

# The Status and Prospects of the Licensed Pharmacist Qualification System in China

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## Abstract

The Licensed Pharmacist Qualification System refers to a series of systems of Licensed Pharmacist management. The establishment and development of the Licensed Pharmacist Qualification System plays an unparalleled role in the improvement of pharmaceutical care and the training of pharmaceutical professionals. This article generally describes the Licensed Pharmacist Qualification System in China, makes a comparison study between Chinese and American Licensed Pharmacist Qualification System and discusses about the future development of the Licensed Pharmacist Qualification System.

**Key words:** licensed qualification; licensed pharmacist; pharmaceutical care

## 1. General introduction on the Licensed Pharmacist Qualification System in China

Licensed qualification, the measure of access control implemented by the government in specific fields of great responsibility, social commonality or public interest, is the essential standard of knowledge, techniques and skills for setting up independent business or working in an independent way. Licensed Pharmacist Qualification System is universally implemented for the access of pharmaceutical professionals in different countries around the world. The Great Britain adopted the system in 1815 and various states in USA began to issue *Pharmacy Act* and *Pharmaceutical Affairs Act* successively since 1869, formulating that only those registered pharmacists who pass the Standardized National Examination for Licensed Pharmacist could work in related posts.

### 1.1 The Development of the Licensed Pharmacist Qualification System in China

*Drug Administration Law of the People's Republic of China* issued in 1984 stipulates that a drug manufacturer or distributor shall have qualified pharmaceutical professionals required for drug manufacturing or distributing. *Provisional Regulations on Licensed Pharmacist Qualification System* promulgated in 1994 and *Provisional Regulations on Licensed Pharmacist of Chinese Medicine Qualification System* promulgated in 1995 symbolized that the Licensed Pharmacist Qualification System started to be carried out in an all-round way. A series of supporting regulations and regulatory documents on examination, registration and continuing education were published thereafter. *Provisional Regulations on Licensed Pharmacist Qualification System* was revised in 1999 and the national unified syllabus, examination, registration and management were enforced accordingly.

### 1.2 The Management of Licensed Pharmacist Qualification System in China

Ministry of Human Resources and Social Security is responsible for the coordination and management of the National Professional Qualification System. State Food and Drug Administration is responsible for the implementation of Licensed Pharmacist Qualification System and the formulation of relevant policies. Licensed Pharmacist Qualification Center affiliated to State Food and Drug Administration is responsible for the organization of the Licensed Pharmacist Examination and the coordination of the implementation of the pharmacist registration management, continuing education and other related work. Policy formulation, the examination proposition, the continuing education and other professional work are carried out with technical supports from the experts and professors from Medical Colleges and the senior management team from institutions of drug research, manufacturing, distributing and using. The drug regulatory departments of provinces, autonomous regions and municipalities directly under the central government are

responsible for the registration management and continuing education of licensed pharmacists in their areas. In addition, Association of Chinese Licensed Pharmacist, which was founded in 2003, plays an important role in the development of professional norms and ethics as well as the trainings on continuing education and rational drug use.

### **1.3 The Implementation of the Licensed Pharmacist Qualification System in China**

#### **1.3.1 the Qualification Examination**

In China, licensed pharmacists refer to those pharmaceutical professionals who pass the unified national examination, obtain the Licensed Pharmacist Certificate, get registered in the local government and work in the institutions of drug manufacturing, distributing and using. The unified national examination of Licensed Pharmacist is held in October every year. Those who pass the examination could obtain the Licensed Pharmacist Certificate.

There are seven subjects in the qualification examination: 1. Pharmacy administration and regulations; 2. Pharmacy knowledge (1); 3. Pharmacy knowledge (2); 4. Comprehensive knowledge and skills • Pharmacy; 5. Pharmacy knowledge of Chinese Medicine (1); 6. Pharmacy knowledge of Chinese Medicine (2); 7. Comprehensive knowledge and skills • Pharmacy of Chinese Medicine. Applicants of Pharmacist should choose subject one, two, three and four while applicants of Pharmacists of Chinese Medicine should choose subject one, five, six and seven. All examinations of the seven subjects are composed of objective questions which should be completed in the answer sheet. The examinations are arranged in for 4 separate half days, each lasting for two and a half hours.

#### **1.3.2 Registration and Continuing Education**

After obtaining the Qualification Certificate, licensed pharmacists could apply for the registration in the drug regulatory department of province, autonomous regions or municipalities directly under the Central Government. They are allowed to work in drug related fields according to their registered category, scope and area after they obtain the Registered Pharmacist Certificate. A licensed pharmacist could register in only one department and work for only one organization. The registration of licensed pharmacist is valid for 3 years. The re-registration is required upon expiration of the certificate. Applicants for re-registration should meet specific requirements and provide evidence of continuing education. Licensed pharmacist should receive continuing education and abide by registration regulations.

#### **1.3.3 Roles**

Licensed Pharmacists should be responsible for the quality of drugs and ensure the basic principle of safe and effective drug use. In practice, licensed pharmacists should abide by *Drug Administration Law* and relevant regulations, be responsible for the supervision and management of drug quality, audit and monitor the prescription deployment, provide medical advice and information, guide rational drug use and conduct clinical works such as the monitoring of therapeutic drugs and the evaluation of the drug efficacy.

### **1.4 The Status of Licensed Pharmacists in China**

According to statistics, China has 174,000 licensed pharmacists by the end of 2009 and around 70,000 of them are registered. As to the distribution of registered licensed pharmacists, about 86% work for drug distributors, about 7%, work for drug manufacturers and the other 7% work in medical institutions. In terms of geographical distribution, there are great divergences between eastern China and western China because of the unbalance economic development levels in these regions. Most registered licensed pharmacists are employed in the eastern and middle parts of China while much less work in the western regions.

## **2. The Mmain Differences between Chinese and American License Pharmacist Qualification system**

Because of the great differences in social and economic development between China and the United States, the License Pharmacist Qualification systems in these two countries are undergoing different phrases.

## **2.1 Qualifications**

China, as a developing country, has insufficient licensed pharmacists, which means that the scale of pharmaceutical professionals can not fully meet the demands of the society. Therefore, the gaps in terms of qualifications for licensed pharmacists between China and the United States still exist. In China, whoever has a diploma higher than secondary specialized education and major in pharmacy or related disciplines (medicine, chemistry, biology, and nursing) can apply for the Qualification Examination. However, there are requirements of working experiences according to the level of academic qualifications. Currently, people with secondary, tertiary, Bachelors' or Master's degree, could apply for the examination after working for seven, five, three or one year respectively. There is no requirement of working experience for candidates with the Doctors' degree.

## **2.2 Routine Management**

The Licensed Pharmacist Qualification System formulates that holders of Licensed Pharmacist Certificate could not apply for the position of licensed pharmacists before registration. Registered Licensed Pharmacists could work in drug manufacturers, distributors and medical institutions. The registration of licensed pharmacists should include the information of the institutions as well as the position. Working for two different employers is forbidden. Licensed Pharmacists should apply for registration change if they want to work in a different area or different field.

## **2.3 Continuing education**

State Food and Drug Administration is responsible for the management of continuing education of licensed pharmacist in the country and the drug regulatory departments of provinces, autonomous regions and municipalities directly under the Central Government are responsible for specific works. In general, the provincial drug regulatory departments hold the training courses of continuing education with the support of accredited Medicine Collages. Continuing education adopts the credit system and mainly focuses on laws and regulations, ethics, Pharmacy, Chinese Medicine and related professional knowledge and skills. All courses are conducted mainly by lectures and divided into three types, compulsory, elective and self-study. Employers of licensed pharmacists should provide them with financial support, time and other necessary conditions for continuing education.

## **2.4 Responsibilities**

In China, licensed pharmacists play an important role in ensuring quality, safety and efficacy of drugs. After the implementation of Drug Classification System in China, licensed pharmacists make great contributions to guiding the rational use of drugs for patients, reviewing prescriptions and providing consulting services of medication. However, the licensed pharmacist is the pre-condition only for opening the business of one drug distributor. Most of Chinese licensed pharmacists work in drug manufacturers and distributors. In China's medical insurance system, 80% of the drug consumption is closely integrated with medical services of medical institutions. Medication of patients is mainly carried out by doctors. Besides, there are two types of qualification systems in China, namely the professional qualification system and the specialized qualification system. Therefore, the vast majority of pharmacists in medical institutions (medicine persons) have the specialized qualification of Pharmacy instead of the licensed pharmacist qualification. For example, in the end of 2009, there are 342,000 pharmacists (medicine persons) in Chinese medical and health institutions, among which only 47,000 are licensed pharmacist.

## **3 The Prospect of Licensed Pharmacist Qualification System in China**

Licensed pharmacists symbolize a vital and irreplaceable pharmaceutical strength in ensuring the quality of drugs and pharmaceutical care, the safety and efficacy of medication as well as the public health. As China's economy develops continuously, the living standards of people upgrade accordingly. Therefore, the public set up higher standards for medical services and health care and licensed pharmacists will play a more important role and rank a higher social position. There are three critical aspects for the future development of licensed pharmacist qualification system in China. Firstly, with a view to the rising demand

of licensed pharmacists, there will be more licensed pharmacist and the licensed pharmacist qualification system will be legally established. Secondly, as the reform of China's government management system develops gradually, the licensed pharmacist qualification system should be implemented in medical institutions. Thirdly, as the public set higher requirements for health care, there will be a shift of attention from drug quality and safety to the quality of pharmaceutical care, and gradually to the requirements of licensed pharmacist. These demands and changes will evoke a reform of Medical schools. Cooperation and support from all walks of the society will be needed for the cultivation and training of pharmaceutical professional as well as continuing education of licensed pharmacists so as to finally improve the level of rational use of drugs and facilitate the development of human health.

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