand for medicines. After joining the WTO, it is expected by the government that Taiwan will soon face fierce competition from multinational pharmaceutical companies. In order to improve product quality and strengthen the international competitiveness of the industry, such policies as GMP, cGMP, data exclusive rights, and drug identification systems have been implemented one after another. The operating costs will continue to increase, but the pharmaceutical factories have to face continued price reductions due to poor finances of the National Health Insurance system, which also results in the continuous profit reduction of the pharmaceutical factories.

Taking into account the enhancement of people's drug safety and the supply of effective and identifiable medicines to medical professionals, pharmaceutical factories have the responsibility to cooperate with the government in promoting the implementation of the drug entity identification system, but they also expect the government to make provisions for funding or awards for the full enforcement of the drug entity identification of drugs made in Taiwan and imported drugs. This study understood the pharmaceutical plant's recognition of the implementation of drug identification system and the benefits of the drug identification system to the people and medical institutions. Therefore, it is hoped to provide medicines that can be discerned by the general public and medical professionals as soon as possible so that Taiwan can be among advanced countries in terms of medicine and pharmaceutics.

This study showed that pharmaceutical factories have recognized the necessity to promote the identification of drug entities in order to take into account the safety of people's medications and solve the problems caused by bulk drugs that are difficult to identify by people and medical staff. This study is looking forward to the establishment of a comprehensive drug identification system in Taiwan as soon as possible to ensure the public drug safety and provide reference information for identification by practitioners and patients in Taiwan.

5.2 Suggestions for Future Research

This study only focused on discussing the relationship among scale, regionality , product volume and structure, costs, the implementation status of each pharmaceutical factory, and the willingness to implement the drug entity identification system, and did not investigate the characteristics of the subject (the expertise of the respondents or the proportion of pharmaceutical companies' operation, etc.), and environmental factors, and the impact of major changes in the relationships among the main variables factors were not discussed. Therefore, these factors are limitations of the model in this study.

This study proposed the following suggestions for future research related to this study:

1. The scope of the respondents to the questionnaire of this study

The target of the questionnaire in this study was Taiwanese pharmaceutical factories. Although the Taiwanese pharmaceutical factory supplies more than 70% of the market's consumption, foreign imported medicines also provide 30% of the pharmaceuticals for users. Therefore, it is recommended that follow-up researchers incorporate the pharmaceutical factories of imported drugs or their respective agents in Taiwan as the respondents for the questionnaire to expand the research coverage.

2. The study object of this study

This study took Taiwan pharmaceutical factories as the study object. If medical institutions or doctors and the public can be included in the survey, there will be a better understanding of the needs for various drugs.

3. Follow-up research of this study

According to the results of the research data, Taiwanese pharmaceutical factories have a broad understanding of drug entity identification, but nearly half of the licensed drugs have not had appearance identification. This study was unable to fully understand the implementation of the pharmaceutical factories through the questionnaire. Therefore, it is suggested by the study that follow-up research be conducted by direct visits to enhance the breadth of the research results.

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