



Study on Protection of the Right to Health, Access to Medicines and the Construction of the Rule of Law for Medicine Patents

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Abstract

The Access to Medicines is related to the basic rights of people's rights to life and health. It has been widely recognized by international conventions and has become a basic duty of the state to ensure and improve the level of citizens' access to medicines. At the same time, in the face of increasingly widespread uncertainties in modern society, building a fair and efficient legal system for medicines access is a necessary measure to promote citizens' trust in the government and maintain the legitimacy of power. In the conditions of 1.3 billion population and an unbalanced and inadequate economic development, China strives to ensure that its citizens' medicines are economically affordable through continuous improvement of the legal system and arrangements, and to encourage local pharmaceutical companies to develop and manufacture better-quality medicines. On the premise of respecting the status of market players and property rights of pharmaceutical companies, China comprehensively uses diversified tools such as information, standards, market access, and competition law enforcement to establish a legal system for medicines accessibility from two channels: supply guarantee and price control. Particular attention is paid to the adjustment of the medical and social insurance and essential medicines systems. In recent years, China has focused on improving the pharmaceutical patent system, promoting the balanced development of local original research medicines and generic medicines, as well as the overall optimization and upgrading of the pharmaceutical industry through the protection of patent rights and appropriate restrictions. Driven by the economic and trade agreement reached between China and the United States in 2020, China's Patent Law will introduce a drug patent term extension system and a drug patent linkage system, and further improve the legal mechanism to encourage innovative activities of pharmaceutical companies.

Keywords: Access to Medicines; Right to Health; Medicine Management Law; Medicine Patents; Patents Law

Abbreviations: UN: United Nations; WHO: World Health Organization.

Introduction

Medicines derived from the natural needs of humans to prevent diseases and protect health. Medicines are also indispensable to the survival and development of human

individuals and communities. Health rights protection is a logical starting point for exploring the accessibility of medicines from a legal perspective. Accessibility of medicines is both a challenge that humanity needs to face together and country specific. On the one hand, humanity is faced with an epidemic that threatens public health and the sustainable development of society. The desire for healthiness is over-boundaries and races. Individuals should have the right to

access medicines to prevent and treat diseases, and any international level of system coordination should reflect the universal value of humanism and fairness care. On the other hand, specific to each country level, each country is obliged to improve the level of medicine accessibility as its basic legal and policy goal. However, countries are at different stages of development of the social economy, pharmaceutical industry, and healthcare system, which means it is necessary to ensure the feasibility of legal systems and policies should base on national conditions and sustainability.

China is the largest developing country with the largest population. How to meet the medicines demand of 1.3 billion people has become a major challenge and task for the government: to ensure that the citizens have equal access to the essential medicines within their accountability, also to activate the research and development ability of domestic pharmaceutical companies, so that to provide medicines with wider indications and better efficacy. China implements a socialist market economic system and governing the country according to law. The production and operation of pharmaceuticals are dominated by corporate market entities. At the same time, the country has a wealth of toolkits to intervene in the pharmaceutical market to achieve public welfare goals. However, the exercise of government power must also prevent abuse of power and avoid disruption of the pharmaceutical market order. As a result, how to properly intervene in pharmaceutical production and operation activities under the constraints of the rule of law, especially the use of private legal tools to adjust patent rights, to balance the public interest and the interests of pharmaceutical companies. In addition, in 2020, the epidemic of the new coronavirus (COVID-19) that swept the world caused the most serious loss of life and economy since this century. In the face of the epidemic, there is no distinction among countries and political systems. The epidemic tests the country's basic ability to protect citizens' rights to life and health. The key lies in how the state promotes the development of therapeutic medicines and vaccines in the most efficient way through institutionalized interventions, and also guarantees the fairness and justice of market supply and citizen access. The construction of the rule of law on the accessibility of medicines has become a key capacity of a country to deal with uncertain risks.

This article intends to analyze the conceptual connotation and national mission of medicines accessibility from the basic standpoint of China's treatment of medicine accessibility and its relationship with human rights. It is further summarized as to what constitutional and legal institutional arrangements China has undertaken to achieve the goals of ensuring and improving access to medicines, and how to balance the interests of pharmaceutical companies and the public through appropriate market interventions. At

the same time, in recent years, one of the reform directions of China's medicine accessibility system is to improve the medicine patent system. China's practice in this regard reflects the efforts and difficulties faced by developing countries in protecting the basic rights of their citizens and protecting and incentivizing the private rights of market entities.

Protection of the Right to Health and Access to Medicines

Access to Medicines and the Right to Health as a Basic Human Right

The right to health, as a basic human right, has been widely spread and recognized throughout the world, mainly from many important international legal documents after World War II. Reflecting on the two world wars and envisioning the future development of human society, the United Nations (UN), the World Health Organization (WHO) and other international organizations have incorporated the right to health into a series of important international legal documents. The preamble of the 1946 Constitution of the World Health Organization emphasizes the equality of the right to health: "THE STATES Parties to this Constitution declare, in conformity with the Charter of the United Nations, that the following principles are basic to the happiness, harmonious relations and security of all peoples: Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition." Article 25 of the 1948 United Nations Universal Declaration of Human Rights clearly stipulated that the right to health is a basic human right enjoyed by everyone and should be guaranteed by law. In addition, some international conventions also listed and regulated the right to health as a basic human right, such like Article 5 of the International Convention on the Elimination of All Forms of Racial Discrimination in 1965, Articles 11 and 12 of the 1979 Convention on the Elimination of All Forms of Discrimination against Women, Article 24 of the 1989 Convention on the Rights of the Child, and Article 25 of the Convention on the Rights of Persons with Disabilities.

As a party to the conventions and a responsible developing country, China has always been committed to implementing the provisions of the international conventions on the right to health. China takes the improvement of citizens' health as an important human rights cause, focusing on the construction of public health infrastructure and the development of medical and health industries. In addition, the right to health is regarded as an element of the concept of

a community of human destiny [1]. Through multilateral and bilateral forums, Government and non-governmental levels, China has participated in international public health affairs in a comprehensive manner and fulfill national obligations to promote global health such as financial support, disaster relief assistance, and information exchange.

The realization of the right to health is closely related to medicines and their accessibility. From the perspective of the connotation of the right to health, Article 12 of the UN International Covenant on Economic, Social and Cultural Rights in 1966 includes the right to health, including the right to receive proper medical care, use of medicines, medical facilities, and services when sick. The United Nations Economic, Social and Cultural Council pointed out that the right to health contains a number of interrelated elements: (1) Availability, which means that in order to protect citizens' right to health, the state should provide adequate and effective operations, including but not limited to professional medical personnel and essential medicines that are compatible with their level of development; (2) Accessibility, which means that the state provides the above facilities, goods or services. It should be non-discriminatory, geographically accessible, and reasonable prices; (3) Acceptability means that the country should respect medical ethics and cultural appropriateness when providing these facilities, goods or services, such as respecting the culture of ethnic minorities, gender equality, confidentiality of medical information; (4) Quality requirements, including skilled medical staff, safe and effective medicines and medical equipment, etc. [2]. The "availability", "accessibility" and "quality requirements" of the right to health are all directly related to the accessibility of medicines, and ensuring and improving the level of accessibility of medicines is the main way to protect and realize the right to health.

Access to medicine is one of the basic method to prevent disease and protect human health, so it takes a social nature that is different from that of general commodities, and social regulations are required. On the one hand, medicines have the trading value and use value of general commodities, and are used to prevent, treat, and diagnose human diseases, and purposely regulate human physiological functions. On the other hand, medicines have a profound social nature, and the quality, quantity, and convenience of public access to medicines directly affect the realization of the right to health. The lack of effective medicines supply leads that quality of life and health is not guaranteed, individual rights cannot be realized, and the development of groups and society is stalled or even retrogressed, so the public lives in poverty and fear. In view of this understanding, China has adopted special legislation to set up a relatively independent professional agency to manage the production, circulation, and payment of medicines. The basic goal of such legislation is to ensure the safety, effectiveness, and accessibility of medicines, and

promote the health of citizens of individuals and society. This is reflected in the Article 3 of the Pharmaceutical Administration Law (Amended in 2019):

Pharmaceutical Administration should be centered on people's health, adhere to the principles of risk management, overall control, and social co-governance, establish scientific and strict supervision and administration system, and comprehensively improve the quality of medicines and ensure the safety, effectiveness, and accessibility of medicines.

Access to Medicines and its State Duties

Connotation of Access to Medicines: Access to medicines refers to the objective state and level for patients to obtain medicines to meet the prevention and treatment of diseases, recovery, and maintenance of health. As far as the constituent elements are concerned, the access to medicines should be a combination of accessibility and affordability based on availability, safety, and effectiveness:

Usability: Usability means that the medicine has the efficacy of treating diseases. Within a certain range of indications, the usability of the medicine is supported and evaluated by safety and effectiveness. Safety requires medicines to play a role in curing diseases but must not cause unnecessary damage to the human body, and toxic and side effects should be controlled within a certain range. Efficacy requires that under the prescribed indications, usage and dosage conditions, the medicine can meet the cure of human diseases and purposely adjust the physiological functions of humans. The so called medicines that do not meet the standards of usability, safety, or effectiveness, such as "counterfeit medicines" and "inferior medicines" as prescribed in Article 98 of China's "Pharmaceutical Administration Law", not only fail to prevent diseases, but may also harm the lives and health of patients. Therefore, usability, safety and effectiveness are the requirements for the "quality" of medicines. Without the "quality" of medicines, it is impossible to talk about the access to medicines.

Accessibility: In technical means, medicines for disease prevention and treatment can be produced at the technical level and can be obtained by the public in a timely manner geographically.

Affordability: Affordability is economic accessibility, which means that citizens (patients) have the ability to pay for medicines to cure their diseases. Only when a medicine is purchased and used at a consumer terminal can its exchange value be realized as a commodity, and the overall social affordability or affordability of a medicine also determines the motivation for medicines innovation and production.

Constitutional Origins and State Duties of the Access to Medicines: Taking medicines as an intermediary, the state protects citizens' right to health by formulating

and implementing laws and policies that guarantee the accessibility of medicines, which is its international law and constitutional duty to respect and protect human rights. The transformation from human rights to the fundamental rights of citizens in the Constitution is an important symbol of the realization of the right to health. The constitutional rights to health correspond to the state's duty to realize, guarantee, and promote human rights. The "Constitution of the People's Republic of China" (hereinafter referred to as the "Constitution") known as the "Mother Law" has the function of deriving legislation and establishing national policies. The main norms in the Constitution to stipulating the rights to health include: (1) Article 33 (para. 3), The state shall respect and protect human rights. Article 36 (para.3), concerning the inviolability of citizens' health. The state shall protect normal religious activities. No one shall use religion to engage in activities that disrupt public order, impair the health of citizens or interfere with the state's education system. (2) Article 45 (para.1), Citizens have the right to material assistance from the state and society when they are aged, ill or have lost the capacity to work. The state shall develop the social insurance, social relief, and medical and health services which is necessary for citizens to enjoy this right. (3) Article 21, Article 26 (para.1), the state shall develop medical and health services, sports, and protect life and the ecological environment. Among them, the first paragraph of Article 21 provides that to protect the people's health, the state shall develop medical and health care, develop modern medicine and traditional Chinese medicine". Since the establishment of the Constitution in 1982, this provision has constituted the direct constitutional basis for China to promote the construction of the rule of law in medicine based on the accessibility of medicines to protect citizens' right to health.

During the implement of reform and opening policy for more than 40 years, China's pharmaceutical industry has made great progress, and legislated Promotion of Basic Medical and Health Care Law, Pharmaceutical Administration Law, Law on Prevention and Treatment of Infectious Diseases, Traditional Chinese Medicine Law, Vaccine Administration Law, etc. Through regulating the medical system and pharmaceutical management, the state develops and protect citizens' right to life and health. To protect such rights and to improve the availability of medicines, the Promotion of Basic Medical and Health Care Law implemented in 2020 provides a comprehensive institutional framework by providing organizations, human resources and funds with all-round system construction guidelines. The first paragraph of Article 4 clearly stipulates: "The state and society shall respect and protect citizens' right to health"; Chapter 5 Guarantee for Supply of Medicines stipulates goals of "guaranteeing the safety, effectiveness and accessibility of medicines" Comprehensively improve the accessibility of medicines in

terms of essential medicine system, medicine review and approval system, quality, price, market supply. However, for a relatively long period of time in the future, China must continue to promote the regulations in pharmaceutical affairs in order to improve the accessibility of medicines. This is an important part of the construction of China's human rights protection system [3].

The state's duty based on the availability of medicines is essentially to establish a sound legal system aimed at protecting and promoting citizens' health. China is establishing a complete legal system, which is based on the market-oriented production and circulation of medicines and comprehensive state intervention. Through the implementation of the law, it provides a medical service system, medical social insurance and payment system, and intervenes and regulates the pharmaceutical market. The accessibility of medicines involves the producers, sellers, medical service institutions and payers of medicines. The payers include patients and social insurance institutions. The producers and patients at the two market terminals of production and consumption of medicines are the key roles of the accessibility of medicines. In a market economy, the production and pricing right of medicines are largely in the hands of pharmaceutical companies, so the availability of medicines requires the establishment of a legal system that regulates the production of medicines. State duties based on the availability of medicines involve the exercise of a wide range of government functions, which is centered on Medicine Products Administration under the Administration for Market Regulation. Intellectual Property Administration, Anti-monopoly Bureau and the health administrative agency have corresponding administrative law enforcement powers.

Principles and Tools of the Rule of Law for Access to Medicines

Principles of the Legal System for Access to Medicines

Medicines have the characteristics of weak price elasticity in demand and strong price differences between patented medicines and generic medicines [4]. In short, market supply and demand mechanism or private law tools are not sufficient to ensure the supply of medicines. The availability of medicines should be based on good law and governance, in accordance with gradual steps, uses the tools of the rule of law to intervene in the production, circulation, purchase and payment of medicines from the two dimensions of market supply and price control.

The availability of medicines is a process of benefit distribution between pharmaceutical companies and patients. In the formulation of rules and specific enforcement,

government agencies play the role of benefit distributors. Good governance is regarded as the common goal of governments around the world, and it is social management that maximizes public interests [5]. Since China's accession to the WTO in 2001, China has been committed to promoting a fair and transparent rule of law, which is consistent with internationally recognized best practices of good governance. Especially in the second decade of the 21st century, China's government has actively promoted the modernization of the national governance system and governance capabilities, integrating the concept of good governance into a wide range of social regulatory fields including the availability of medicines. The legal governance of medicine accessibility in China is practicing or striving to realize the basic principles of transparency, efficiency, and gradual progress:

(1) The principle of transparency. The principle of transparency requires that the making processes of legal norms and policy should be opened to the public. The public can participate in, for example, the formulation of medicine patent law, the selection of basic drug catalogs, and can make suggestions through various channels. In addition, various norms, policies, and drug patent information should be opened to the public for inquiries in a convenient way, forming a "benign documentary doctrine" of pharmaceutical law.

(2) The principle of cost benefit. The rule of law for medicine accessibility should fully consider the costs to all parties. For example, medicine marketing review, drug patents, medical social insurance and other systems involve different lengths of time, and the complexity of the regulations will also affect the compliance of the parties. Time and compliance costs will inevitably affect the interests of pharmaceutical companies and the health rights of patients. Therefore, the rule of law for access to medicines needs to minimize unnecessary costs in the system to maximize the overall benefits of society.

(3) The principle of gradual progress. There is no priority difference between healthy and unhealthy, and different kinds of diseases. The universality of human rights and the consistency of basic rights protection require that the availability of medicines cover all citizens. However, given the limited financial resources and medical resources, it is impossible to guarantee the medication needs of all citizens at the same time. Therefore, the regulation of the availability of medicines needs to be gradually developed in accordance with the national conditions and actual conditions in the region.

It is worth noting that essential medicines accessibility is the primary level of medicine accessibility, and the availability of medicines other than essential medicines is the development after the primary level is met [6]. From the

perspective of the citizen groups of medicine availability, the basic medicine system can be divided into three development stages: (1) The relief stage of collective health rights, which mainly faces the poor in society and pays attention to medicine price control; (2) At the request stage of collective health rights, face each individual in the society as a whole, and emphasize the "cost-benefit" of the selection of essential drugs; (3) The request stage of the right to individual health is geared to individualized protection of the right to health, such as rare diseases. It emphasizes the meaning of "essence" in the interpretation of essential medicines, and "select the best" medicine for individual diseases [7]. The essential medicine system is one of the basic systems of the rule of law for medicine accessibility, and its stage of development can also be understood as the development level of medicine accessibility. The protection of the right to health is a never-ending undertaking. The rule of law for the accessibility of medicines should be based on the stage of economic and social development, and gradually develop from collective to individual, from price to quality, and strive to eliminate different levels of health protection derived from individual wealth and disease, and the goal is to finally realize the availability of medicines for all members of society.

As a socialist country, China is striving to achieve the equalization of basic medical and health services. China's regional and intra-regional development imbalance is gradually shrinking, but the gap is still obvious, and citizens in eastern coastal areas and large cities are commonly enjoying a higher level of medical services and access to medicines [8]. The imbalance of regional development in China and the universality of protection of citizens' right to health determine that China needs to set framework laws, goals and adopt transfer payments across the country on the road to advance the legal system for medicine accessibility. Such regulatory measures have taken the lead to meet the accessibility needs of all citizens for essential medicines and medicines for common major diseases. On the other hand, it is necessary to ensure the flexibility of the law and give local governments the power to adjust financial capital and medical social insurance independently. While striving to promote universal access to medicines, China also pays attention to the protection of individual health rights. For example, in terms of rare disease medicines, 29 kinds of the 55 marketed medicines for 18 categories of rare diseases that have been included in the China's national medical insurance list, of which 9 kinds of medicines are fully paid by public medical insurance [9].

Under the premise of respecting the status of medicine manufacturers and sellers in the market, the government should comprehensively use information, standards, market access, competition enforcement, government procurement, tax subsidies and other diversified tools to

establish accessibility of medicines from two channels: supply guarantee and price control, in which medical social insurance and essential medicine systems are the core of China's relevant legal system construction.

Legal System for Medicine Supply

The main way to ensure the supply of medicines is to stimulate the output of domestic medicine production and to promote the structural transformation and upgrading of the pharmaceutical industry. From the perspective of medicine production, distribution and consumption, the first thing in the realization of medicine accessibility is that medicine production can meet the medicine needs of patients, and the structure of the pharmaceutical industry is continuously upgraded and optimized. At present, China's pharmaceutical industry is dominated by generic medicines, and original research medicines are beginning to flourish. In some low-profit and high-risk medicine research and development (R&D) fields (such as rare disease medicines), the level of industrial development is relatively lagging. Overall, China's pharmaceutical industry is facing obstacles to industrial transformation and upgrading due to the high cost of research and development of original research medicines.

The supply of China's pharmaceutical market mainly relies on market operation, and the government respects the status of market players and independent management rights of pharmaceutical companies. Corresponding intervention measures are tools of the rule of law with a low degree of intervention, including private law, information or economic regulation tools. Such tools with the characteristics of marketization and flexibility can be adjusted in time according to changes in the supply and demand of the medicine market and are suitable for specific medicines according to the selection of time, amount, and ratio. (1) Private law mainly provides pharmaceutical companies with rights over research and development medicines through the patent system, including monopoly management rights and a long patent protection period. (2) Information tools are mainly the information platform built by the government for medicine supply and demand. The focus is to communicate information on shortages of medicines and raw materials across the country and in the region, government procurement information, and real-time delivery of supply and demand information to pharmaceutical companies, guiding the latter to adjust according to medicine market demand Production scale. At present, the National Health Commission of China has established a comprehensive management information platform for national medicine supply guarantees, which basically realizes the openness and transparency of medicine procurement management and data sharing. (3) Economic tools include taxation, subsidies and other financial tools. On the one hand, preferential tax policies are used to reduce

or exempt taxes on specific medicines for a certain period. On the other hand, subsidies are used to provide financial support for the development and production of specific medicines.

Another way to ensure the supply of medicines is to expand imports of special medicines. Although increasing the supply level of domestic pharmaceutical companies is the main way to solve the accessibility of Chinese medicines and has the significance of ensuring national strategic safety and optimizing the industrial structure, China's pharmaceutical industry is in a state of strong production capacity but weak R&D capabilities. The innovation and production of medicines for certain special diseases, such as anti-cancer medicines, AIDS medicines, and medicines for rare diseases, are relatively in backward development. There is also a significant gap between the efficacy of domestically produced generic medicines and imported original medicines. This condition cannot be reversed in a short period of time. The legislation to ensure the import of special medicines is currently a way to ensure the availability of medicines in developing countries such as China. At present, China's expansion of imports of special medicines mainly adopts simplified approval procedures to shorten the time to market, such as the default system for clinical trial applications, and import inspections based on corporate inspection results. Although the import tariff reduction and exemption measures will jointly promote the availability of imported medicines accessibility, but there is still an increasing contradiction with the consumption level of patients. The legal dilemma includes obstacles to the parallel import of patented medicines and the trade-off between medicine availability and safety.

Legal System for Medicine Price Intervention

Price is an important adjustment lever for the allocation of market resources. The level of medicine prices and their changes directly determine the level of medicine costs and the vigor of market competition [11]. As the market-oriented reform of the economic system continues to deepen, the government's role in the formation of medicine prices has gradually weakened, and the control of medicine prices has been gradually liberalized. The market-oriented medicine price formation mechanism has the risk of rising medicine prices. There are not only reasonable price increases caused by changes in supply and demand and rising costs, but also unreasonable price increases caused by illegal monopoly and price manipulation and setting high prices by the monopoly of medicine patents. Rising or high prices of medicines directly increase the burden on patients and reduce the economic accessibility of medicines. It requires the government to comprehensively use a variety of legal tools to control medicine prices and maintain order in the

medicine market.

To maintain the order of the medicine market, the Anti-Monopoly Law, Anti-Unfair Competition Law, Price Law, Promotion of Basic Medical and Health Care Law and Medicine Administration Law are being improved and strengthened. In 2019, the Medicine Administration Law was revised to set up Chapter 8 on medicine prices and advertisements. Articles 84 to 88 focus on the regulation of medicine prices, including monitoring, supervision and inspection of medicine prices, and investigation of price violations. Regarding the principle of medicine price setting, profiteering and price fraud are prohibited. Article 91 also stipulates that the price and advertising of medicines, which are not provided for in this law, shall be governed by the Price Law, the Antitrust Law, and the Anti-Unfair Competition Law, the Advertising Law etc. The first paragraph of Article 62 of the Promotion of Basic Medical and Health Care Law stipulates that the state shall establish and improve a medicine price monitoring system, conduct cost price investigations, strengthen medicine price supervision and inspection, and investigate and deal with price monopoly, price fraud, and non-compliance, illegal acts such as fair competition to maintain the order of medicine prices.

In the face of complex medicine technology and market environment, government agencies are facing increasingly severe challenges in monitoring and regulating medicine prices. It is difficult to give a specific and clear basis for judging whether a price or its increase is reasonable. In fact, government agencies are not producers and sellers, and cannot replace the sellers' position in the market price formation mechanism. There are many obstacles in methodology and administrative costs in evaluating the price behavior of producers and sellers. Therefore, the supervision of medicine price behavior focuses on judging whether there is restrictive competition or unfair competition behind the price behavior from the perspective of market competition. The 2017 China Development and Reform Commission's Price Behavior Guide for Shortage Medicines and Active Pharmaceutical Ingredient Operators clearly prohibits sellers from reaching horizontal or vertical price monopoly agreements to manipulate market prices, prohibits sellers from abusing market dominance to conduct transactions at unreasonable prices, and restrict acts such as transactions, refusals to trade, imposing unreasonable fees, and discriminatory treatment. However, the general anti-monopoly law framework is limited in investigating and punishing illegal monopoly behaviors in the pharmaceutical industry, and the deterrence of the implementation of China's Anti-Monopoly Law is not enough to resist the lure of huge profits from illegal medicine monopoly. Therefore, China's medicine price regulation also needs to be linked with the implementation of the pharmaceutical industry competition

law, and the scope of competition law enforcement will completely cover the upstream and downstream of the pharmaceutical industry and the entire field, and the medicine monopoly, price manipulation and other behaviors will be subject to huge penalties, market prohibitions, even the criminal punishment.

In the case of a reasonable increase in medicine prices or high patent monopoly prices, the government lacks methods for mandatory intervention. The feasible way is to rely on medical social insurance to intervene in medicine prices from the purchase and sale. The establishment of the social medical insurance system is the main reason for the government's intervention in medicine prices in market economy countries, and the medical insurance payment has been the core content of government medicine price management [10]. The medical insurance payment price is composed of a set of interrelated systems, including essential medicine catalogs, government procurement, medicine storages, and payment system.

First, the national basic medical insurance medicine catalog defines the scope of the system's operation. To ensure the rationality of medicine selection, China is reforming relevant regulations in the following three aspects: (1) Covering more major diseases such as cancer, AIDS, and rare diseases, and constantly improving the quality and cost-effectiveness of medicines in the catalog; (2) A proper balance should be maintained between the medicines used in the reference list and the medicines used by the physicians. The medicine catalog is legally binding on medicine purchase, medication and reimbursement, but there are inherent laws in medical behavior. Therefore, to delineate the scope of the medicine catalog, it is necessary to retain the physician's professional discretion, and the types of medicines in the same disease should be enriched; (3) Implement dynamic adjustments to the medical insurance medicine catalog, focus on structural optimization, and increase the proportion of new medicines included and promote medicine innovation.

Second, adjust prices through government procurement. There are obvious market failures in the pharmaceutical market, the economic strength between pharmaceutical companies and individual patients is huge, and the problem of information asymmetry is serious, and patients do not have the ability to bargain equally. Therefore, the government should assume the role of an agent for all patients or consumers, relying on its financial capabilities and organization and coordination capabilities to carry out equal transactions and price negotiations with pharmaceutical companies to reduce medicine circulation links and unnecessary social transaction costs. Centralized procurement and mass procurement of medicines belong to a special type of government procurement. Distorts market

competition, vicious price competition, administrative monopoly and other general problems in government procurement may also occur in medicine procurement activities. China is strengthening general legal constraints, such as the Government Procurement Law, Tendering and Bidding Law, and Civil Code Contracts, and adheres to the basic goals of medicine procurement, assessing the reasonable price range of medicines, and examining the supply capacity of the procurement target companies. Strictly implement the provisions of the second paragraph of Article 62 of the Promotion of Basic Medical and Health Care Law stipulate that the state strengthens the management and guidance of classified medicine procurement. Bidders participating in medicine procurement bidding shall not bid at a price lower than the cost, and shall not use fraud, bid collusion, abuse of market dominance and other methods of bidding, and implement the corresponding liability for violations.

Third, the medicine storage and supply system are a legal tool to stabilize medicine prices and ensure the availability of medicines in response to market medicine shortages and public emergencies. Article 63 of the Promotion of Basic Medical and Health Care Law stipulates that the state establishes two levels of central and local medical storages to protect emergency needs such as major disasters, epidemics, and other emergencies. This provision shows that the medicines storage system is mainly for emergencies. Although the stock of pharmaceutical products will not produce significant effects for many years under the normal conditions and consume a lot of public funds, the SARS, Ebola, and Covid-19 epidemics have highlighted the important functions of the medical material storage system in saving citizens' lives, ensuring public health, and maintaining the order of production and life in special periods. Chapter IX of Medicine Storage and Supply in the Medicine Administration Law includes medicine storage system and emergency requisition (Article 92), essential medicine system (Article 93), medicine supply and demand monitoring system (Article 94), list management system for shortage of medicines (Article 95), priority review and approval of special new medicines (Article 96), Supply guarantee mechanism (Article 97). Such regulation rules provide the general rules for that medicine storages and supply system, and specific operational matters such as coordination of functions and authorities, informatization management, and storage base construction need to be specified in secondary legislation. Medicine storage involves the multi-party coordination and authorities' allocation among health agencies, emergency management agencies, and market supervision agencies. The categories, management and use of medicine storage need to be established on an information system based on the medicine market and emergency plans. Relative storage facilities and management systems should be developed. Therefore, the medicine storage and supply is

a subsystem that needs to be systematically constructed.

Finally, medicine paid by social insurance is the terminal that directly affects the financial burden of patients. In 2018, China's medical social insurance expenditures for hospital medicines reached 31.2 billion US dollars. At present, China's public medical expenses and personal burdens are increasing together. One of the main reasons is that the use of medical insurance funds in China has focused too much on the policy goal of "safety", but does not paid enough attention to the capacity building and financial support of pension insurance management institutions, which has made it lack of supervision and incentives for physicians and patients' moral hazards, resulting in medical insurance funds frauds cases happened in some areas. The supervision of medical insurance funds, a public property, involves the distribution of interests among multiple groups in the medical field. However, China has only one framework of the Social Insurance Law, which is simple in terms of regulations and needs to formulate specific rules that are more operable in the future.

Pharmaceutical Social Security and Its Legal System

For a long time, in the process of China's reform of the medical system, the basic medicine system and the legal construction of the social medical insurance system are basically established and become the critical part of protecting citizens' access to medicines and the safe net to protect health rights, though they are not very complete.

China's medical social insurance developed along with China's reform and opening process since the late 1970s, and experienced three stages:

(1) 1979-1992, The exploratory stage. In 1979, China began to implement the policy of reform and opening, and the development of the commodity economy changed the basic aspects of life including medical care and employment. China gained experience from western countries and began to explore a social medical insurance model that is compatible with its own economic system. The key points of the reform in this stage are to control medical expenses. At the same time, China began to establish the medical insurance legal system, and issued the Notice on Further Strengthening of Public Medical Management, Opinions on Trial Implementation of Employee Major Illness Coordination, and other regulations. Such regulations rules made by national government departments showed the huge government authority to push the reform and development in the planned economy era.

(2) 1992-1997, social medical insurance reform pilot with the policy of combination of social pooling and personal

accounts. In 1992, China officially turned to the direction of market economy development, and many large collective enterprises were dissolved. Self-employed workers cannot get free medical care provided by the previous collective enterprises, and the construction of the medical security system is very urgent. Marked by the Pilot Opinions on the Reform of the Employee Medical System promulgated by the State Council in 1994, China has begun to gradually establish the reform goal of a “pooling and accounting” social medical insurance system covering all workers in cities and towns and establish a financing mechanism and operating mechanism that are shared by the government, employers and employees, and promote the reform of China’s medical insurance legal system.

(3) 1998-2009, the formation stage of the basic medical insurance system. At this stage, a three-pillar system of the basic medical insurance system was initially formed, including the basic medical insurance system for urban employees, the new rural cooperative medical insurance system, and the basic medical insurance system for urban residents. In 1998, the State Council promulgated the Decision on Establishing a Basic Medical Insurance System for Urban Workers, marking the formal establishment of a basic medical insurance system for urban employees based on pooling and accounting in China; in 2003, according to the State Council’s Opinions on the Establishment of a New Rural Cooperative Medical System, the pilot of the new rural cooperative medical insurance system was launched nationwide. In 2007, the State Council issued the Guiding Opinions on the Pilot Program of Urban Residents’ Basic Medical Insurance, and the pilot work of urban residents’ medical insurance was gradually launched. The successive promulgation of these administrative regulations and departmental rules has greatly enriched China’s medical insurance legal system.

(4) The new stage of legalization of medical insurance since 2010. In 2010, China promulgated the Social Insurance Law which is the first comprehensive law in the field of social insurance. It established the status of China’s basic medical insurance in legal form and become a milestone in the construction of China’s medical insurance legal system and comprehensively summarizes the years of China. The exploratory experience in the field of social insurance has opened a new era of legalization of social medical insurance. The Promotion of Basic Medical and Health Care Law of 2019 makes clearer provisions for China’s basic pension insurance system in terms of funding guarantees. In 2020, Opinions of the Central Committee of the Communist Party of China (CPC) and the State Council on Deepening the Reform of the Medical Security System points out the basic direction for China’s medical security system reform in the next ten years and guides the construction of the rule of law toward

a more equitable, coordinated, and high-quality coordinated development of medical services.

The basic medicine system is the foundation of China’s medicine supply security system, and its development is relatively late compared to medical social insurance. Comparing the medicines listed in the essential medicines list with the medicines reimbursed by medical social insurance, there is no obvious difference between the two in terms of safety, effectiveness, and cost-benefit ratio. Essential medicines have stronger attributes in terms of necessity for prevention and treatment, guarantee of supply, and priority use. China’s Essential Medicines Catalogue has gone through policy promotion to the development of the rule of law, and is generally divided into three stages:

1. Policy exploration from 1992 to 2006. Since 1992, China began to explore the formulation of guidelines and policies for essential medicines based on the experience of WHO and developed countries. In 1992, the former Ministry of Health announced the implementation of the Working Plan for National Essential Medicines and issued the table of contents of National Essential Medicines in the version of 1994 and 1996. At this stage, China has not yet formed a systematic system and regulation. It mainly implements the National Essential Medicines catalogue nationwide in the form of policy regulatory documents to guide the production and use of medicines. The relevant practical experience has laid a foundation for China’s subsequent formal establishment of systems and regulations.

2. The basic medicine system was initially established from for 2007-2011. The establishment of the national essential medicine system in China began in 2007 with the Outline of the 11th Five-Year Plan for the Development of Health Services by the State Council. In 2009, the Opinions of the Central Committee of the CPC and the State Council on Deepening the Reform of the Medical and Health System and the Implementation Opinions on Establishing the National Essential Medicine System clearly set forth the goals and blueprint for China’s essential medicine system. The latter pointed out that the national essential medicine system is implement an effective management system for the selection, production, distribution, use, pricing, reimbursement, monitoring and evaluation of essential medicines, and link up with the public health, medical services, and medical security systems. The Management Measures for the National Essential Medicine List (Interim) promulgated in the same year officially upgraded the National Essential Medicine List to legal norms.

3. The essential medicine system has been consolidated and improved since 2012: At this stage, the essential medicine system pays more attention to the fair accessibility of essential medicines, focusing on the construction of information systems for special population protection, supply guarantee mechanisms, use incentive mechanisms,

evaluation and monitoring. In 2019, Article 93 of the Medicine Administration Law stipulates that the state implements an essential medicine system, selects an appropriate number of essential medicine varieties, strengthens the organization of production and storages, improves the supply capacity of essential medicines, and meets the demand for basic medicines for disease prevention and treatment. The essential medicine system has officially become a legal level norm. Article 59 of the Promotion of Basic Medical and Health Care Law stipulates that the state implements an essential medicine system and selects an appropriate number of essential medicines to meet the basic medicine needs for disease prevention and treatment. The state publishes a list of essential medicines based on the clinical application of medicines. Practice, medicine standard changes, new medicine launches, etc., make dynamic adjustments to the essential medicine list. Essential medicines are prioritized into the basic medical insurance medicine list in accordance with regulations. The state improves the supply capacity of essential medicines, strengthens essential medicine quality supervision, and ensures the equity of essential medicines Accessible and reasonably used”.

Since China's new round of medical reforms, the establishment and improvement of the social medical insurance system and the basic medicine system have played an important role in ensuring citizens' access to basic medicines, reducing economic burdens, and promoting the development of the right to health. It basically supports China's current goal of medicine accessibility.

Promoting the Reform of the Patent System for the Availability of Medicines

The Development of China's Original Research Medicine Industry and the Legal Effect of Patents

The accessibility of medicines in China is in a transitional stage from facing the poor in society to the public as a whole. The development of human rights to health and the improvement of the accessibility of medicines will never end, and the legal construction of medicines accessibility in China should be to is the pursuit of higher-level goals of protecting citizens' individual health, providing individualized, and high-quality medicines. The realization of these goals should be based on the high-level development of the pharmaceutical industry. At present, China's pharmaceutical industry is in a critical period of transition from low-quality imitation to high-quality imitation and innovation. On the one hand, China's pharmaceutical industry has been in huge scale but not strong for a long time, with generic medicines occupying an absolute dominant position and focusing on advertising

rather than R&D. Some high-efficiency medicines for major diseases rely heavily on imported patented medicines. The scope of government procurement price negotiations for patented medicines is limited, and the burden on patients is heavy. There is a significant gap between Chinese generic medicines and original medicines. The quality consistency evaluation of generic medicines that started in 2013 is scheduled to be completed by the end of 2018, but most generic medicine companies cannot meet the standards, and this time limit has to be cancelled. On the other hand, after years of investment and institutional support, the independent R&D capabilities of Chinese pharmaceutical companies have been greatly improved, and they the harvest period of the original medicines is coming. Compared with 2017, in 2018, the number of types of domestic Class I original research medicines (medicines that have not been marketed at home and abroad) registration applications, the number of new medicine clinical trial applications and the number of new medicine marketing applications have achieved rapid growth, and the annual review the 106 new medicine varieties approved include 9 domestically produced Class 1 original research medicines and 67 imported original research medicines. The improvement of the efficiency of the medicine review system, the selection of medical insurance and the support of the financial science and technology innovation board are institutional factors for the development of China's original research medicines. In short, to promote the transformation and upgrading of the pharmaceutical industry and the supply-side structural reform of the pharmaceutical market, to achieve a higher level of medicine accessibility, further legal construction is required. With reference to the experience of developed countries in the pharmaceutical industry such as Europe and the United States, the focus of China's medicine access legal system should be the construction of medicine patent law.

There is a dilemma between technical and affordable accessibility in medicine patent law. The lack of comprehensive restriction on patent rights may promote the technical accessibility of medicine within a limited scope, but it will damage the technical and affordable accessibility of a wider group of people. Simply granting patents to medicines and approving their market economic benefits as private property is far from realizing the social and public interest goals of patents as public property. Only through the systematic construction of patent law for medicine, can an appropriate balance of interests be achieved between the original research medicine companies, generic medicine companies and the public, between technical and affordable accessibility of medicine.

The high cost of R&D determines the high dependence of the pharmaceutical industry on patents, and patents are the fundamental institutional guarantee that encourages

pharmaceutical companies to innovate medicines. Mankind obtains medicines with better efficacy and prevention and treatment of more diseases from the technical possibilities to a large extent rely on the construction and improvement of patent law. Patent law also promotes the technical accessibility of medicines in the sense of patent information disclosure. Compared with the original research medicine companies protecting the secret recipe of medicines in the form of trade secrets, medicine patents can realize the widespread dissemination and progress of pharmaceutical technology.

Affordable Availability of Medicines and Patent Limitations

The other side of medicine patents is to directly lead to high medicine prices and reduce patients' affordable accessibility to medicines. Patents grant original research medicine companies monopolistic operating benefits during their validity period, and medicine patents are the most important reason for high medicine prices. A horizontal comparison of international medicine prices shows that the price gap between patented and non-patented medicines is dozens as large. After the expiration of the medicine patent period and the generic medicines appearing in market, the competition will lead the price of medicines with the same curative effect to drop by 80% [11].

The high price of original research medicines also indirectly affects the technical availability of medicines. Driven by the interests of patent monopoly, the primary goal of R&D investment in the pharmaceutical industry is the disease field with the greatest profit return. One of the important metrics is the patient's ability to pay. Most pharmaceutical companies focus on projects with high return rates and are likely to target R&D groups and targets in the wealthy class in developed countries that often suffer from diseases. On the other hand, only less than 5% of the world's medicine R&D funds are used to develop medicines for the treatment of diseases that seriously affect developing countries [12]. The WHO Consultative Expert Working Group on Financing and Coordination of R&D pointed out in the 2012 research report, whether in the public or private sector, current incentive system failed to generate enough new medicine research and development to meet the health needs of developing countries [13].

Pharmaceutical patents in the sense of purely private rights reduce the affordable accessibility of medicines and can only promote technical accessibility within a limited range of medicines and groups, resulting in a reduction in the level of accessibility of medicines to citizens of a country or global humans as a whole. It violates the value goal of patents in promoting public interest. In fact, from its beginning to its

globalization, the patent law has always emphasized its goals of enhancing public interest. As far as system functions are concerned, the monopoly of knowledge is not the purpose of patent pursuit. As far as system functions are concerned, the monopoly of knowledge is not the purpose of patent pursuit. Monopoly is only to encourage more inventions and creations, promote knowledge dissemination, technological progress, consumer welfare and social and economic development, etc. The promotion of overall social welfare is patent's ultimate value goal. For example, Article 1 of China's Patent Law stipulates that this law is enacted for the purpose of protecting the legitimate rights and interests of patentees, encouraging inventions, giving an impetus to the application of inventions, improving the innovative capabilities, and promoting scientific and technological progress as well as the economic and social development. The patent law needs to take into account the interests of patentees, users of patented technology and the public so as to achieve the best social benefits of the patent system.

The Development of China's Medicine Patent Legal System

At the beginning of reform and opening policy, in order to improve the overseas trade environment and promote the development of scientific and technological innovation, China began to draft the Patent Law in 1978. In 1980, China became a member of the World Intellectual Property Organization, WIPO. In 1984, the Standing Committee of the National People's Congress passed the Patent Law. In view of the fact that many countries did not provide patent protection for medicines and China's pharmaceutical industry was relatively weak, and according to the relevant reservation clauses of the Paris Convention for the Protection of Industrial Property, the Patent Law excluded medicines from the protective scope. Article 25 stipulates that methods for diagnosis, treatment of diseases and medicine and substances obtained by chemical methods shall not be granted patent rights.

In the context of trade policy negotiations between China and the United States, the 1992 Patent Law was revised for the first time. As the world's largest developing country, China has a huge demand for medicines. In order to maximize trade benefits and fully protect its own pharmaceutical companies, the United States urgently requires China to raise the standards of intellectual property protection, threatening to trade sanctions, and include China into The US Special Section 301 blacklist. In 1992, China and the United States negotiated and signed a memorandum of understanding on the protection of intellectual property rights. China promised to allow American companies that obtained pharmaceutical patents from 1986 to 1992 to enjoy market exclusivity in China for 7 and a half years. In accordance with the relevant provisions of the memorandum of understanding, the Patent

Law was amended:

(1) Provide product patents and method patent protection for medicines, chemical substances, food, beverages and condiments. (2) In addition to the original production, use, and sales, the patentee's rights introduced import rights; (3) In terms of the protection period of patents, the protection period of invention patents had been extended from 15 years to 20 years; (4) Compulsory licensing canceled local implementation requirements. According to this amendment, China has started the process of legalization of medicine patents, and medicine inventions in China can be protected by product patents, method patents, or both. Such protection requirements have exceeded the development level of China's pharmaceutical industry and are the result of political games under the continued high pressure from the United States. Although China had not yet joined the WTO at that time, the Patent Law has basically met the requirements of TRIPS through this amendment.

In order to join the WTO and fully integrate with TRIPS, China revised the Patent Law for the second time in 2000. In this amendment, the Patent Law introduced promise sales, pre-litigation interim measures, and abolished the final decision, also improved the compulsory licensing system. At the same time, to be in line with the Patent Cooperation Treaty, it clarified the right of an entity or individual to file an international patent application and the conditions that should be met. This amendment has further strengthened the protection of patents, simplified the patent examination and approval procedures, and made China's patent law a step forward in international coordination.

In 2008, the Patent Law was revised for the third time. Unlike the previous two passive amendment under the external pressures, this time the active revision of the law is to further improve the patent law based on the needs of China's own development, and to strengthen the patent rights. The protection of the government also considers the balance with the public interest. The significant change in medicine patents was the enrichment of medicine experimentation exceptions, that is, Article 69 of the Patent Law stipulates that such circumstances not regarded as infringement of patent rights: In order to provide the information required for administrative examination and approval, manufacture, use, or import patented drugs or patented medical devices, as well as those specially manufactured or imported patented drugs or patented medical devices for them.

The former State Food and Drug Administration has been deepening the reform of medicine approval since 2015 and has issued a series of pharmaceutical industry policies aimed at promoting the structural adjustment and technological innovation of the pharmaceutical and medical device industry, improving industrial competitiveness, and

meeting the clinical needs of the public. In May 2017, in order to encourage innovation in medicines and medical devices, the former State Food and Drug Administration issued the Relevant Policies on Encouraging Innovation in Medicines and Medical Devices to Protect the Rights and Interests of Innovators (draft for comments), which includes establishing medicine patent links and improving medicines test data protection regulation. In October 2017, the General Office of the Central Committee of the CPC and the General Office of the State Council issued the Opinions on Deepening the Reform of the Review and Approval System and Encouraging the Innovation of Medicines and Medical Devices. These policies proposed that to promote medicine innovation and the development of generic medicines, China will explore to establish a medicine patent link system, to develop a pilot program for the compensation of medicine patent term and to improve and implement the medicine trial data protection system. In 2018, the Patent Law Amendment (1st Draft) added a medicine patent term extension system. These three systems all use patents to encourage medicine R&D, promote the technical accessibility of medicines, and expand the patent rights in the Patent Law.

In January 2020, China and the United States signed the Economic and Trade Agreement between the Government of the People's Republic of China and the Government of the United States of America Washington, which was a 23-month period of 13 rounds of high-level economic and trade negotiations between the two parties. The first phase agreement reached is a practical step towards the ultimate resolution of the China-US economic and trade frictions and reflects the core concerns of both sides. The Section C Pharmaceutical-Related Intellectual Property in Chapter 1 Intellectual Property includes the legal protection of medicine trial data, medicine patent links, and the extension of the validity period of the four patents. The implementation of the agreement has a significant impact on the ongoing fourth revision of the Patent Law and has become a key factor in the future construction of China's medicine patent law. At present, in accordance with the agreement reached between the two countries, the revised draft of the Patent Law adds a medicine patent term extension system and a medicine patent linkage system aimed at early resolution of patent disputes. The latter has an impact on the work linkage mechanism between the medicine patent administrative authority and the court.

Evaluation of the Accessibility of China's Medicine Patent Legal System

Compared with the relevant regulations in developing countries such as India, China provides an earlier legal protection of medicine patents, which has an impact on the development of the country's pharmaceutical industry. In

1992, the Patent Law, which had only been implemented for 8 years, adopted the medicine patent protection standards of the developed countries in TRIPS before China joined the WTO. China failed to enjoy the transitional arrangements provided by TRIPS to developing countries. The industry has long been in a relatively stringent intellectual property legal environment, and its development has been significantly restricted.

China's pharmaceutical industry has been slow to develop due to its late start and lack of effective guidance and support from policies and laws. In addition, it is prematurely restricted by the Patent Law and missed the best stage of development, leading to the current low-level repeated productions and independent innovation capacity. It not only results in a significant gap with Indian pharmaceutical companies in the international market, but also leads to the difficulty to meet the pharmaceutical demand in the domestic market. Although the development of an industry is affected by many factors such as politics, economy, technology, and law, a large number of studies have shown that the rule of law for pharmaceutical patents has a pivotal effect on the development of the pharmaceutical industry [14].

In recent years, China has increased its legal and policy guidance and incentives for the pharmaceutical industry. The pharmaceutical industry is constantly growing, and its independent innovation capabilities have been greatly improved. At the same time, China's intellectual property legislation has got rid of the passive transplantation situation and has entered the stage of independent arrangement [15]. In 2020, the Opinions of the Central Committee of the CPC and the State Council on Establishing a More Complete Factor Market Allocation System and Mechanism regards the reform of technological elements as further stimulating the creativity and market vitality of the whole society, and promoting the quality of economic development, efficiency, and dynamics. It requires strengthening the protection and use of intellectual property rights. By improving the medicine patent system, China will construct an environment conducive to medicine R&D technological innovation and an appropriate incentive mechanism and guide the balanced and high-quality development of China's original research medicine industry and generic medicine industry, thereby continuously improving the availability of medicines for Chinese citizens. By drawing lessons from the past, learning from the experience of other countries, and taking advantage of the deepening reform of medicine approval, the fourth revision of the Patent Law, and the just-completed implementation of the Medicine Administration Law and the Promotion of Basic Medical and Health Care Law, China will build its medicines patent rule of law, with the basic goal of balancing the development of generic medicines and original research medicines, provides comprehensive legal support

for the improvement of medicine quality and innovation in China's pharmaceutical industry, thereby comprehensively promoting the availability of medicines in China.

Conclusion

The availability of medicines is a common proposition facing human survival and development. Based on the most fundamental human rights of life and health protection, the state needs to formulate corresponding policies and laws according to its own economic and social development. Influenced by the traditional Confucian political ethics "respect for nature and protect the people", China's authorities have always regarded the protection of people's lives and health as one of the main sources of political legitimacy, and it continues to the goal of protecting people's livelihood in today's China's strategy of ruling the country according to law, which is also reflected in the construction of the legal system regarding the availability of medicines. After more than 40 years of reform and opening policy and the construction of a socialist market economy with Chinese characteristics, China has gradually established a legal system for the availability of medicines based on market operation with the government intervening in all aspects of medicine supply, competition environment, and payment guarantee, and with the essential medicine system and the medical social insurance system as the cores. Facing the goals of high-quality development of the pharmaceutical industry, building an innovative country, and realizing a higher level of citizen medicine accessibility, China will focus on improving and constructing a medicine patent system in the future to realize the balance between the industrial economic benefits and the public benefits of medicine accessibility.

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