

Promote Medical Scientific Achievements Transformation based on Process Management

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Abstract

The low conversion rate of pharmaceutical scientific achievements is one of the problems to be solved in China's pharmaceutical industry. analyze the transformation activities of drug scientific achievements from the perspective of process management to clarify the transformation process, promote the transformation of drug scientific achievements, improve drug access, and avoid drug regulatory risks. Based on the analysis of the current situation of the transformation process, it is proposed to improve the basic research, original innovation ability and intellectual property awareness of drugs. To construct the mode of "relay transformation" of drug scientific achievements; Improve drug regulatory capacity, optimize the drug regulatory system and balance the interests of all parties. It is of great practical value and significance for promoting the innovative and high-quality development of China's pharmaceutical industry and meeting the people's drug needs and requirements.

Keywords

Scientific Achievements Transformation; Medicine; Countermeasures.

1. Introduction

The pharmaceutical industry is a high-tech and strategic pillar industry of the country. It is the focus of competition among countries all over the world. The pharmaceutical industry is also related to people's life and health safety. China attaches great importance to the development of the pharmaceutical industry and has introduced a series of policies and measures to promote the innovation and upgrading of the pharmaceutical industry. However, there is still a big gap between the innovation level of China's pharmaceutical industry and that of developed countries, and the people's demand for high-quality and cheap drugs has not been effectively met. Part of the reason is that the transformation of pharmaceutical scientific and technological achievements in China is at a low level and the conversion rate is low [1]. The transformation of pharmaceutical scientific and technological achievements is an important way to realize the combination of pharmaceutical "science and technology" and "economy", and an important way to promote the innovative and high-quality development of China's pharmaceutical industry and meet the needs of the people for drug use. Therefore, "difficult transformation" and "low transformation" of pharmaceutical scientific and technological achievements are one of the problems to be solved urgently in China's pharmaceutical industry at present. It is of great practical and valuable significance to study the difficulties in the transformation of pharmaceutical scientific and technological achievements and put forward relevant countermeasures and suggestions to promote the transformation of pharmaceutical scientific and technological achievements.

The transformation of pharmaceutical scientific and technological achievements is characterized by high investment, high risk and long periodicity, which is also the main difficulty of the transformation of pharmaceutical scientific and technological achievements.

The process stage division and management of science and technology activities are beneficial to save the overall time and cost of science and technology activities. The theory and method of process management play an important role in promoting the success of science and technology activities [2]. Process management is one of the core concepts of total quality management, and has certain applicability in the field of scientific research management. It can not only improve the R&D performance of scientific research institutions, but also promote the knowledge sharing, process and function flexible integration of scientific research departments [3]. The "process" in ISO9000:2015 Quality Management System Fundamentals and Terminology refers to a group of activities related or interacting with each other that produce expected results with inputs, including resources such as people, things and funds, and expected results including output, products or services, etc. Consistent and predictable results can be achieved more effectively and efficiently only when activities are understood and managed as processes that operate as interconnected coherent systems. Process management is the use of a set of practices, techniques and tools to plan, control and improve the effectiveness, efficiency and adaptability of the process [4]. Analyzing scientific research activities from the perspective of process management mainly includes clarifying the input and expected results of the process, the process of the whole activity, the required resources, the main control points and control methods, and the evaluation of the expected results of each process [5].

Therefore, this article will from the perspective of process management of drugs in the transformation of scientific and technological achievements, clear medicine the main stages of in the process of transformation of scientific and technological achievements and control points, and in combination with the study and related data analysis, the following data are from the 2018 China statistical yearbook of science and technology and the higher education (2013-2017), statistics collection), on the basis of It is of great value and significance to analyze the current situation, main characteristics and difficulties of each process stage and put forward countermeasures and suggestions to promote the transformation of pharmaceutical scientific and technological achievements in China, which will promote the innovative and high-quality development of China's pharmaceutical industry and improve the accessibility of medicines.

2. Key Characteristics and Control Points of Transformation of Pharmaceutical Scientific and Technological Achievements

2.1. Promote the Transformation of Scientific and Technological Achievements and Improve the Balance of Drug Accessibility

2.1.1. Drug Prices and Access

The particularity of drugs is that they are used to treat human diseases. The transformation of scientific and technological achievements of drugs is not only to promote the combination of "science and technology" and "economy", promote the innovation and development of the pharmaceutical industry, and realize economic value, but also to timely meet the needs of patients for the treatment of diseases and improve the quality of human life. Therefore, the transformation of pharmaceutical scientific and technological achievements should not only consider its economic contribution, but also consider the issue of drug accessibility, that is, to ensure that patients can obtain high-quality drugs at an affordable price, timely and continuously. The factors affecting drug accessibility mainly include drug price and medical insurance system [6].

In order to solve the problem of "expensive medical treatment", reduce the economic burden of patients and reduce the price of drugs has become one of the important goals of the current medical and health system reform. Although China has in 2015 (Notice on Printing and Issuing Opinions on Promoting Drug Price Reform (Fagai Price [2015] No. 904)) to cancel the government's price controls on most of the drugs, formation dominated by market competition

mechanism of drug prices, but on the patent medicine such as exclusive monopoly or pharmaceuticals price negotiation purchasing pharmaceuticals and health care access, etc. The government's drug procurement mechanism and medical insurance payment method have a significant impact on the price of patented drugs, and play a good role in inhibiting [7]. The intervention of government policy factors in the exclusive or monopoly drugs such as patented drugs to restrain or reduce the high price of patented drugs will improve the accessibility of drugs, but it will also lead to the reduction of profits of related drugs. Due to the high cost and 20-year patent protection period of innovative original research drugs, the actual marketing time of innovative original research drugs is only 5-8 years due to the long periodicity of research and development of innovative original research drugs (12-15 years on average) [8]. However, once the protection period is lost, there will be a large number of generic drugs, which will greatly reduce the profits of the original innovative drug research enterprises. Therefore, the original innovative drug research enterprises will set high prices during the drug patent protection period to achieve the expected return on investment. The profitability of innovative drugs helps the industry to increase R&D investment, attract venture capital and improve the industry-University-Research cooperative R&D system. The strong profitability of innovative drugs is one of the key factors for the realization of a virtuous cycle of innovation in the pharmaceutical industry of the United States [9].

Therefore, the price intervention of the government on exclusive or monopoly drugs such as patented drugs reduces the profit of related drugs and makes it difficult to achieve the expected profit. To a certain extent, it also restrains the enthusiasm of investment in innovative drug research and development and the impetus of transformation of drug scientific and technological achievements. Therefore, in the process of transformation of pharmaceutical scientific and technological achievements, the government departments need to control the balance between the accessibility of drugs, the innovation incentive of pharmaceutical industry and the transformation power of pharmaceutical scientific and technological achievements.

2.1.2. Intellectual Property Protection and Access to Medicines

Compared with other industries, patent plays the most important role in the protection of pharmaceutical scientific and technological achievements [10]. However the patent system in to protect the interests of the related subjects and the pharmaceutical industry innovation motivation also hindered the accessibility of drugs at the same time, concrete embodiment in patent medicine between the price of high price and cheap generics formed by contrast, but in the long run, the patent system to promote the transformation of scientific and technological achievements, innovation in the pharmaceutical industry and drug development, It satisfies the public's availability of innovative drugs and promotes drug accessibility to a certain extent [11]. Therefore, the government also needs to control the balance between the strength of patent protection and the promotion of drug technology diffusion and the improvement of drug accessibility in the transformation process of drug scientific and technological achievements.

2.2. Promote the Balance between the Transformation of Pharmaceutical Scientific and Technological Achievements and the Avoidance of Pharmaceutical Regulatory Risks

Timely access to high quality medicines is to ensure that drugs are safe and effective, and to complete the process from research and development to marketing as quickly as possible to meet the needs of patients. Drug regulatory system, especially drug evaluation and approval system, plays an important role in the transformation of drug scientific and technological achievements. Due to frequent drug safety incidents, the production and sale of counterfeit drugs are huge, and drug supervision is becoming more and more difficult [12]. Due to the drug regulatory department in order to avoid because the license is invalid or unsafe drugs to enter the market first to blame and give preference to be very cautious conservative regulatory path,

the complexity and uncertainty of its regulatory decision stems mainly from the following two aspects [13]: (1) the listing of drug evaluation before and after the expected manageability security incident; (2) Medical needs of the public. Drug regulatory decisions are characterized by a focus on the worst case, where reliability constraints direct drug regulatory attention to the most unlikely benefits and the greatest risks associated with drug use [14]. Therefore, some scholars believe that the existing drug regulatory system has set up unnecessary obstacles for drug research and development, and hindered or delayed the opportunity for patients to obtain innovative drugs [15].

Practice has proved, on the other hand, the change of China's drug approval for examination and approval system of innovative medicine played a good role in promoting transformation of scientific and technological achievements, made drug quantity, quality improvement, transformation of scientific and technological achievements into the main body scope, improve the medical technology trading market activity, and improves the efficiency of scientific research institution and the drug regulatory agency of communication, market-oriented to promote the new drug research and development [16]. Drug approval, for example, examination and approval of standard and strict make new drugs significantly lower probability of successful listing, time limit for examination and approval of new drugs more than clinical trial application, but improve the value of the new drug certificate for ascending the new drug certificate of this form of medicine science and technology achievements transformation value and market recognition, as well as the innovative drugs to give priority to, to speed up the review of the examination and approval system, Shorten the transformation cycle of innovative drug scientific and technological achievements, and also play a role in encouraging and guiding the research and development of innovative drugs to a certain extent; The implementation of the drug marketing licensor system has realized the separation of drug ownership and production rights, which enables drug R&D personnel and research institutions to have drug ownership, and improves the initiative of scientific research personnel and research institutions in the transformation of drug scientific and technological achievements. Therefore, drug regulatory authorities need to effectively control the balance between risks and benefits of drug supervision during the transformation of drug scientific and technological achievements, and ensure the quality and safety of drugs while promoting the transformation of drug scientific and technological achievements.

3. Analysis on the Current Situation of Transformation Process of Scientific and Technological Achievements in Medicine

3.1. Laboratory Research Stage -- The Investment in Basic Research is Relatively Low, and the High Quality and Original Innovative Scientific and Technological Achievements are Insufficient

The research stage of the transformation of pharmaceutical scientific and technological achievements in the laboratory mainly refers to the link between target identification and preclinical research in the transformation process of pharmaceutical scientific and technological achievements. A large amount of human and financial resources are needed to identify disease targets, discover new molecular entities, and carry out incremental drug innovation on the basis of the research stage of pharmaceutical scientific and technological achievements transformation laboratory. As shown in Figure 1, it can be seen that the R&D manpower and investment in China's pharmaceutical manufacturing industry are mainly concentrated in the field of applied research and experimental development, while the investment in basic research is less, especially in the aspect of R&D investment. Basic research is an important force to promote the innovation and development of China's pharmaceutical industry. China's pharmaceutical industry has a strong dependence on basic research, but the

lack of investment in basic research and unreasonable allocation of resources lead to most of the existing scientific and technological achievements are developed based on foreign original innovation [17].

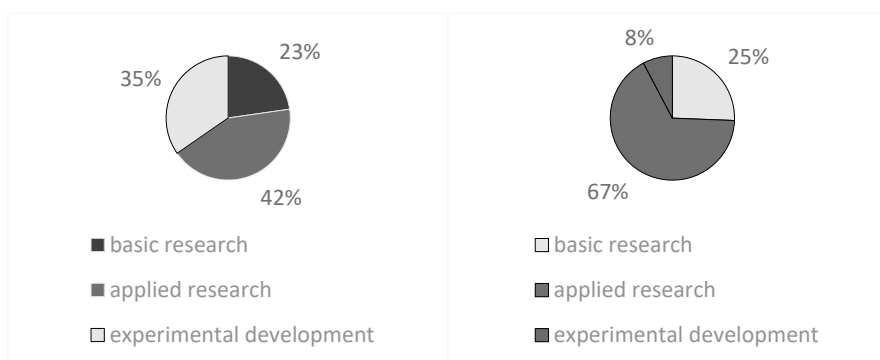


Figure 1. The distribution of full-time equivalent of R&D personnel (left) and internal R&D expenditure (right) in China's pharmaceutical manufacturing industry in 2017

3.2. Pilot-scale Process -- Drug Regulatory System has an Important Influence on the Transformation

Compared with the "pilot" process of the transformation of scientific and technological achievements in the general industry to reduce the risk of transformation and improve the efficiency of transformation through pilot production, trial use and trial marketing, the transformation of scientific and technological achievements of drugs still needs to go through strict clinical trials and marketing approval by the drug regulatory authorities. Drug clinical trial is the link with the highest R&D investment (accounting for nearly 60% of the total investment) and the longest time (6-7 years on average) in the process of drug R&D. It takes 10 to 15 years for a new drug to reach the market, while it takes 7.2 years on average from clinical trials to completion of marketing approval. Despite this, the success rate in clinical trials is very low, averaging only 16% [18].

At the same time, due to the frequent occurrence of drug safety incidents, drug regulatory authorities are constantly improving the regulatory requirements and standards for the "pilot test" process in order to ensure the safety of drugs, and the cost and time of the "pilot test" process for the transformation of drug scientific and technological achievements are further increased on the existing basis and further prolonged. Data show that the total number of intermediate procedures per clinical trial for a drug and the total number of clinical investigators for a drug increased by 57% and 64%, respectively, between 2000 and 2003 and 2008 to 2011, and that the standards for subjects in clinical trials for a drug also improved further. The number of subject eligibility criteria increased by 58%, resulting in a 21% and 30% drop in subject enrollment and retention rates, respectively [18]. In addition, compared with the efficiency of developed countries, there is still a big gap in the efficiency of drug marketing approval in China, which leads to a further extension of the transformation cycle. These factors undoubtedly further increase the difficulty, increase the risk and reduce the success rate of transformation of pharmaceutical scientific and technological achievements.

In conclusion, compared with the "pilot" process of transformation of scientific and technological achievements in other industries, the "pilot" process of transformation of scientific and technological achievements in drugs not only has higher input, risk and long periodicity, but also is significantly affected by the regulatory system of drug regulatory authorities. In addition, it is necessary to recruit volunteers for clinical trials and conduct clinical trials in medical institutions with qualifications for clinical trials, which increases the

difficulty and complexity of the "pilot" process of transformation of pharmaceutical scientific and technological achievements.

3.3. Commercialization Stage -- Balancing the Power of Transformation of Scientific and Technological Achievements with the Accessibility of Medicines

The commercialization process of drug scientific and technological achievements mainly includes large-scale production, drug bidding and procurement, medical insurance access and post-marketing research. Drug bidding procurement mainly relates to the current government departments on the patent drugs such as exclusive or monopoly drugs price intervention, government procurement, health insurance directory access through negotiation policy factors such as price negotiations while it is possible to lower the price of patent medicine to improve drug accessibility for medicine science and technology achievements transformation power also has certain negative effect. In addition, the medical insurance system enables the drugs that can be included in the medical insurance list to be reimbursed by the patients to a certain extent, so that the market sales of the drugs can be greatly increased, which can promote the transformation of scientific and technological achievements of drugs to a certain extent, and make up for the negative impact caused by the reduction of drug prices.

However, there are still some problems and deficiencies in the access of innovative drugs in China's medical insurance directory, including the long actual adjustment period of the medical insurance directory and the long waiting period from the listing of innovative drugs to their entry into the medical insurance directory (only 2-3 months in Japan and 54 months in the average waiting period for negotiated drugs in 36 countries in China). In that year, the proportion of innovative drugs included in the medical insurance list was relatively low (93.4% in Japan and 54.5% in China). The list of innovative drug treatments included in the medical insurance is relatively narrow, mostly cancer drugs [19]. In addition, the Chinese medical insurance directory at this stage still adopt expert selection system, which mainly through expert opinion to determine whether innovative drug access to health insurance directory, involved in the whole process and the transformation of scientific and technological achievements of scientific and technological achievements of registration and evaluation of scientific and technological achievements, some scholars pointed out that in medical insurance directory links should also adopt innovative drug selection letter drug evaluation results of scientific and technological achievements, To improve the evaluation system of pharmaceutical scientific and technological achievements, improve the quality of pharmaceutical scientific and technological achievements, so as to improve the success rate of transformation of pharmaceutical scientific and technological achievements [20]. It can be seen that at the present stage, China has not fully played the role of medical insurance directory in promoting the transformation of drug scientific and technological achievements in terms of medical insurance access.

In addition, due to the importance of patent for the pharmaceutical industry is much higher than other industry, drug return of transformation of scientific and technological achievements commercialization stage mainly in the drug patent protection period, but the "excessive" affect drug accessibility, patent protection of pharmaceutical science and technology achievements transformation while it is possible to promote the "science and technology" and "economy", However, it may not necessarily promote the innovation and upgrading of China's pharmaceutical industry and improve the welfare of patients. At present, there is still a big gap between the innovation level of China's pharmaceutical industry and that of developed countries, which is still dominated by generic drugs. Currently, China's drug patent regulations are relatively advanced and strict, and the patent development of China's pharmaceutical

industry has not kept pace with them, which is not conducive to the development of China's pharmaceutical industry [21].

4. Countermeasures to Promote the Transformation of Pharmaceutical Scientific and Technological Achievements from the Perspective of Process Management

4.1. Improve the Ability of Basic Pharmaceutical Research, Original Innovation and Awareness of Intellectual Property Rights

The transformation of pharmaceutical scientific and technological achievements is inseparable from high-quality pharmaceutical scientific and technological achievements, and patent plays a very prominent role in the transformation of pharmaceutical scientific and technological achievements. "Scientific and technological achievements" is a proper term in the management of science and technology in China. In the international market, it cannot be legally protected and universal like intellectual property, nor can it protect the economic rights and interests of inventors in an exclusive way by legal means like patent in intellectual property [22]. The high-value economic rights and interests of pharmaceutical scientific and technological achievements can only be effectively realized and guaranteed through the form of intellectual property rights. As a result, China's pharmaceutical industry especially the scientific research colleges and universities need to increase investment in the field of pharmaceutical basic research, attaches great importance to the pharmaceutical basic research, improve research ability and the original innovation ability, to produce the original innovative pharmaceutical science and technology achievements and intellectual property rights awareness, especially patent consciousness, form with independent intellectual property rights, high quality original innovative drugs of scientific and technological achievements.

4.2. Establish a "Relay Transformation" Mode of Pharmaceutical Scientific and Technological Achievements Transformation

Scientific research institutions and small and medium-sized enterprises are the main forces and sources of original drug innovation and drug patents, while large pharmaceutical enterprises often carry out incremental drug innovation on the basis of purchasing related technologies and patents. The closer the transformation of pharmaceutical scientific and technological achievements to the front, the higher the risk and the higher the uncertainty. Scientific research institutions take scientific inquiry and the pursuit of scientific truth as the main goal, and due to the advantages of talents and the financial support from government departments, etc., Therefore, it has great advantages in the "laboratory stage" of the transformation of pharmaceutical scientific and technological achievements, especially in the front-end "disease target identification", "screening and discovery of lead compounds".

Mainly refers to small and medium-sized enterprise technology innovation of small and medium-sized biotech firms, albeit on a smaller scale and less staff, but compared with large pharmaceutical companies have excellent technology research and development innovation ability, can in the scientific research colleges and universities of basic research and the results of original innovation on the basis of further development in order to meet the clinical needs and requirements, Therefore, small and medium-sized technology enterprises have great advantages in the "preclinical research" (optimization of lead compounds) at the back end of the "laboratory stage" of the transformation of drug scientific and technological achievements. Large pharmaceutical companies because of the familiar with drug approval listed relevant laws and regulations and procedures, and drug regulatory departments and medical institutions have rich communication experience and experience, and has strong pharmaceutical marketing, marketing ability and capital advantage, so in transformation of

scientific and technological achievements "pilot" and "commercialization" process has a certain advantage.

In fact, practice has also proved that the "relay innovation" mode of small and medium-sized R&D enterprises and large pharmaceutical enterprises is the general law and characteristics of pharmaceutical industry innovation [23]. However, at present, Chinese scientific research institutions do not play a role in the field or stage of drug research and development that they should play a leading role in, and achieve original and breakthrough innovation of drugs. Instead, they are excessively involved in the field or stage of drug research and development that pharmaceutical enterprises should play a leading role in [24]. Therefore, it is necessary to establish the scientific research institutions - the small and medium-sized technology research and development enterprise - large pharmaceutical enterprise "of" transformation "rally medicine science and technology achievements transformation model, clear center of gravity and the major task allocation, using their own characteristics and advantages of effective crack medicines each process stage of the difficulty in the transformation of scientific and technological achievements, promote the transformation of scientific and technological achievements.

4.3. Improve the Ability of Drug Supervision, Optimize the Drug Supervision System and Balance the Interests of All Parties

The pharmaceutical industry is greatly affected by government policies. The regulatory system and regulatory policies of drug regulatory departments have an important impact on the transformation of drug scientific and technological achievements, especially in the "pilot test" process of the transformation of drug scientific and technological achievements. Therefore, the drug regulatory authorities need to further improve the ability of drug supervision, improve the efficiency of drug evaluation and approval, balance the risks and benefits of drug supervision, optimize the drug regulatory system, reduce the cost and risk in the "pilot test" process of transformation of drug scientific and technological achievements, and promote the transformation of drug scientific and technological achievements.

In addition, the government should balance the interests of all parties involved in the transformation of pharmaceutical scientific and technological achievements, especially in the "commercialization" process. The "commercialization" process of the transformation of pharmaceutical scientific and technological achievements is the stage to realize the return of the transformation of pharmaceutical scientific and technological achievements and realize the high income, which has an important influence on the transformation of pharmaceutical scientific and technological achievements, but it also involves the problem of drug accessibility. Therefore, the government department needs without affecting drug research and development innovation enthusiasm and power transformation of scientific and technological achievements, on the basis of drug procurement through patent protection, drug-price negotiations and health care access policy measures such as reducing drug prices, improve drug accessibility and effectively balance between good industry and medical institutions and patients' interests. For example, the current centralized drug bidding system in China is not conducive to achieving the dual goals of improving the accessibility of drugs and encouraging industrial innovation at the same time. It needs to improve the bidding agency, volume procurement and regional differentiation of drug prices [25].

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