



Regulation and supervision methods of online drug transactions in China

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ABSTRACT

In order to improve the regulation and supervision performance of online drug transactions in China, we propose some methods for enhancing the regulation and supervision in this work. For the development of the online drug transaction, we analyze the situation in China, as well as comparing with the regulation and supervision modes between China and foreign countries. The online drug transactions market in China is developing rapidly, meanwhile the illegal problems are getting serious. Inspired by the experience from foreign countries, we should speed up to formulate legislations for online drug transactions. Electronic supervision technology should be utilized to ensure drug quality. The industry association and the consumer in the role of social supervision is also very important.

Keywords: Regulation and supervision, online drug transactions, information technology

INTRODUCTION

China began to explore online drugs transactions since 1998. At the end of 2005, the State Food and Drug Administration issued the first regulatory document to promote and regulate drugs online transactions, which was "internet-based pharmaceutical information services tentative provisions". In December 29, 2005, Beijing JingWeiYuanHua Pharmaceutical Co., Ltd. got the first "Internet drugs transaction service qualification certificate" by the Beijing Food and Drug Administration Audit and site acceptance [1]. Drugs online transactions have the characteristics of convenient, affordable, rich information, privacy protection. While bringing convenience to people, there are a lot of false drug information and sales of counterfeit and inferior drugs behavior in internet, also let the work of supervision and management of drug online transactions into a national problem. This paper analysis the current online drugs transactions situation and existing problems and through the comparison with foreign supervisory management mode, I puts forward some suggestions to strengthen the supervision and regulation of online drug transactions.

ANALYSIS OF CURRENT SITUATION

Unlimited potential: In recent years, the online drugs transactions market in China is developing rapidly. The improving online shopping environment, the increasing consumer confidence, and the perfecting payment, logistics, authentication and other conditions which is closely related to online shopping, all provide a good opportunity for online drugs transactions. From the number of approval enterprises viewpoint, by October 20, 2013, there are 4527 enterprises who have access to Internet drug information service qualification, of those the profit enterprise occupied 655 and the rest 3872 are non-profit enterprises in China State Food and drug administration official public information database. The non-profit enterprises mainly are pharmaceutical production and operation enterprises and medical device companies who display products, promote brand, expand influence and provide public sharing medical information through the network; while the profit enterprises are mainly neutral third party medical information Service Corporation, they provide unshared drugs information which was processed from the pharmaceutical enterprise and consumer demand information, There are 182 enterprises to obtain the Internet drugs

transaction service qualification, which is associated by 8 independent third party drug trading service enterprises, 52 enterprises through its own website to trade with others and 122 enterprises providing trading services enterprises to individual consumers. There are 56 pharmaceutical retail chain enterprises approved at first 10 months of 2013 (including the part of the reapplied enterprises), the year-on-year growth by 350% comparing with 16 applied enterprises in 2012 [2]. From the trading volume viewpoint, China's online pharmacy council statistics show that China's medicine retail B2C scale is 1.665 billion for the whole 2012, while this figure is 400 million in 2011. The online drugs transactions in China maintain more than 300% growth, which is expected to reach 15 billion in 2015. Although it occupies in the medicine retail market share is still very low, but the online drugs transactions market potential cannot be underestimated.

False drug information on the internet: The Internet is virtual, concealment, anonymous, difficult to locate the subject, low illegal cost and hard to fight and regulate characteristics, which provides the opportunity for criminals, thus the online publication of false drug information and sales of counterfeit and inferior drugs phenomenon emerge in endlessly and run rampant. The criminals build illegal websites or use public blog service platform, in the name of "scientific research institutions" "rehabilitation center" "army hospital" and "experts and scholars", using absolute commitment languages and the psychology of consumers lack of pharmaceutical knowledge and seek whatever treatment they can get, who sale some illegal drugs online claim to treat incurable diseases and chronic disease specific, which bring serious harm to people's life and property security. At the same time, there are irregularities in some legal websites who have qualifications but lack of self-discipline consciousness. such as the websites bring online drugs transactions together but only for a drug information service qualification; and the websites with drugs online trading qualification but sale the prescription drugs illegally, etc. Because of the lax management and profit driven, some comprehensive portal website, e-commerce platform and search engine provide links to the publication of false drugs information and sales of counterfeit and inferior drugs websites, which have played an important role [3]. Due to the large user visits and fast spread, they bring great threat to safety of consumers.

Supervision and management modes of other countries

Laws and regulations: The United States was among the first to carry out online drugs transactions nation, and FDA take on the online drugs transactions principle is to protect consumers' rights and interests and not limited to electronic business too much. The federal government amended the "Controlled Substances Act" and promulgated "2008 Ryan Haight Online Pharmacy Consumer Protection Act", which added the contents of the illegal sales of prescription drugs on "The federal food, drug and Cosmetic Act". Each state also formulated relevant regulations on online drug transactions, such as New York drew up the "Online Pharmacy Consumer Protection Act", while the online pharmacy without permission to sell drugs to anyone in Florida would punish at two felony according to the state law. At the same time, the state federal protected consumers online drug transactions process safe, effective and privacy by "The Health Insurance Portability and Accountability Act, HIPAA". The British government allowed registered pharmaceutical trading enterprises to open online pharmacies and sell prescription drugs and related products. The British drug online trading regulations mainly include: "The Medicines Act" regulated the drug sales, supply and advertising; "The Pharmacist Law Act" specifically used to guide and standardize the pharmacist service; The Royal Pharmaceutical Society of Great Britain issued "Professional Standards and Guidance for Internet Pharmacy Services" specifically for online pharmacy service management, and made the rules at eight aspects of website requirement, security and privacy protection, patient selection, drug supply, information and advice, mailing and delivery drugs, foreign prescriptions, records and other provisions.

Role of industry association: Industry associations play a great role in the supervision and management of foreign online drug transactions, such as the National Association of Boards of Pharmacy (NABP) started an voluntary program in 1999 called The Verified Internet Pharmacy Practice Sites (VIPPS). An online pharmacy is permitted to display the VIPPS Seal on the VIPPS Web site only if it meet a series of strict standards (Licensure, DEA registration, Prior discipline, Location, Validity of prescription, Legal compliance, Privacy, Patient services, Web site transparency, Domain name registration and Affiliated Web sites). By clicking on the VIPPS Seal links the user can verify the granted information about the pharmacy on NABP website, there are 35 online pharmacies earn VIPPS accreditation and all can sell prescription drugs on the Internet. NABP audited the accredited online pharmacies annually and renewal of accreditation every three years. NABP recommends consumers to buy drugs at VIPPS accredited online pharmacies and NABP also recognizes that some non-accredited Internet pharmacies may be operating legitimately. Of those entities that approve non-accredited Internet pharmacies, LegitScript.com is the only one that adheres to NABP-recognized standards. There are 215 websites at present, the public can query to verify the legality of Internet pharmacies in LegitScript.com and provide a suspect website report way. To help consumers identify legitimate online pharmacies, Royal Pharmaceutical Society of Great Britain (RPSGB) implemented Internet Pharmacy Logo plan from 12, 2007. Now the newly established (in 2010) General Pharmaceutical Council

(GPhC) is responsible for the plan, the UK registered pharmacies have the duty to add symbol of the link in homepage, by clicking which will can query the registration information of online Pharmacy and pharmacist at the GPhC site.

Application of advanced technology: Facing with the complex online drugs trading environment, the foreign countries have took advanced technology to ensure the transaction security. The United States of America applied the RFID (Radio Frequency Identification) technology for the warehouse control in prescription and over-the-counter products and tracking, recording, shipping and receiving of products and product identification from 2004, RFID technology uses only global unified code to ensure drug safety and drug supply integrity, which forms the electronic records of products from production to sales. In order to prevent the third party to steal the buyer information and better protect consumer privacy, most the Britain online pharmacies have used the SSL (Secure Sockets Layer) encryption technology on the bank card account information.

Methods on the online drug transactions regulation and supervision in china

Communication and coordination mechanism between departments: The China State Food and Drug Administration in charge of national supervision of online drug transactions, is responsible for the formulation of laws and regulations to regulate the online drug transactions, carry out special actions, collaborate with other ministries strike false drugs information and sales of counterfeit and inferior drugs on the Internet, and contact the propaganda department to expose the typical cases, warning consumers identify legitimate network drug information. Provincial and municipal food and drug administration is responsible for regulation of online drug information release and trading within the jurisdiction are in the scope of authority duty, and establish bridging communication mechanism with State Food and Drug Administration. In order to strengthen communication and coordination between departments and establish long-term effective mechanism for supervision and management of online drug transactions, the State Food and Drug Administration had established online drug trafficking cases disposal process and communication and coordination mechanism with the Ministry of public security, the State Administration for Industry and commerce, the Ministry of industry and information technology, postal and other departments on the basis of "Internet Websites management coordination scheme", which embodied in to the agency responsible for the drug trading site pre-approval and trading supervision, the industrial and commercial departments are responsible for the drug trade service enterprise registration and illegal advertising investigation, the Ministry of information industry shall be closed down the illegal websites, the postal department ensure the safety of drug circulation channel and the public security department shall be investigated for criminal responsibility according to the law on criminal behavior.

Specific legislation: We only have several regulatory documents to regulate online drug transactions at present, the main content of whom are the provisions of the main body qualifications and the administrative examination and approval procedures. But there are less provisions about the main obligations and legal responsibility right in online drug transactions activities, and the legal effect is low, part of them are not practical, the penalties for illegal behavior is not enough, not the intensity of the punishment of illegal behavior, resulting in the lack of a powerful law enforcement basis. It is necessary to improve the legal environment for online drug transactions in China. We see the abroad who not only complement the existing laws but also formulate special laws and regulations for online drug transactions, such as the United States' "Online Pharmacy Consumer Protection Act", thus they have regulation to follow. While industry associations also formulate strict accreditation standards, service standards to regulate online drug transactions cooperatively. We should perfect the "Drug Administration Law" to add penalties for violations and deepen the new "Good Supply Practice" accreditation work to meet the needs of the development of online drug circulation. Facing with the severe online drug trading environment, it is reported that the China Food and Drug Administration working with relevant departments is studying to revise "Internet drug sales management approach" and formulate online drug transactions standards. It will set online drug selling management standard and applicable scope in accordance with the consistency of virtual and reality principle.

Cooperation with search engine: Drug is a special commodity, consumers need to go through professional doctor diagnosis and use under the guidance of professionals. In order to have access to safe medical information and products for consumers through the Internet and enhance consumer self-protection and safety consciousness, the State Food and Drug Administration launched the "online purchasing medicine safety warning column" from 2008, in order to intensify consumer propaganda and education, popularize online purchasing medicine precautions, illegal website features and report way. The investigate of false drugs information and sales of counterfeit and inferior drugs website were exposed, and released "Internet purchasing medicine safety warning announcement", which has published 22 period. Facing with the situation difficult to effectively monitor search engines, the State Food and Drug Administration and the Baidu Inc carried out strategic cooperation called "safe medication, search escort" in 2013 February, the former will provide approved drugs and the authority of the approved online pharmacies with

formal qualification data to Baidu, while showing the drug data information, online pharmacies information and drug safety top-prompt information in the search results to provide services for Internet users.

Electronic supervision technology: Online drug transactions have broken the traditional transaction mode, consumers can not come into contact with the actual goods, therefore it is unable to guarantee drug quality. China began to implement the drug electronic supervision work since 2006. To the end of 2, 2012, China has put narcotic drugs, psychotropic drugs, blood products, traditional Chinese medicine injections, vaccine and essential drugs into electronic supervision system by three period, whose goal is to realize the electronic supervision on all drugs and whole process by the end of all 2015. The application of electronic supervision technology can ensure the drugs security in the production, circulation, use in all aspects, combat counterfeit drugs behavior effectively, trace and recall the problem drugs quickly, maximize to protect the legitimate interests of the enterprises and ensure drug safety for the people. Therefore, online trading drugs should be included in the electronic supervision system in China to protect consumers to purchase safe and effective drugs. In 2011, the State Food and Drug Administration launched the Internet drug market monitoring and public service key technology research and development and application demonstration projects pilot work, which covers the scope of medicines, medical equipments, health food, cosmetics ,related production and operation enterprises, internet-based information and transaction services enterprises, medical institutions and individual consumers. By the combination of regulations, standard specification and technical means, the internet-based trusted information and transaction services environment will be established to regulate and monitor the whole approval, information and activities of online drug market.

Social supervision method: Industry associations and organizations play an important role in the supervision and management of online pharmacies in foreign countries, they carry out strictly online pharmacy accreditation plan and professional standards and guidance service work to regulate the drug online transactions behavior and guarantee drug use safety. China has established the Chinese online pharmacy Council and released "Online Pharmacies honesty and self-discipline convention". But the main duty of Chinese online pharmacy Council is a national learning and research organization composed by online pharmacy, chain drugstores, related cooperative enterprises and research and consulting institutions. And the enterprise quantities are not many, the role of the council and the influence of the convention is limited. Drawing lessons from foreign experience, the Chinese Licensed Pharmacists Association should play role of supervision and management in online drug transactions, through similar industry certification program to achieve the dual supervision of online drugs transactions behavior. With consumers awareness of their own rights promotion, they will become an important social forces in the supervision and management of online drug transactions. The government and enterprises should strengthen the legal education for consumers, popularize online purchasing medicine safety knowledge, guide consumer purchase and use drugs safety and reasonably , while providing various forms of report way and complaint platform, establishing the efficient disposal of report and complaints workflow, to promote the healthy development of drugs online trading market through power of whole society.

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