

Regulations on Protection of Traditional Chinese Medicines

(Promulgated by Decree No. 106 of the State Council of the People's Republic of China on October 14, 1992, and effective as of January 1, 1993)

Chapter I General Provisions

Article 1 These Regulations are formulated for the purposes of improving the quality of types of traditional Chinese medicine, protecting the legitimate rights and interests of traditional Chinese medicine producing enterprises, and promoting the development of traditional Chinese medicine.

Article 2 These Regulations apply to types of traditional Chinese medicine produced and manufactured within the territory of China, including prepared traditional Chinese medicines, extracts and preparations from natural medicinal materials, as well as artificial traditional Chinese medicines.

Those types of traditional Chinese medicine for which patents are applied for shall be dealt with under the provisions of the Patent Law, and not under these Regulations.

Article 3 The State encourages research and development of types of traditional Chinese medicine with clinical effects, and practices a classification protection system for types of traditional Chinese medicine with reliable quality and certain curative effects.

Article 4 The administrative department of public health under the State Council shall be responsible for the supervision and control of the protection of types of traditional Chinese medicine throughout the country. The State competent authority for the production and trading of traditional Chinese medicine shall assist the administrative department with the control of the protection of types of traditional Chinese medicine throughout the country.

Chapter II Classification and Approval for the Protection of Types of Traditional Chinese Medicine

Article 5 Types of traditional Chinese medicine under the protection of these Regulations must be those listed in the national pharmaceutical standards. Upon the determination of the administrative department of public health under the State Council, protection of types of traditional Chinese medicine listed in the pharmaceutical standards of provinces, autonomous regions and municipalities directly under the Central Government may be applied for.

The protection of types of traditional Chinese medicine shall consist of first class protection and second class protection.

Article 6 For types of traditional Chinese medicine which conform to any of the following conditions, first class protection may be applied for.

- (1) having special curative effects for a certain disease;

(2) artificial medicines prepared from varieties of wild medicinal materials analogously under first class protection; or

(3) used for the prevention and cure of special diseases.

Article 7 For types of traditional Chinese medicine which conform to any of the following conditions, second class protection may be applied for.

(1) conforming to the provisions of Article 6 in these Regulations, or having once been listed under first class protection but now being cancelled;

(2) having outstanding curative effects for a certain disease; or

(3) effective substances and special preparations extracted from natural medicinal materials.

Article 8 New medicines approved by the administrative department of public health under the State Council shall be protected within a period of protection as described by the administrative department. For those of them which conform to the provisions of Article 6 or 7 in these Regulations, an application for the renewal of the protection may, six months before the expiration date of protection approved by the administrative department of public health under the State Council, be offered according to the provisions of these Regulations.

Article 9 Procedures for handling applications for the protection of types of traditional Chinese medicine are as follows:

(1) Any traditional Chinese medicine producing enterprise may, if it thinks that the type of traditional Chinese medicine it produces conforms to the provisions of Article 5, 6, 7 or 8 in these Regulations, apply for protection with the local competent authority for the production and trading of traditional Chinese medicine in the province, autonomous region or municipality directly under the Central Government. The local competent authority for the production and trading of traditional Chinese medicine shall write down its comments on the application, then transmit it to the administrative department of public health at the same level, which shall make a preliminary examination and write down its comments and submit the application, with comments, to the administrative department of public health under the State Council. Under special circumstances, a traditional Chinese medicine producing enterprise may directly apply to the State competent authority for the production and trading of traditional Chinese medicine which shall write down comments on the application and transmit it to the administrative department of public health under the State Council, or may directly apply to the administrative department of public health under the State Council.

(2) The State examination and evaluation committee for the protection of types of traditional Chinese medicine shall, under the authorization of the administrative department of public health under the State Council, be responsible for the examination and evaluation of the types of traditional Chinese medicine for which the protection is applied for. The committee shall provide an examination and evaluation conclusion within six months as of the date of receiving an application.

(3) Based on the conclusion of the State examination and evaluation committee for the protection of types of traditional Chinese medicine, the administrative department of public health under the State Council shall, in consultation with the State competent authority for the production and trading of traditional Chinese medicine, decide whether or not to grant the protection thereto. For the types of traditional Chinese medicine of which the protection has been approved, the administrative department of public health under the State Council shall issue a Certificate of Protection of Types of Traditional Chinese Medicine.

The administrative department of public health under the State Council shall be responsible for the formation of the State examination and evaluation committee for the protection of types of traditional Chinese medicine, members of which shall, in consultation with the State competent authority for the production and trading of traditional Chinese medicine, be appointed from experts in the field of medical service, scientific research, inspection, as well as trading and management of traditional Chinese medicine.

Article 10 Any enterprise applying for protection of types of traditional Chinese medicine shall provide the State examination and evaluation committee for the protection of types of traditional Chinese medicine with complete sets of materials as required by the administrative department of public health under the State Council.

Article 11 The administrative department of public health under the State Council shall make announcements in the designated professional newspapers and periodicals regarding the types of traditional Chinese medicine to which protection has been granted or those for which the period of protection has expired.

Chapter III Protection of Protected Types of Traditional Chinese Medicine

Article 12 The period of protection for types of traditional Chinese medicine is as follows:

The period of first class protection is thirty years, twenty years and ten years respectively.

The period of second class protection is seven years.

Article 13 Within the period of protection, the prescriptions and pharmaceutical techniques of types of traditional Chinese medicine under first class protection shall be kept secret and shall not be published by the producing enterprises having been granted the Certificate of Protection of Types of Traditional Chinese Medicine, the competent authorities for the production and trading of traditional Chinese medicine, the administrative departments of public health, and other units or individuals concerned.

Departments, enterprises and units concerned which have the duty to keep secrets shall set up necessary security systems as required by the State.

Article 14 Transfer to any foreign country of prescriptions and pharmaceutical techniques of types of traditional Chinese medicine under first class protection shall be dealt with according to the relevant State provisions of security.

Article 15 Where, due to special circumstances, it is necessary to extend the period of protection of a type of traditional Chinese medicine under first class protection, the producing enterprise shall, six months before the expiration date of protection, submit an application for extension according to the procedures described in the Article 9 of these Regulations. The extended period of protection shall be decided by the State examination and evaluation for the protection of types of traditional Chinese medicine, however, an extension approved each time shall not exceed the period of protection granted for the first time.

Article 16 The period of protection of types of traditional Chinese medicine under second protection may be extended for seven years upon expiration.

If it is necessary to extend the period of protection of a type of traditional Chinese medicine under second class protection, the producing enterprise shall, six months before the expiration date of protection, submit an application for extension according to the procedures described in the Article 9 of these Regulations.

Article 17 The production of protected types of traditional Chinese medicine within the period of protection shall be restricted to enterprises which have been granted the Certificate of Protection of Types of Traditional Chinese Medicine, unless otherwise provided for in Article 19 of these Regulations.

Article 18 Where more than one enterprises produce a type of traditional Chinese medicine under protection before the protection is granted by the administrative department of public health under the State Council, those enterprises who have not applied for the Certificate of Protection of Types of Traditional Chinese Medicine shall, within six months as of the date of announcement, report the case to the administrative department of public health under the State Council and provide relevant materials according to the provisions of Article 10 of these Regulations. The administrative department of public health under the State Council shall designate a pharmaceutical inspection institution to inspect the quality of the reported type of medicine as has been done with the type under protection. Based on the inspection, the administrative department of public health under the State Council may take the following measures:

(1) If it is up to the national pharmaceutical standards, the Certificate of Protection of Types of Traditional Chinese Medicine shall be issued through consultation with the State competent authority for the production and trading of traditional Chinese medicine.

(2) If it is below the national pharmaceutical standards, the registered document of approval of this type of traditional Chinese medicine shall be revoked according to the laws and regulations governing pharmaceutical administration.

Article 19 For protected types of traditional Chinese medicine in short supply for clinical needs, the administrative departments of public health in provinces, autonomous regions and municipalities directly under the Central Government shall, as proposed by the State competent authority for the production and trading of traditional Chinese medicine, and with the approval of the administrative department of public health under the State Council, issue registered documents of approval to the enterprises which produce in their localities the same types of traditional Chinese medicine as the protected types for imitation. The imitation

enterprises shall pay reasonable use fees to the enterprises who hold the Certificate of Protection of Types of Traditional Chinese Medicine and transfer the prescriptions and pharmaceutical techniques of the protected types. The amounts of the use fees shall be decided by the two sides through consultation. If the two sides fail to reach an agreement, the administrative department of public health under the State Council shall make a ruling.

Article 20 Enterprises producing protected types of traditional Chinese medicine and the competent authorities for the production and trading of traditional Chinese medicine shall improve conditions of production and the qualities of the protected types as required by the administrative departments of public health in provinces, autonomous regions and municipalities directly under the Central Government.

Article 21 Registration of protected types of traditional Chinese medicine within the period of protection in any foreign country shall be subject to the approval of the administrative department of public health under the State Council.

Chapter IV Penalties

Article 22 If anyone divulges secrets in violation of the provisions of Article 13 of these Regulations, the unit to which he belongs or the higher authority shall impose upon him disciplinary sanctions. If a crime has been constituted, criminal liability shall be investigated according to laws.

Article 23 If anyone, in violation of the provisions of Article 17 of these Regulations, imitates a protected type of traditional Chinese medicine without approval, the administrative departments of public health at or above the county level shall punish him as a producer of fake medicines.

If anyone fabricates the Certificate of Protection of Types of Traditional Chinese Medicine and relevant certification documents to produce and sell medicines, the administrative departments of public health at or above the county level shall confiscate all medicines involved and illegal gains, and may concurrently fine him not more than three times the prices of the standard equivalents of medicines involved.

If the aforesaid acts have constituted crimes, the judicial organs shall investigate for criminal liabilities.

Article 24 A party who refuses to accept the decision of punishment made by the administrative departments of public health may apply for administrative reconsideration or institute administrative proceedings according to the relevant provisions of laws and administrative regulations.

Chapter V Supplementary Provisions

Article 25 Requirements and application forms for the protection of types of traditional Chinese medicine shall be decided by the administrative department of public health under the State Council.

Article 26 The administrative department of public health under the State Council shall be responsible for the interpretation of these Regulations.

Article 27 These Regulations shall come into effect on January 1, 1993.