

Study on the Influence Factors and Promotion Strategies of Contract Manufacturing on Marketing Authorization Holder

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Abstract

Marketing Authorization Holder system is conducive to promoting China ' s pharmaceutical innovation and improving drug quality. However, there are still problems of drug quality, delivery, technical confidentiality and commission cost in the commissioned production of drugs. Improving the cooperative relationship can solve these problems so as to promote the commissioned production activities of drug license holders and give full play to the effect of MAH system. Based on the concept of commissioned production cooperation and the interest demands of drug license holders in China, this paper analyzes the main influencing factors of drug commissioned production cooperation, including the basic conditions of entrusted production enterprises, the degree of resource complementarity and the level of interaction between the two parties. This paper proposes strategies to improve bilateral cooperation.

Keywords

Marketing Authorization Holder; Entrusted Production Enterprises; Cooperative Relationship; Influence Factors.

1. Introduction

Marketing Authorization Holder (MAH) system is a key reform content under the background of China ' s medical and health system reform. Promoting drug innovation and improving drug quality in China. China ' s newly revised (Drug administration law) was introduced in 2019, formally establishing a nationwide MAH system [1].

After the pilot reform of MAH, the relevant subjects reported actively. Taking Shanghai as an example, by the end of June 2020, there were 54 applicants in Shanghai applying for 137 applications, and 31 categories were class I innovative drugs. A total of 69 varieties were approved for listing. It includes the research and development of Shanghai type I innovative drug Aiyoute, whose main role is the treatment of metastatic colorectal cancer. The clinical trials from the early stage to the later stage of drug research are carried out locally, and there are no similar innovative drugs in the world. Thanks to the pilot reform of MAH system, Aiyoute has become a successful case of rapid listing of innovative achievements in research and development institutions. However, the implementation of shortcomings in the implementation of MAH system, especially in the commissioned production process. In March 2020, U.S. pharmaceutical companies ' products did not meet GMP requirements because of their commissioned manufacturers in China, and their commissioned drugs were suspended from import, sale and use, resulting in market losses of more than 100 million yuan. The quality problem of drug commissioned production is only the tip of the iceberg. Studies have shown that there are questions in the commissioned production, such as the questioning of the holder ' s responsibility for drug production and sales, the risk of whether the entrusted production

enterprises can produce according to the contract requirements, and the risk of government supervision in different places [2].

The concept of commissioned production partnership was proposed in the context of the continuous development of corporate business in the last century to reduce transaction costs and provide better products [3]. Due to the existence of multiple stakeholders in commissioned production, their behavior and decision-making are different or conflicting, which affects the interaction between the parties [4]. In today's fierce market competition, it is difficult for enterprises to survive and develop solely by their own strength, and the traditional exclusive competition also gives way to competition based on cooperation. Cooperative relations have become an important source of competitive advantages for enterprises. Close and efficient cooperative competition can help enterprises achieve win-win results, especially for high-tech industries or industries with complex technology, cultivating a good cooperative relationship has become an increasingly important practical demand[5]. In the commissioned production practice of drug license holders, good cooperation relationship is conducive to strengthening the control of drug production business (drug quality, drug delivery and drug technology confidentiality) and reducing the commissioned production cost of drug license holders. By improving the commissioned production cooperation relationship, it is conducive to promoting the successful practice of drug commissioned production cooperation under the MAH system and ensuring the smooth development of drug commissioned production, which is the strategic value of enhancing the commissioned production cooperation relationship for the holder. The smooth implementation of commissioned production is conducive to the holder's focus on improving drug R & D technology, accelerating the speed of drug listing and sharing the competitive advantages of drugs after listing.

Cultivating the cooperative relationship between the licensee of drug listing (hereinafter referred to as the 'holder') and the entrusted production enterprises is not only beneficial to the licensee of drug listing to exempt the transaction costs of entrusted production, drug quality and intellectual property rights, but also to promote the steady and healthy development of China's MAH system.

2. Concept of Drug Entrusted Production Cooperation

In the study of cooperative relationship literature, Jap [6] defines cooperative relationships as a relatively long-term resource exchange, flow, and connection between an enterprise and one or more organizations. Liao Chenglin [7] defines the cooperative relationship as that the enterprises participating in the cooperation are established based on each other's interests, which is often accompanied by a long-term reciprocal commitment of resource trading behavior. The two parties can obtain the required resources and capabilities to achieve the expected cooperation goals. In the literature in the field of entrusted production, the expression of cooperative relationship is as follows: Chen Zhixiang [8] believes that the purpose of cooperative relationship in commissioned production is to achieve win-win results, reflecting the integration and optimization of internal and external resources of enterprises. The above definitions of cooperative relations all reflect information such as resource exchange, mutual interests and long-term nature in cooperation.

Based on this, this paper defines the concept of commissioned production cooperation relationship between drug listing license holders as follows: in the process of production cooperation, drug listing license holders establish a resource exchange and cooperation mechanism with the entrusted production enterprises to achieve the cooperation state of benefit sharing, so that the two sides are satisfied with the results and are willing to carry out long-term cooperation. The core of the cooperative relationship between the two sides is resource exchange and benefit sharing. Resource exchange refers to the exchange of resources

between the two sides at the cost of their own resource input in exchange for the resources of the other side of the cooperation or the new resources formed by the cooperation between the two sides, which is the premise of the establishment of cooperative relationship. If the resources of one side are not sufficient to achieve resource exchange, even if the commissioned production contract is signed, the cooperative relationship will be affected by insufficient capacity in the subsequent cooperation. Interest sharing refers to the fair sharing of cooperation benefits between the two sides, that is, the two sides can obtain corresponding benefits according to their respective contributions in cooperation, and there is no violation of their own interests by partners. The unfair distribution of benefits weakens the interests of one side in cooperation, and deepens its prejudice against partners, which affects the subsequent development of cooperation relations. Both sides have the ability to achieve resource exchange and obtain corresponding benefits. Such cooperation can satisfy the results of both sides and develop for a long time.

3. Producer's Demand for Profit of Drug Listing License

3.1. Ensuring Drug Quality

In " (Drug administration law), " drug market license holders ensure the safety, effectiveness and quality controllability of commissioned drugs through the review of drug quality management, risk prevention and control and liability compensation capabilities. Drugs, as commodities with special properties, can prevent and quality diseases and protect the public medication safety and the legitimate rights and interests of patients only by ensuring the quality of drugs. For drug license holders, the safety of drug quality requires that the drugs commissioned by them do not cause serious damage such as toxicity or mutation. In the event of serious drug damage, the holder of the drug listing license will bear legal responsibility and face economic compensation, license revocation or other penalties affecting its operation. The effectiveness and controllability of drug quality are not up to standard, although it is not easy to produce serious drug accidents, but it has lost the treatment and diagnosis of patients entrusted with the production of drugs. Good quality drugs can create a good brand image of drugs and lay the foundation for maximizing profits [9].

3.2. Guarantee Time and Quantity of Drug Delivery

China 's pharmaceutical industry slow listing of new drugs, fewer varieties, the overall quality of drugs is not high, low-level homogeneous competition between enterprises [10]. The new drugs developed by the holders have a large market demand, but they cannot have a stable supply of drugs, which affects the treatment course and treatment effect of patients and is easy to be seized by similar competitive drugs. Therefore, in order to obtain good drug listing income in the fierce market competition environment, the need for stable drug supply. The new drug R & D investment cycle is long and the cost is high. It is unrealistic for drug license holders to build production plants or production lines before completing the second phase of clinical trials, because it is still uncertain whether drug R & D is successful in the clinical trial stage. But building factories or production lines later in the second phase of clinical trials will take two to three years, possibly delaying the process of drug listing. At present, most pharmaceutical manufacturing enterprises in China are not entrusted manufacturing enterprises specialized in undertaking pharmaceutical commission orders, and they also have their own product lines to operate. Therefore, drug listing license holders need to pay attention to the production capacity of the entrusted manufacturing enterprises and evaluate whether the time and quantity of drug delivery can meet the requirements.

3.3. Protection of Drug Intellectual Property Rights

One of the purposes of the implementation of China's drug listing license holder system is to promote China's pharmaceutical innovation and new drug research and development. With China's economic development and demographic changes, China will usher in the accelerated development period of pharmaceutical enterprises. The intellectual property achievements of new drug research and development will quickly be transformed into practical value and competitive advantage, which is of great significance to drug listing license holders. Drug industry is a knowledge-intensive industry. Drug R & D technology is a hot spot in market competition. High R & D and high investment are typical characteristics of head enterprises. Innovative new drugs can build technical barriers for enterprises and monopolize the market and profits of drug market segmentation. However, the current drug R & D cycle is relatively long, from the beginning of R & D to obtain market returns, mostly need more than ten years, is a high investment, high risk and high-income industry. Compared with other property, new drug intellectual property is a non-exclusive and non-competitive product, that is, the use of intellectual property does not exclude the use and possession of others. However, although the current intellectual property system in China is constantly improving, there are still enterprises that ignore the protection of patent technology and other achievements. In the process of drug entrusted production, the related technical achievements of new drug production will be shared by the entrusted production enterprises. The holder of drug listing license needs to pay attention to the intellectual property protection of partners, to avoid the leakage of technical secrets related to new drugs and threaten their own interests [11].

3.4. Reducing Production Cost of Drug Entrustment

In the commissioned production of the pharmaceutical industry, commissioned enterprises cannot reduce production costs through outsourcing. The reason is that the entrusted production enterprises are more willing to raise prices and reduce service costs because of their pursuit of profits. In addition, commissioned production contracts cannot predict all possible problems and solutions in the future. Additional cost of coordination and communication is needed when disputes arise, and all possible situations and settlement costs are included in the contracts, which cannot adapt to the complex and changeable business environment, and will also limit the adaptability of both parties. Drug R & D accounts for a relatively high proportion of drug costs. For innovative new drugs, the average R & D investment is more than USD 1 billion, and the cycle is more than 10 years. The success rate from the first clinical stage to the listing is less than 10 %. Even so, the new drugs developed do not necessarily bring profit returns, and enterprises should also formulate reasonable marketing strategies to gain a favorable position in the drug competition market. Therefore, for drug license holders, excessive production costs increase business risks [12].

4. Analysis on Influencing Factors of Entrusted Production Cooperation of Drug Listing License Holders

Based on the above analysis of the concept of entrusted production cooperation, this paper divides the core of cooperation into two aspects: one is whether the resource exchange mechanism can be completed, and the other is whether the interests can be shared in cooperation.

4.1. Basic Conditions of Entrusted Production Enterprises

Taking the newly revised "(Drug administration law)" as an example, the holder of drug listing license is responsible for the production and operation of drugs and is fully responsible for the quality of drugs. When the quality of drugs produced by the entrusted manufacturing enterprise is not qualified, it will bring legal disputes and survival crisis to the listed license

holders. Whether it is the holder of R & D institutions or the holder of pharmaceutical production enterprises, after choosing the mode of entrusted production of drugs, it means abandoning the construction of their own pharmaceutical production resources and seeking cross-organizational pharmaceutical production resources.

Drug listed holders outsource the production part of drugs to reduce investment in production resources, but their requirements for the production part will not be reduced. Pharmaceutical production needs to have the corresponding conditions and thresholds. The basic resources of the entrusted production enterprises refer to the necessary conditions for the production of drugs, including production equipment, production process, experience and technical personnel. The better these conditions are, the more secure the quality and safety are, and the two sides also reduce the possibility of relationship rupture caused by quality problems.

In addition, the quantity and time of drug delivery are also factoring that need to be considered in the cooperative production of drugs. This requirement is not only completed in accordance with the requirements of the completion contract. In the face of complex and volatile market environment, it may suddenly require an increase in drug production, or may suddenly require early delivery. Production requirements in emergency situations. For example, due to the increased demand for certain drugs commissioned for production due to the epidemic situation or other situations, the entrusted production enterprises have overcome the relevant production difficulties and met the market demand in a timely manner, which will not only bring economic benefits to both parties, but also strengthen the evaluation of the pharmaceutical listing license holders on the production enterprises, believing that it is trustworthy.

If the entrusted manufacturing enterprises attach importance to technical confidentiality, they also have an impact on the bilateral cooperation. The leakage of core knowledge caused by production will affect the stability of bilateral cooperation. Drug R & D has the characteristics of high technical knowledge density and large R & D investment. Although many enterprises recognize the importance of IPR protection, the intensity of IPR protection has not been further improved. At present, the protection of intellectual property rights in China needs to be strengthened, and most enterprises rely on knowledge spillover to enhance product competitiveness. However, for members with advanced R & D technologies in the industry, cooperation with external enterprises increases the risk of imitation of enterprise technology, and inhibits R & D enthusiasm and willingness to entrust production cooperation.

4.2. Resource Offset

When the exchange of resources in cooperation is of different importance to both parties, it will result in one party's resource dependence on the other, especially when key resources needed by enterprises are controlled by external partners. This asymmetric resource dependence will enable partners to obtain certain power to enterprises. The deeper the degree of resource dependence is, the greater the control power of partners is, and forcing dependent enterprises to act in line with the expectations of external partners.

Asymmetric dependence between partners can easily lead to opportunistic behavior, enterprises with low dependence on cooperative resources will sacrifice the interests of enterprises with high dependence on cooperative resources to seek more benefits for themselves. This is an opportunism caused by asymmetric dependence on resources. Its main feature is that the resource-rich party can draw on the dominant position in cooperation to formulate cooperation rules that are in line with their own interests. It does not need to violate the contract agreement or use the contract loopholes to infringe the interests of the client by reducing investment and providing inferior goods in the cooperation process, and directly force partners to modify or re-formulate new contracts in the subsequent cooperation.

Resource complementarity means that the resources of both parties are complementary, and the value created by resources in cooperation exceeds the sum of the value created by resources of a single enterprise. The resource differences between the partners and the path dependence formed in the cooperation are unique resource exchange paths for both partners, which are difficult to be imitated and replaced by other enterprises in the market. The higher the degree of resource complementarity, the higher the value of resources in cooperation brings to both parties, and the more difficult it is for other potential players in the market to provide the same value. When the degree of resource complementarity is high, the partners will form a balanced dependence, take the way of resource integration, work together to overcome the constraints of enterprise resources, reduce the risk of implementing opportunism, and ensure the fair distribution of benefits. Resource complementarity emphasizes that this balanced dependence is the importance of the respective resources of the two cooperative enterprises to their partners, which makes the two sides covet the value brought about by this cooperation rather than easily undermine the cooperative relationship.

4.3. Interaction Level

The opportunistic behavior of entrusted production enterprises under the MAH system is not only caused by the asymmetry of resource dependence between the two sides, but also can still use the contract loopholes and secretly violate the contract of entrusted production to infringe the interests of license holders in the process of entrusted production cooperation.

In the initial economic research, rationality means pursuing self-interest. From the initial complete rationality to the limited rationality, the condition of the rational person hypothesis is from the actor 's complete mastery of information to the actor 's personal ability limitation and the limited mastery of information, but the connotation of the two kinds of rational assumptions contains the actor 's pursuit of individual interests. The pursuit of individual interests leads to the inconsistency of objectives between the two sides, which shows that the two sides have different priorities for planning, implementation and control in cooperation. Environmental uncertainty mainly refers to the change and complexity of the environment. Due to the limited capacity of the two parties and the uncertainty of the environment, the commissioned production contract signed before the cooperation between the two parties cannot predict the problems in actual production, which will lead to cooperation conflicts in the case of inconsistent objectives of the partners. Partners will ask partners to give in to meet their interests by means of argument and threat [13]. Due to the differences between the interests of both sides, will try to use the conflict in cooperation to maximize their own interests, resulting in opportunistic behavior. This kind of friction and tension between the two sides caused by cooperative conflicts weakens the cooperative relationship between the two sides. In addition, there is information asymmetry between the partners. Information asymmetry mainly refers to the different degree of mastery of cooperation-related information between the two sides, which mostly leads to opportunistic behavior of information superiority parties. That is to say, most of the parties who know more about the information want to use advantageous information to obtain more benefits, including concealing, tampering with information related to cooperation, and making the actual cooperation process develop in a direction conducive to their own interests, rather than in accordance with the results agreed in the contract between the parties.

It can be seen from the above analysis that due to bounded rationality, environmental uncertainty and information asymmetry in cooperation, license holders of drug listing may be encroached on legitimate cooperation benefits by entrusted production enterprises in cooperation. Cause income inequality between the two sides. Therefore, this paper analyzes the connotation of interaction level from three aspects: trust, communication and information sharing. Trust can reduce the impact of environmental uncertainty on cooperative relations. In

essence, trust is that the two sides believe that the partners will not behaviors that are detrimental to their own interests, and use previous information to anticipate future behaviors. In the process of future environmental change, the partners can use this sense of security to replace the inner unease. But trust is not omnipotent. Facing the threat of inconsistent goals between the two sides, we can strengthen the cooperation between the two sides through communication. Active communication can make different values, responsibilities and expected behavior respected and understood. Lack of communication exacerbates misunderstandings, misjudges partners' behavior and undermines the stability of partnerships. Information asymmetry will not only reduce the interests of information vulnerable parties in cooperation, but also cause concerns and suspicions of both sides, reducing the degree of mutual trust and trust between the two sides. However, information sharing is beneficial to reduce the information asymmetry between enterprises, increase the satisfaction of cooperation between the two sides, and promote the long-term development of cooperation. Because trust, communication and information sharing are not generated by the inherent characteristics of the enterprise, but by the gradual interaction between the two parties in the process of cooperation, therefore, this paper named the influencing factors of the cooperative relationship as the level of interaction.

5. Strategies for Improving Cooperative Relationship between Drug Listing License Holders and Trusted Manufacturers

5.1. Setting Reasonable Goals to Investigate Entrusted Production Enterprises

Because the entrusted production enterprise undertakes the core function of drug supply, which is the basis for the smooth operation of the whole entrusted production link, the assessment of its enterprise conditions should be considered from two aspects of hardware and software. Hardware, including pharmaceutical production equipment, production scale, process level and previous product quality. Software includes the basic quality of employees, perfect quality management system and flexible supply capacity. To ensure the quality of drugs, enterprises should first have qualified production equipment. Modern pharmaceutical industry is essentially a manufacturing industry, and the importance of equipment is self-evident. Drug holders should pay attention to the selection of equipment with advanced technology and high production efficiency to ensure the quality of drugs. In addition, the quality of products in the past is also a focus that should be paid attention to. The qualified rate of drug quality produced by the manufacturer in the past can be observed, or the qualified rate of small batches can be compared with that of other manufacturers. The professional skills and quality management system of enterprise employees affect product quality from the perspective of management. The holder should understand that the manager of the equipment is the staff. Good equipment also needs proper maintenance and operation to play its maximum function. Employees' proficiency in equipment and sense of responsibility need to be observed. In addition, a perfect quality management system not only reflects the management ability of production enterprises, but also can effectively control the quality of drugs at a reasonable level. The supply capacity of enterprises is also the guarantee of supply. The time and quantity of drug delivery are equally important to the holder. When a holder entrusts multiple drug manufacturers to share different links of drugs, the delivery of various finished products and semi-finished products is at.

5.2. Balancing Resource Dependence of Drug Entrusted Production Cooperation Parties

Since the holders of drug listing licenses are dependent on the production resources of the entrusted production enterprises, in order to balance the asymmetric situation of resource dependence between the two sides and reduce the opportunistic behavior caused by

asymmetric resource dependence, it is necessary to strengthen the resource dependence of the entrusted production enterprises on the holders of drug listing licenses. There are two ways to enhance the advantages of the holders and improve their status in cooperation. The second is to strengthen the relationship-specific investment of entrusted production enterprises. In terms of enhancing the cooperative status of the holder, the holder should realize that orders and profits have great influence on the entrusted production enterprises. Therefore, the holder can improve the cooperative willingness of the entrusted production enterprises through three ways, including price incentive, order incentive and payment incentive. Price incentives refer to the total amount of money given to manufacturers to commission the production of drugs or a single transaction at a price higher than the market price is sufficient to impress partners. Order incentive means that the holder can improve the cooperation willingness of the entrusted production enterprises by continuously increasing orders. The last payment incentive, in the way of payment and payment time, the holder can choose to pay in installments or one-time payment, can be paid in advance, can also confirm the product quality after receiving repayment. Ideally, the holder entrusts a large number of orders and pays one-time payment at a price higher than the market price, which can increase the attraction to the entrusted production enterprises, and make the entrusted production enterprises cooperate actively, hoping to become the main drug supplier of the holder. However, for practical reasons, the holder may, at an early stage, focus on the ability of the entrusted manufacturing enterprise to meet its production obligations in small quantities and in installments.

5.3. Improving the Level of Cooperation and Exchanges between the Two Sides

5.3.1. Cultivating Mutual Trust between Holders and Entrusted Production Enterprises

The cooperative relationship between the two sides is affected by the trust of both sides, and the distrust of either side will affect the quality of the overall cooperative relationship. In addition to signing formal contracts to protect their legitimate rights and interests, the weak party in the cooperative relationship should also attach importance to informal means, that is, to promote the relationship with partners, including trusting partners. Mutual trust between the parties can encourage both parties to attach importance to the long-term interests of this relationship, and enhance competitiveness and reduce transaction costs. For holders, instead of worrying about the opportunism of the entrusted manufacturing enterprise, trust partners boldly, don't worry about entrusting the production to falsely report high prices, the production process of stowaway cuts, reduce disputes arising from misunderstanding. This requires the holder to first establish a friendly attitude towards the entrusted production enterprises, in the pursuit of long-term cooperation to integrate the interests of both sides. At the same time, we should also consider the issue from the standpoint of the entrusted production enterprises. When the cooperative environment changes and major decisions are faced, we should think more about the feelings and interests of the other party and try not to harm the interests of the partner. Only in this way can the entrusted manufacturing enterprises feel the goodwill of the holder and the attention to the cooperative relationship, and promote the partners to regulate their own behavior and live-in harmony with the holder. However, the holder's trust is not blind, unconditional. To trust the entrusted production enterprises, we need to start from two aspects. One is the direct experience, namely, the actual commission experience, and the other is the indirect experience, namely, reputation or corporate image. When the holder is not aware of the entrusted manufacturing enterprise, it may be preferable to give priority to the larger size of the enterprise and to have more cooperation with other manufacturing enterprises.

5.3.2. Strengthening Bilateral Organizations and Interpersonal Communication

Holders can start from strengthening the human relations between the two sides, and strengthen private relations with the senior and middle-level leaders and grass-roots

employees of the entrusted production enterprises, such as private mutual visits and gathering activities. On the one hand, they can learn more about the internal information of the pharmaceutical production enterprises and reduce the risks caused by information asymmetry. On the other hand, they can also cultivate emotions outside the work of the two sides, and attract more time, energy and emotional investment from the entrusted production enterprises in cooperation with the holders. When partners encounter difficulties, give the help they can, cultivate their goodwill and 'courtesy'. And through frequent contacts with the other party's senior leadership and grass-roots staff, to express the concern and loyalty to the other party, increase the emotional loss caused by the termination of cooperation between the two sides. Drug license holders should try their best to establish an organizational communication system with the entrusted production enterprises. Through regular meetings and exchanges, they should master the process of drug entrusted production, exchange their cooperation experience and summarize and prevent strategies for previous cooperative production problems. Pay attention to the opinions and evaluation of the license holders of drug listing in the entrusted production enterprises, improve the relevant work, smooth communication channels, and strengthen the understanding and support of both sides.

5.3.3. Establish Information Sharing Platform

The establishment of an information sharing platform based on IT technology has two functions. One is to promote information sharing between the two sides and avoid misunderstanding and information distortion. The second is to strengthen office automation for both sides, strengthen the speed of information flow, break through the shackles of time and space through the Internet, and reduce the cost of communication in cooperation. The holder should persuade the entrusted production enterprises to share information on the progress of entrusted drug production, stock of raw materials and finished products and other related changes as far as possible, to provide information support for decision-making. In practical cooperation, the conflict of cooperation between the two sides may be due to the lack of understanding of the real situation. The distortion of information transmission can be avoided by information sharing, increasing the control of front-line production and understanding the ability and interest pursuit of each other. If there is a large conflict of interest, both sides can also predict the risk events in time or in advance, leaving a buffer time for the subsequent coordination of both sides. Office automation can present the production progress and historical records of each partner for entrusting a number of entrusted production enterprises at the same time. It can be documented for the quality problems, technical problems and conflicts that have occurred in the past. When a cooperative dispute occurs, it can first dispatch relevant information, clarify the attribution of responsibility and follow up the solution quickly, reduce the consequences of the problem, provide solutions for future problems and strengthen the management level of both sides.

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