

Optimization of drug supply guarantee mechanism in China under the background of Healthy China

Qianzheng Xia, Xue Jiang, Yonghong Han

Jiangsu Vocational College of Nursing, Huaian 223000, China

Abstract: The supply of drugs in short supply is related to the development of the national pharmaceutical industry, and is an important foundation for promoting the construction of healthy China. At present, the drug shortage in our country is the coexistence of the whole and the provinces, each province has different degree, different kind of drug shortage. At present, some provinces and cities have established the drug shortage information reporting system and procurement measures, but there is still a lack of perfect drug supply guarantee mechanism. In this regard, this paper puts forward countermeasures and suggestions from four aspects: establishing emergency plan, constructing information system, guaranteeing the supply of low-cost drugs and deepening medical reform.

Key words: Drugs in short supply; Drug supply guarantee; Healthy China

The Outline of the “Healthy China 2030” Plan clearly states that the supply and early warning of drugs should be strengthened, and the reserve system and emergency supply system of drugs should be improved. Studies have shown that drug shortages can have a significant impact on all stakeholders in the drug supply chain, especially patients and hospitals. The Notice on the Management Measures for Printing and Distributing the National List of Drugs in Short Supply (for trial implementation) officially defines drugs in short supply in China, which is an important breakthrough in the country’s supply and guarantee system for drugs in short supply. This paper will analyze the current situation and existing problems of the supply guarantee mode of shortage drugs at home and abroad, and put forward suggestions on the supply guarantee mode of shortage drugs in our country.

1. Drugs in shortage

“Drug shortage” means that all the drugs produced by pharmaceutical companies cannot meet the needs of pharmaceutical consumers. The American Pharmacists Association and the Drug Information Service at the University of Utah describe a drug shortage as a supply problem that leads to the use of clinical alternatives that affect patient care and pharmacy dispensing. The U.S. Food and Drug Administration defines a drug shortage as an inability to meet existing and planned needs at the user level for all clinically available drugs in the supply of alternative medications. The Royal Netherlands Society for the Promotion of Pharmaceutics considers the expected drug not available within 14 days to be a drug shortage; Health Canada considers a drug shortage to be a situation where the supply of any drug along the supply chain fails to meet the patient’s needs in a timely manner.

The definition of drug shortage in Chinese academic circles is: because of various reasons, in a certain region, within a certain time range, the supply of drugs can not meet the clinical demand phenomenon, these drugs include unstable dosage, low price, enterprises do not often produce and regular supply shortage of drugs in the region.

2. The current situation of the supply of drugs in short supply in China

(1) Current distribution of drugs in short supply in China

Through the analysis of the national drug supply security comprehensive management information platform and CNKI and other databases in the past 5 years, we found that: (1) the inter-provincial and national drugs in short supply coexist. According to the data report of China Medical Statistics Network, the number of drugs in short supply in each province (city) in China in the past 5 years is between 60-90, however, 80% of the provinces (cities) are in short supply of only 1-3 kinds of drugs. (2) The shortage of basic drugs and low-priced drugs is more serious. According to the monitoring and early warning of the shortage of drugs in provinces (cities), although there is no centralized shortage of drugs in a certain treatment field, the shortage rate of basic drugs in all regions (cities) exceeds 30%, and most provinces have a high defect rate of low-priced drugs.

(2) The current situation of measures to ensure the supply of drugs in short supply in China

At present, the measures taken by the provinces (municipalities) to the shortage of drugs are mainly: (1) drug shortage information report. Most provinces have set up monitoring stations and provide the society with information on drug shortage on a monthly basis, and a few provinces (municipalities) have improved the monitoring stations, such as Jiangxi Province, which has added monitoring stations covering all public health institutions in the province, and Guangdong Province, which has formed a market-oriented pharmaceutical enterprise alliance. (2) The lack of inter-provincial measures for the management of medical and drug shortage reserves. According to the research results of some scholars, China has not yet established a shortage of drug inventory management system in many provinces, Gansu province is responsible for one province, Jiangsu province is responsible for three provinces; Shaanxi province has established a shortage drug reserve base for 11 pharmaceutical circulation enterprises, and Guangdong province has issued a list of required out-of-stock drugs and given the expected carrying capacity when selecting distribution enterprises. (3) The way to buy drugs in short supply. Most provinces are directly connected to the network procurement, and a small number of provinces have adopted another procurement model, such as Shanxi Province, “Essential drugs bidding” in the non-clinical urgent drug varieties for centralized procurement, encourage enterprises to

actively seek, adjust and reserve drugs; Jiangsu Province has adopted the inquiry mode, and a few provinces (municipalities) allow medical institutions to negotiate prices independently on the network. Some provinces according to their actual situation to formulate measures to ensure the supply of shortage of medicine: Gansu province to undertake designated pharmaceutical, direct-sales drug enterprises, which can be sold throughout the province, without the size of the sales enterprise, the number of conditions such as restrictions; Jiangsu Province has implemented a classified reserve of drugs in short supply, requiring each district city and grass-roots hospital to establish a corresponding list of drugs in short supply and prepare corresponding plans; The Fujian provincial government regularly publishes the list of defective drug procurement enterprises that fail to supply according to regulations, resulting in the lack of clinical drugs in hospitals; And Gansu province has set up an information sharing system on medical and drug shortages.

3. The mode of ensuring the supply of drugs in short supply abroad

The United States has issued and implemented the Guidelines on Drug Shortage Management Policies and Procedures, and launched a mechanism for dealing with drug shortages based on the mandatory reporting system. FDA has set up a special drug shortage working group to deal with problems related to drug shortage. Its drug shortage treatment process is mainly divided into three stages: first, shortage information reporting and collection. The second is the determination of drug shortage information. According to the market demand of drugs and the attributes of drugs, the expert group determines the authenticity, demand, substitution and clinical necessity of drug shortage. The third is the disposal, according to the research results, for all kinds of stock problems to formulate corresponding countermeasures.

Since 2012, the EU began to establish a shortage of drugs disposal mechanism, and for the first time, drug registration enterprises must report shortages into the Regulation, and the regulation is clearly stipulated as the European Medicines Agency's Committee on Drugs for use. There are two ways to report the shortage of drugs: one is for the centrally registered drugs, the manufacturer will report the shortage to the European Medicines Agency; The second is that for drugs that are not centrally registered, the out-of-stock situation needs to be reported to its national authority, and the NCA determines whether there is a shortage problem.

4. Our country shortage of drug supply security mechanism optimization strategy

The Notice on the National Shortage of Drugs List issued by the National Health and Health Commission clearly points out that the drug guarantee for specific groups should be strengthened, starting from the three links of production, circulation and use, to ensure that the common people have access to higher quality and cheaper drugs. According to the factors causing the drug shortage, relevant departments should build a set of drug supply guarantee mechanism based on emergency measures and long-term guarantee measures to ensure the safe and adequate supply of drugs.

(1) Establish measures to deal with drug shortage in emergency situations

When there is a shortage of drugs, the competent departments concerned may make use of the comprehensive management platform of drug supply guarantee to comprehensively integrate the information, get a timely and comprehensive understanding of the production and reserve situation of drug production and trading enterprises, and take the emergency degree, type of shortage, degree of harm and scope of drug shortage as the basis. Adopt emergency network procurement, consultation and adjustment between provinces, apply for temporary import from abroad, speed up the resumption of production and other ways to deal with the problem, so as to minimize the loss and harm caused by the drug shortage. If the drugs provided by more than one manufacturer are out of stock, the relevant departments can contact other manufacturers to coordinate the solution; If it is exclusively produced or operated, and it is a drug in urgent need of medical treatment, it can use financial subsidies, appropriate increase in drug prices and other policies to encourage enterprises to increase production.

(2) Establishing a unified national drug supply and security information system

The provincial health, development and Reform Commission, the Department of Finance and other relevant departments will take the lead to expand the scope of drug monitoring to the key links of production and circulation, and on this basis explore the establishment of a provincial drug supply security comprehensive management platform that integrates multi-source information collection and supply business collaborative application platform of drug shortage, drug shortage information release platform, drug shortage monitoring and early warning information system. In order to build and improve the information collection and summary analysis mechanism of drug shortage, drug shortage early warning mechanism, drug shortage list management system, department consultation linkage mechanism and real-time monitoring and early warning and hierarchical response system of drug shortage. Based on the provincial comprehensive management platform of drug supply security, a national comprehensive management platform of drug supply security is constructed to promote full coverage of information monitoring, so that the information related to drug shortage can be shared across the province and the country, thus providing accurate information support for the emergency treatment and security of drug shortage, and facilitating the classification and accurate implementation of drugs in shortage.

(3) Implementation of low-cost drug supply and assurance

For the shortage of drugs caused by clinical necessity, small dosage or low transaction price, lack of production power of enterprises, etc., fixed-point production can be implemented and scientifically screened, and the fixed-point production enterprises can be decided by bidding; Low-cost drugs can be centralized procurement and fixed-point procurement to ensure a long-term, safe and stable supply of such drugs. It is necessary to give full play to the regulatory role of the state to solve the problem of insufficient supply of drugs caused by the bad behavior of drug production and distribution enterprises and the "death of winning bids" caused by the low cost of drugs.

(4) Deepen medical reform

Do a good job of docking between the National Essential Drugs List, the provincial Supplementary essential drugs list and the Basic Medical Insurance Drug List. For drugs that have not been listed in the essential drugs list but may be out of stock, the provincial health and health commission or the medical insurance Bureau and other relevant departments should organize experts to evaluate them. When there is a shortage, they should be based on the shortage situation. To determine their priority drug locations across the country to ensure their effective supply nationwide. Accelerate the reform of the Medicare payment model. From the root, the optimal allocation of medical insurance funds should be carried out. At the same time, the supervision of medical services should be strengthened, and excessive services should be strictly controlled, so as to directly promote the consciousness of doctors to choose high-quality and low-cost drugs and form an incentive mechanism.

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1. Research on drug supply guarantee mechanism in the context of Healthy China; Huai 'an City Social Science Research Public Health service special topic -2022WSB10

2. Research and Practice of Modern Apprenticeship Talent Training Mode under the background of 1+X Certificate -- Taking Chinese Pharmacy major as an example, the 5th Jiangsu Province Vocational Education Teaching Reform Research topic, ZYB573