

Research on the Path of Improving the Technological Innovation Ability of Chinese Pharmaceutical Industry Based on Technology

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Abstract

Based on the perspective of professional knowledge and professional technology, this paper focuses on the path to improve the technological innovation ability on the technical level, and provides advice and reference for promoting the pharmaceutical industry to achieve the improvement of technological innovation ability and the structural upgrading of the entire industry. It is found that in the project approval process of innovation subject, the key is to realize the guiding role of market demand on the project approval process of scientific research. In the research and development of innovative drugs, it is necessary to focus on the adaptation and transformation of laboratory technology in scale-up production. In the process of innovation achievement delivery and transformation, the focus is to truly complete the extension from the patent application stage to the product launch stage.

Keywords

Technical Level, Innovation Ability, Ascension Path

1. Introduction

The improvement of innovation capability at the “technical level” refers to the adoption of a series of comprehensive measures based on the perspective of professional knowledge and technology to realize the improvement of technological innovation capability and the structural upgrading of the whole industry, which includes both the innovation of technology itself and the support of various parties to the subject of technological innovation. In the process of technological innovation in pharmaceutical industry, universities and scientific research institutions have a solid professional knowledge base, rich experience in technologi-

cal innovation, and are the main innovation subjects at the technological level. Enterprises have the ability to accurately control the market demand, the ability to predict the innovation prospect based on the actual demand and the developed industrialization ability of innovative products, and are the important subject of innovation on the other side. This paper focuses on the path of improving technological innovation ability at the technical level, and provides suggestions and references for the innovation and upgrading of the pharmaceutical industry.

2. Project Approval Process—The Key Is to Realize the Guiding Role of Market Demand on the Project Approval Process of Scientific Research

Project approval refers to the process in which the innovation subject chooses a solution path through analyzing the problem in the stage of “problem discovery”. It involves the selection of research fields, the determination of research topics and other links, and finally sets up a specific scientific research topic, and plans out specific research ideas, methods and steps. Project approval is the basis of technical research, so innovation at the technical level must ensure the integration of innovative elements in the project approval process. The ultimate goal of technological innovation is the transformation of innovative productivity. Therefore, the innovation of project establishment should not only make a breakthrough in technology, but also consider the industrial application prospect of technology, that is, whether the innovation results can be transferred from the laboratory to the market. In order to achieve this level of innovation, the key issue is to give full play to the guiding role of market demand in the process of project approval and encourage the active participation of all parties in technological innovation [1].

2.1. Develop Comprehensive Project Approval Based on Discipline Development and Market Demand

For a long time, the pharmaceutical industry of scientific research project topic is divided into two kinds, one kind is based on the development of the discipline of fundamental research, focuses on subject frontier in the field of hot spots, mainly on the basis of exploratory innovation, known as the “vertical” subject, the source of city science and technology management department for the country or more funds, research projects; The other is the applied research based on the actual demand of enterprises or the market, which mainly transforms the existing or planned scientific research achievements into actual productivity, and is based on solving the practical problems of the pharmaceutical industry. It is called the “horizontal” subject, and the main source is the technical cooperation between enterprises and universities. The most important requirement of technological innovation in the pharmaceutical industry in project approval is the combination of foundation and application—that is, the comprehensive project approval of “horizontal and vertical combination”, which should not only meet

the vertical professional development and solve the basic research problems, but also pay attention to the horizontal practical needs and solve the practical application problems. Only the organic combination of the two directions can lay an important directional foundation for the transformation of technological innovation achievements in the link of project approval.

1) To consolidate basic research and development guided by frontier hot topics

Basic academic innovation is the foundation of technological innovation. Only with a solid foundation can independent innovation at the technological level be truly realized. This requires innovation subjects to set their vision far, take the cutting-edge hot spots in the field of medicine as innovation orientation, and cultivate their “internal skills” by consolidating basic research.

In recent years, the “individualized medicine” [2] is a hot spot in international medicine industry direction, mainly in the drug’s chemical structure level by different structure innovation, according to different patients, on the pharmacology and pharmacokinetics implementation through clear targets, with the conduction of the signaling pathways, achieve targeted drug delivery of direct lesions; In the pharmacy with the help of “high-end dosage form”, through the patient compliance of good drug delivery, in order to improve the use of drugs. At present, most of the advanced technologies related to these fields are monopolized by foreign countries and are basically in the initial stage in China, but they have great demand and application prospect in practical clinical drugs.

In addition, in the fields of malignant tumor, Cardiovascular and cerebrovascular diseases, neurodegenerative diseases, autoimmune diseases, psychiatric diseases, viral infectious diseases and rare diseases, there are many technical gaps that need to be supplemented, and the subject of technological innovation should pay more attention to them. Because this will not only be a new breakthrough in the field of technology, but also to provide patients with medicines to solve the burden of disease, reflecting the unique public value of the pharmaceutical industry.

2) Promote the establishment of comprehensive research projects with class I new drugs as the binding point

Basic research focused on the “internal strength” the science of uniting the innovation main body, is for the pharmaceutical industry technology innovation “the base”, want to truly achieve pharmaceutical innovation level of ascension, to avoid “only technology flow” style of study, in a breakthrough on the basis of the subject at the same time, must pay attention to discipline innovation achievement to the transformation of industry productivity, that is commonly known as the “transverse and longitudinal combination”. The best combination for that is a new class of drugs. In China’s relevant regulations, class I new drugs refer to drugs that have not been marketed and sold at home and abroad, including: bulk drugs and their preparations prepared by synthetic or semi-synthetic methods; New effective monomers and their preparations extracted from natural sub-

stances or by fermentation; Optical isomers and their preparations in known drugs prepared by resolution or synthesis, etc.; Preparation of a drug with fewer components from a marketed multi-component drug; New compound preparations; The addition of preparations already marketed in China is a new indication approved at home and abroad. The definition of class I new drug requires that the innovation subject must realize the innovation of basic research and applied research at the same time, not only to achieve disciplinary breakthrough, but also to achieve the application transformation of innovation results.

Technological innovation is a comprehensive proposition. Innovation subjects should not only have solid research level, but also have advanced consciousness and vision. Therefore, a class I new drug can be regarded as a strategic innovation target, and research breakthroughs and productivity innovation at each research stage can be emphasized in the process of technological research, so as to promote the overall innovation and upgrading of the pharmaceutical industry through the synergy of all parties.

3) Attach importance to the in-depth study of drug mechanism and make up for the missing link of R&D mainly focused on imitation

The research on pharmacological effects and pharmacokinetics is a major missing link in China's current research and development mainly focused on generics, especially involving in-depth research on adverse drug reactions, drug safety, pharmacovigilance and other aspects. The most obvious manifestation is that pharmacokinetic parameters and pharmacovigilance instructions in many drug instructions are replaced with "unknown", which is not conducive to rational drug use, but also hinders the export of some drugs, especially to quality-oriented pharmaceutical markets such as Europe and the United States. Moreover, this problem not only appears in the chemical generic drugs, but also in the mechanism research of traditional Chinese medicine, there are many problems that need to be paid attention to.

These problems in the transformation of research results are easy to be ignored in extensive development, but these problems are not only the expansion points of vertical extension, but also the key points of horizontal application. In-depth research can be developed into both vertical depth and practical research topics, which are worthy of researchers' increasing attention and investment. Technological innovation in the pharmaceutical industry requires not only breakthroughs in major achievements, but also in-depth research into the details and attention to the academic gaps exposed in each research stage, so that the technological achievements are conducive to product research and development and can also promote the progress of the pharmaceutical industry.

2.2. Give Diversified Incentives Based on the Actual Needs of Innovation Subjects

1) Classification of technological innovation levels, improve the national support system

The present stage of national major issue guidelines, including the national natural science funds and major new drugs, etc., are to encourage the independent innovation as the main starting point of the frontier hot spots, encourage the innovation main body in view of the major diseases which cause serious damage to people's health, independently created a batch of with independent intellectual property rights, good potency and less side effects, big market prospect of chemical medicine, biological medicine and Chinese medicine innovation varieties. We will give priority to the research of innovative drugs with new structures and targets, and vigorously support the research and development of new drugs in traditional Chinese medicine and biotechnology. This kind of planning guidance based on national guidelines has provided a strong impetus to the technological innovation of the pharmaceutical industry, which has driven the innovation enthusiasm of the whole pharmaceutical industry in recent years.

However, on the other hand, due to the industry characteristics of high investment and high risk and the lack of "basic skills" in some fields, some innovative achievements may not be transformed into drugs that patients can use in a short period of time. Therefore, the imitation of some urgent clinical drugs, especially the "first imitation" of some major varieties, has important positive significance both in technology and people's livelihood. Therefore, it is suggested that the country should consider setting different levels of technological innovation, which should not only have major issues to improve the independent innovation ability, but also encourage "creative" "first imitation" and innovation in imitation [3]. Different levels of support should be given to these research projects according to the innovation level and application value, and various innovation subjects in the pharmaceutical industry should be encouraged to form a multi-level technological innovation level according to their own strength. In order to improve the national support system for technological innovation, ensure the mobilization of innovation enthusiasm of each subject, so that technological innovation can be balanced development in the two directions of "exploration" and "practice".

2) Support for diversified project establishment and encourage subject innovation at all levels

At present our country has been basically formed by the state, all levels of departments in charge of science and technology research project system, at the national level, both in view of the national natural science foundation of longitudinal based innovation, there is also a major new drug project in view of the practical innovation, the provinces, according to the actual situation in the province to carry on the project of comprehensive subject. However, at present, the main participants of the national project are university researchers, and the main groups covered in the university are divided into two categories: one is the newly emerging young researchers, who can get a lot of research support through the youth project; The other is some well-known, more achievements of the old professors, they will have a certain advantage when applying for large-

scale projects.

This brings a problem for many in the age of 40, but have not reached a certain “popularity” “backbone” of the researchers, in terms of project declaration policy to take care of, will face a certain degree of “cover” blank, caused the researchers on the subject to declare under a lot of challenges and difficulties. At the same time, the classification and restrictions on the application of these projects will also discourage the innovation enthusiasm of these “backbone”. But in fact, these middle-aged researchers have more experience and development potential, and should play an important role in technological innovation. Therefore, it is suggested that the government should consider making more supportive policies for this part of researchers, such as the “backbone Program” similar to youth program, to give them more hardware and software support for technical research and achievement application, and give full play to their role as “connecting the preceding and the following”.

3) Adjust the management ideas of innovation results and improve the inclusiveness of innovation

At present, the management of technological innovation results mainly includes the assessment and evaluation of university researchers and the acceptance of the results of industry-university-research cooperation. Although each management side clearly gives more priority to technological innovation in each examination and approval link, innovation is not inclusive enough in the evaluation management. The main manifestations are as follows: at present, the assessment and evaluation of university researchers mainly focus on their longitudinal achievements, including the number of longitudinal projects and high-level papers, and less on horizontal research achievements; The assessment and evaluation of industry-university-research cooperation mostly takes successful innovative products, research conclusions and other results related to the success rate as the main indicators, and pays less attention to the promotion of “soft power” without results. Technology always lags behind the actual demand, coupled with the nature of innovation with high risk of failure, the actual success rate of technological innovation is an unpredictable indicator, and low output after high input is an inevitable innovation cost.

Therefore, managers should “prioritise” innovation based on results, but also make innovation itself more inclusive. The management of colleges and universities should reform the assessment index, not only pay attention to vertical results, but also give more proportion to horizontal research and horizontal cooperation. The management of the industry, university and research institute should not only focus on “results”, but also set the improvement of the comprehensive strength of the industry, university and research institute as a more important evaluation index. The same attention and support should be given to the industry-university-research institute cooperation projects that have expanded the scale of cooperation objects, increased the number of cooperative projects or improved the structure of cooperative innovation, and promoted the process of innovation

research despite the lack of innovation results. Through the tolerance of innovation cost, give each subject more innovation “security”, let them dare to innovate, and then mobilize the enthusiasm of technological innovation, and encourage more subjects with innovation strength to join the team of technological innovation in the pharmaceutical industry, jointly promote the innovation and upgrading of the pharmaceutical industry.

3. Research and Development—Focus on the Adaptation and Transformation of Laboratory Technology in Enterprise Scale-Up Production

Research and development refers to the creative use of new knowledge of science and technology to explore significant improvements in technology after the project is approved to determine the research topic; Or in order to substantially improve the technology and products, the scientific research achievements into reliable quality, feasible cost, innovative products, materials, devices, processes, etc. There are four basic elements in R&D: creativity; Novelty; The application of the scientific method; The generation of new knowledge. Major outputs include new knowledge, new materials, products, devices, processes, etc. with significant improvements. The research and development of the pharmaceutical industry mainly refers to the transformation of the research objectives in the project tender into the practical application of the research results, which mainly involves the innovation research at the laboratory level and the scale-up production at the enterprise level [4]. The key is the adaptation and transformation of laboratory technology in enterprise scale-up production, because it will directly determine whether the technological innovation results can be transformed into actual productivity. Therefore, both technical innovation subjects and all sectors of society supporting innovation subjects should pay more attention to this key transformation process, so as to improve the comprehensive efficiency of R&D.

3.1. Take Technology Application as the Guidance, Carry out Comprehensive Research with Equal Emphasis on Basic and Application

Pure focus on academic development of basic research is the key to cultivate “internal strength”, but really promote the pharmaceutical industry innovation and upgrading of the main force is comprehensive research. “Synthesis” includes not only the synthesis of innovation subjects, but also the synthesis of research methods, and more importantly, the synthesis of basic and applied research methods. It is worth noting that the realization of this comprehensive research is not simply relying on the laboratory results into the production line such a simple transformation, but to pay attention to the integration of technological innovation in every link and stage of research and development.

1) Advance the market demand and application prospect to the R&D stage, and realize the diversified cooperation between the university and the enterprise

The technological innovation achievements with application value are not

transformed, but developed, which means that market demand and application prospect should be taken into account in the technological research and development stage, so that the technological innovation achievements can not only have vertical academic expansion, but also meet the practical application of market demand. To achieve this innovation goal, the most important thing is the diversified cooperation between universities and enterprises, which should not only consolidate the existing industry-university-research collaborative innovation mode, including university and enterprise joint project establishment, enterprise and university project docking system and university and university project establishment and enterprise participation. Cooperation between universities and enterprises in this way has certain requirements on cooperation opportunities, because universities are better at basic research and mainly pursue innovation in academic research, while enterprises are better at applied research and mainly focus on technological application innovation.

Therefore, it is suggested that some basic research should be put in schools, and enterprises should join in the application experiment stage, so as to effectively protect the intellectual property rights of university research and give full play to their respective strengths. On the other hand, cooperation between universities and enterprises should be promoted to be more diversified. For example, the cooperation of enterprise order-type bidding—that is, the enterprise provides the project demand catalog, and the university researchers apply according to the requirements of the catalog and their own capabilities. The enterprise and university will review the application respectively, and then sign the contract with specific details according to the intentions of both parties. The advantage of this cooperation mode lies in that the most important requirement of enterprises for horizontal technology is to solve technical problems, rather than requiring over-complete and over-detailed technical research. Therefore, such cooperation is more targeted, can directly solve practical technical problems, and can avoid disputes caused by the cooperation of funds and intellectual property rights.

2) Based on market demand and discipline development needs, focus on “horizontal and vertical” combination of talent training

In addition to technology, there is another important factor for pharmaceutical industry innovation and upgrading—talent. At present, the supply of technical personnel in China is redundant at the middle and low levels, but there is a shortage of personnel supply at the high-end innovation level. Therefore, we can see that under the background of advocating technological innovation, the pharmaceutical industry will have an increasing demand for high-tech R&D and innovative talents. Therefore, as a talent training base, colleges and universities must take talent training as a long-term planning strategy [5]. In fact, this is also another important significance of carrying out comprehensive research. After comprehensive training of “horizontal and vertical” graduate students, they can have higher “hands-on” ability after employment and better meet the talent demand

of enterprises in technological innovation.

Therefore, colleges and universities should pay more attention to the cultivation of students' practical ability, encourage teachers to carry out research in both basic and applied directions through project approval or financial support, and promote technological innovation and talent cultivation at the same time. On the other hand, western regions with relatively few technological innovation resources can make full use of their traditional Chinese medicine resources and provide more assistance in the innovative research related to traditional Chinese medicine by adopting a way adapted to local conditions. And establish long-term talent training and distribution base, so that more students are willing to go, willing to stay. Especially for local students, more preferential policies should be given to talents who can revitalize the local economy or start their own businesses, and high-quality innovative talents should be used to promote the technological innovation and development of western pharmaceutical industry.

3.2. Establish a Platform Public Base and Promote the Industrialization Research of Laboratory Results

Between laboratory and production line, there is a key link called amplification, mainly through a certain scale of production testing, validation laboratory technique can realize the production scale production, this "small" to "big", not only test the conversion prospect of laboratory technology, also verify the innovation production of implementation. The equipment requirements of many amplification and conversion links will exceed the strength of the innovation subject, so it can be said that transformation is the link where the innovation subject needs help and support most.

1) Set up a public pilot test base to bridge the technical gap between the laboratory and the production line

In fact, if it is a technological innovation project directly derived from the demand of the enterprise, the original intention of the project is to solve the practical problems in the research and production of the enterprise, it does not involve transformation. The projects that really involve the transformation of laboratory results into production lines are basically independent innovation projects, that is, the research results of the project are independently applied by university teachers. And usually, after some enterprises show cooperative interest in the innovation results, the two sides begin to negotiate the enlargement and transformation. After the start of cooperation negotiations, enterprises often have some technical requirements for innovation results based on actual production, but the research of these technical requirements is generally difficult to complete under the conditions of the existing scale of the laboratory. The most common is that enterprises often require the technology to be pilot-scale to verify the feasibility of mass production. However, the scale of laboratory tests is limited, and usually only a small test can be done, which is easy to become an obstacle to the transformation of technological achievements. Therefore, it is

necessary for universities and government science and technology departments to take the lead in establishing a public pilot test base through public funding or social capital investment, so as to make up for the technological equipment gap faced by laboratories in the amplification and conversion process of independent innovation achievements.

However, attention should be paid to two problems at the same time. One is the protection of intellectual property rights of related technologies. Different equipment can be classified into “simulation workshop”, so that researchers can use a single “workshop” for a certain period of time, so as to avoid technology leakage in the pilot test through “exclusive”; Second, while encouraging social investment, relevant public management departments should carry out daily supervision over the operation and maintenance of the base to ensure the publicity of the platform. At the same time, the use conditions of projects with strong innovation and large market demand should be appropriately relaxed, or diversified ways such as “equity” project sharing in the pilot test should be used to improve the accessibility of the public platform, so as to avoid the cost level becoming a barrier to use.

2) Establish clinical project cooperation centers to promote the participation of enterprises at the clinical research level

After the breakthrough of laboratory technology, another important problem in the research and development process is the clinical research of drugs, especially for a class I new drugs with a high degree of technological innovation, the safety and effectiveness of drugs must be verified through clinical research. Clinical research requires not only a large amount of human and material input, but also a large sample of patient volunteers and the guidance and supervision of clinicians and clinical pharmacists, all of which cannot be undertaken by a single innovation subject alone. So the management is necessary to set up clinical project cooperation center, which not only through multiple channels of dialogue, the actual work based on the actual demand for innovation main body, help colleges and enterprises in clinical studies link cooperation and docking, for clinical trials can enterprise level, to actively pull hospitals, physicians and pharmacists to participate in [6].

In addition to promoting collaboration in clinical research, Even as much as possible with the help of the innovation main body complete declaration associated with clinical examination and approval work, to promote the significance of clinical trials, recruiting volunteers and patients with clinical trials and medical ethics and human rights related legal supervision and management, established a nationwide network of rare diseases or patients with special diseases in the field of database, and other work related to clinical trials. In this way, it is not only conducive to the research and application of technological innovation achievements, but also to explore more technical gaps through clinical trials, so as to further expand the research. At the same time, it has an important practical role in monitoring adverse reactions and advocating rational drug use.

4. Achievement Delivery and Transformation—Focus on Extending from Patent Application Stage to Product Launch Stage

In the process of achievement delivery and transformation, the focus is on successfully applying for patent, registering and approving technological innovation achievements, and successfully listing them on the market, that is, truly transforming technological innovation achievements into innovative products. In this process, there are not many technical problems involved, but more people from all walks of life, including the management of innovation subjects, government science and technology departments, drug approval and supervision departments, give help to technological innovation subjects, including universities and enterprises, in order to consolidate and stimulate their enthusiasm for innovation.

4.1. Strengthen Multi-Party Cooperation and Support to Promote the Flow of Innovation Achievements to the Market

1) Attach importance to the construction of science and technology management departments in universities and give full play to their comprehensive service role in technological innovation

As more and more colleges and universities expand “academic innovation” into “technological innovation”, the role of science and technology management department of colleges and universities is becoming more and more important [7]. And University Science and Technology Division, in effect, is equivalent to a “comprehensive service office of science and technology” in colleges and universities, mainly be responsible for the application of university teachers in the subject, university-enterprise cooperation, information release, promotion and intellectual property management, and other aspects of work, especially in the technical innovation “go out and bring in” link play a important role in the mediation platform. Colleges and universities should continue to focus on and technology of construction, the government department of science and technology should be the communication with colleges and universities and technology to establish a long-term cooperation mechanism, and technology transfer center of colleges and universities and technology organization, association for science and technology and innovation post to assist enterprises and colleges and universities should give policy support docking platform, at the same time to help to the enterprises to promote cooperation in university, Especially in the research and investigation process of related topics, we should actively inform relevant enterprises to cooperate and participate.

University Science and Technology Division, on the other hand, also should according to the actual needs of a gleam of researchers, adjust the working way and working train of thought, in to do a good job of existing at the same time, actively expand service areas of science and technology, to establish the platform of college and enterprise cooperation, promote enterprise and universities par-

ticipate in each other, do a good job in “investment” and “self propaganda”. Gradually, more guidance will be given to front-line researchers in terms of drug registration and approval, so that the process and steps of research and development comply with relevant national regulations on approval and registration, and the index data related to approval and registration can be covered in research reports. And University Science and Technology Division should also be timely grasp the new trends of drug registration for examination and approval of, and timely notify the researchers to adapt and adjust accordingly, to establish a line of scientific research personnel and drug, head of the government’s long-term information exchange mechanism, through multi-channel dialogue platform make departments can master the research line of actual dynamic, It also enables college teachers to obtain planning guidelines and policy trends in the industry in time in the laboratory.

2) Promote the development of intermediate service industry and speed up the flow of innovation achievements to the market

Although the science and technology service of science and technology management organization is authoritative, it is far from meeting the actual demand of innovation subjects, so it is quite necessary to promote the development of science and technology service industry. The science and technology service industry is an organization that can provide professional science and technology service for the innovation subject according to the actual demand through the participation of market forces. In view of the technology-intensive characteristics of the pharmaceutical industry, it provides scientific and technological information collection, professional consultation, partner introduction, and promotion of industry-university-research cooperation. It is an important medium for “marriage” technology and market. Many researchers have expressed a desire to “outsource” applications and approvals beyond technology by partnering with competent, qualified and reputable technology services.

Therefore, university administrators can expand the level and scale of scientific and technological services provided to university researchers through strict review and check and cooperation with professional scientific and technological service intermediaries. Local competent departments of science and technology may, according to the actual needs of innovation subjects, train and assist science and technology service intermediaries and establish platforms for exchange and cooperation. Innovation subjects engaged in different stages of research are encouraged to try to carry out different degrees of cooperation with service intermediaries, so as to establish a complete pharmaceutical R&D, production and listing service industry chain, standardize and scientifically achieve sustainable development of innovation [8].

4.2. Promote the Reform of Drug Approval and Evaluation System Based on the Improvement of the Accessibility of Technological Innovation Achievements

The real significance of technological innovation in the pharmaceutical industry

is to transform the technological innovation achievements into drugs that can be really used by patients through innovative research and development and achievement transformation. To achieve this goal, in addition to solve the problem of technology innovation main body itself, including the Center for Drug Safety Evaluation, National Medical Products Administration (NMPA), Food and Drug Inspection Office of department of pharmaceutical administration and Medical Insurance Management Department, Drug Bidding and Purchasing Department and other government departments are in technology development and achievements transformation links play an important positive role. On the one hand, it can effectively promote the transformation efficiency of innovation results and improve the accessibility of patients to technological innovation results; On the other hand, the profit return after the transformation of innovation results can stimulate the initiative of innovation subjects for re-innovation, so as to realize a virtuous cycle and overall upgrading of innovation in the pharmaceutical industry.

1) Guided by the actual needs of patients, grading accelerates the marketization of innovation results

Drug registration and approval is a process in which NMPA systematically grades the safety, effectiveness and quality controllability of drugs to be marketed and sold according to the application of drug registration applicants and legal provisions [9]. As this link is the “release” checkpoint for drug marketing, which directly affects the marketization of innovation results, registration and approval system and efficiency are particularly important in the mobilization of innovation enthusiasm. In recent years, the pharmaceutical industry innovation momentum is rapid, and the pending tasks of national Drug Evaluation Center are increasing rapidly year by year. In order to cope with the new requirements of drug approval brought by the development of the industry, THE National Center for Pharmaceutical Audit has started to carry out the work to improve the quality and efficiency of the review, including one-time approval of clinical trials, speeding up the review of major special varieties, the pilot of the “review of the volume” of generic drugs and strengthening the construction of the review team.

However, due to too many backlog tasks, most innovation subjects, especially enterprise innovation subjects, hope to promote the transformation process of innovation achievements by effectively improving the approval efficiency. Therefore, relevant examination and approval departments are required to implement the reform work to promote the efficiency of drug registration examination and approval. In particular, it is necessary to establish different gradations of innovation according to different degrees of innovation, and guide innovation subjects to adjust the direction of technology research and development by different rates of approval and listing system, data protection period and market exclusive protection, with clinical urgent needs as the main focus. Can establish diversified information feedback mechanism at the same time, the use of public informa-

tion platform, WeChat, weibo and multimedia to applicants and social periodically release the latest dynamic and innovative planning guide for examination and approval, a lot of feedback on work progress and achievements of the reform, and establish and industry information exchange mechanism of each main body in time to get the actual dynamic industry, As an important basis for policy adjustment and system reform.

2) Strengthen supervision of post-listing safety evaluation with safety and effectiveness as release standard

Safety and effectiveness is the “threshold” quality requirement of drugs, which is based on the attitude of being responsible for patients and the quality of drugs is controlled in principle. Confirmed so drug registration filing must contain chemical information institutions or components, drug stability study data, acute toxicity test, long-term toxicity test, allergic test data security and dependency test data such as able to prove that the research of drug safety and effectiveness of the basis, to ensure the science of drugs in clinical use [10]. However, for traditional Chinese medicine and natural medicine, due to the particularity of their raw materials and research technology, the current technology level is not able to achieve the same research accuracy as chemical drugs, especially in the identification of mechanism of action and impurities. In particular, many innovation subjects can not meet the accuracy requirements of drug declaration, leading to the failure of the declaration of traditional Chinese medicine varieties.

To solve this problem, on the one hand, innovation subjects must increase the technical input in the functional mechanism of TCM and the analysis of TCM components. On the other hand, on the premise of fully verifying the safety of clinical drugs, the approval department can also adjust some requirements for study accuracy. For varieties that have clinical efficacy and meet safety requirements, they can be approved to be listed after the establishment of safety records, and focus on monitoring their safety evaluation after listing, establish regular safety evaluation files, especially strengthen the risk supervision of such varieties. In order to promote the safe and effective drug varieties on the market, stimulate the innovation enthusiasm of relevant innovation subjects, encourage them to continue to do further expansion research on the mechanism and composition of varieties accurate analysis, or give priority to the same research project.

5. Discussion

Technical innovation is the important link to realize upgrading of productivity, improve the capacity of its main idea is how to through the planning guide, return policy tilt and innovation, encouraging innovation main body to face the development frontier, market demand and actual production industry, for both can meet the clinical needs, and can promote the development of medicine industry technical difficulties for technical innovation. In order to achieve this goal, it is indispensable to improve the technical level of the innovation subject and to reward the innovation achievement of the innovation subject. In fact, on-

ly in the pharmaceutical industry to establish incentive-innovation-returns-incentive mechanism of virtuous cycle, to give the most scientific innovation and the guidance of the actual tolerance, can really encourage innovation main body of technological innovation in the long term strategic priority, by point belt line, in line with the surface, make innovative pharmaceutical industry to the long-term development of the guide, to truly achieve the strategic planning goal of establishing a powerful country in pharmaceutical independent innovation.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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