

Order of the State Council of the People's Republic of China (No. 374)

The Regulation of the People's Republic of China on Traditional Chinese Medicines, which was adopted at the 3rd executive meeting of the State Council on April 2, 2003, is hereby promulgated, and shall come into force on October 1, 2003.

Wen Jiabao, Premier

April 7, 2003

**Regulation of the People's Republic of China on Traditional Chinese Medicines**

Chapter I General Provisions

Article 1 The present regulation is enacted with a view to inheriting and developing the traditional Chinese pharmacology, guaranteeing and promoting the development of the undertaking of traditional Chinese medicines, and protecting the health of human bodies.

Article 2 The entities or individuals engaging in the services of traditional Chinese medical treatment, prevention, care and recovery, the education, scientific research and foreign exchanges on traditional Chinese medicines, and in the administrative activities of the undertaking of traditional Chinese medicines inside the territory of the People's Republic of China, shall abide by the present regulation.

The research and development, production, operation, use, supervision and administration of traditional Chinese medicines shall be in compliance with the Pharmaceutical Administration Law of the People's Republic of China.

Article 3 The state protects, supports and develops the undertaking of traditional Chinese medicines, implements the guideline of stressing both traditional Chinese medicine and Western medicine, encourages the mutual study and supplements as well as the common improvement of traditional Chinese medicine and Western medicine, urges the organic combination of traditional Chinese medical science and Western medical science, and completely develops China's undertaking of traditional Chinese medicines.

Article 4 For the development of the undertaking of traditional Chinese medicines, we shall comply with the principle of combining succession with innovations, maintain and carry forward the characteristics and advantages of traditional Chinese medicines, actively make use of modern science and technology, promote the development of the theories and practices of traditional Chinese medicines, and enhance the modernization of traditional Chinese medicines.

Article 5 The people's governments at or above the county level shall include the undertaking of traditional Chinese medicines into the plans of national economic and social development, and harmonize the development of the undertaking of traditional Chinese medicines with the economy and society.

The local people's government at or above the county level shall, when making the regional sanitation planning, arrange the overall establishment and distribution of medical institutions of traditional Chinese medicines as well as improve the network of urban and rural services of traditional Chinese medicines in light of the situation of social and economic development in this region and the residents' needs in medical treatment.

Article 6 The administrative department for traditional Chinese medicines under the State Council shall be responsible for the administration of traditional Chinese medicines nationwide. The relevant departments under the State Council shall, within the scope of their respective duties, be responsible for the work related to traditional Chinese medicines.

The department for traditional Chinese medicines under the local people's government at or above the county level shall be responsible for the administration of traditional Chinese medicines within its own administrative division. The relevant departments under the local people's government at or above the county level shall, within the scope of their respective duties, be responsible for the work related to traditional Chinese medicines.

Article 7 The people's governments at or above the county level shall grant awards to the entities and individuals who have made remarkable contributions to the succession and development of the undertaking of traditional Chinese medicines or have made prominent achievements in their work of traditional Chinese medicines in remote regions.

## Chapter II Medical Institutions and Practitioners of Traditional Chinese Medicines

Article 8 Whoever intends to open a medical institution of traditional Chinese medicines shall meet the standards for setting up medical institutions of traditional Chinese medicines and the local regional sanitation planning, which are made by the administrative department of health under the State Council, and shall go through the formalities for approval in accordance with the Regulation on the Administration of Medical Institutions, but shall not engage in the activities of traditional Chinese medical treatment until having obtained the practicing permit of medical institution.

Article 9 The medical institutions of traditional Chinese medicines shall, when undertaking the activities of medical treatment service, bring the characteristics and advantages of traditional Chinese medicines into full play, follow the law of the development of traditional Chinese medicines, make full use of the functions of traditional Chinese medicines in prevention of diseases, health care and recovery, etc. by using traditional theories and methods and in combination with modern scientific and technological means, and provide the masses with services of traditional Chinese medicines at reasonable prices and good quality.

Article 10 Lawfully established urban or rural sanitary service institutions at the basic level such as community sanitary service centers (stations), town and township hospitals, etc., shall be able to provide services of traditional Chinese medical treatment.

Article 11 Practitioners of traditional Chinese medicines shall, in accordance with the relevant provisions in laws, administrative regulations and departmental rules on sanitary administration,

pass the qualification examination, and shall not engage in the service activities of traditional Chinese medicines until having been registered and having obtained the practicing certificate.

Those who have learned traditional Chinese medical science from masters and those who do specialize in this field shall, in accordance with the provisions of the administrative department of health under the State Council, pass the qualification assessment of practicing physicians or practicing assistant physicians, and shall not engage in the service activities of traditional Chinese medicines until having been registered and having obtained the practicing certificate.

Article 12 Practitioners of traditional Chinese medicines shall comply with the corresponding principles of diagnosis and treatment, standards of medical treatment techniques and technical operation rules on traditional Chinese medicines.

Generalist physicians and rural doctors shall have basic knowledge of traditional Chinese medicines, knowledge and techniques of using traditional Chinese medical science for diagnosis and treatment, and the basic skills in dealing with common diseases and frequently occurring diseases.

Article 13 A medical institution that intends to make an advertisement of traditional Chinese medical treatment shall, in accordance with the provisions, apply to and submit the relevant documents to the department responsible for the administration of traditional Chinese medicines under the people's government of the province, autonomous region or municipality directly under the Central Government where it is located. The department responsible for the administration of traditional Chinese medicines under the people's government of the province, autonomous region or municipality directly under the Central Government shall, within 10 working days as of the receipt of the relevant documents, examine them and make a decision on whether to issue the registered document of approval for advertising traditional Chinese medical treatment. To the medical institution meeting the prescribed requirements, the registered document of approval for advertising traditional Chinese medical treatment shall be issued. The medical institution failing to obtain the registered document of approval for advertising traditional Chinese medical treatment shall not make advertisements of traditional Chinese medical treatment.

The contents published in an advertisement of traditional Chinese medical treatment shall be consistent with those that have been examined and approved for publishing.

### Chapter III Education and Scientific Research on Traditional Chinese Medicines

Article 14 The state takes measures to develop the undertaking of education on traditional Chinese medicines.

Various educational institutions of traditional Chinese medicines shall strengthen the teaching of basic theories of traditional Chinese medicines, stress the combination of the basic theories with the clinical practices of traditional Chinese medicines, and advance the quality education.

Article 15 Whoever intends to establish any of the various educational institutions of traditional

Chinese medicines shall meet the standards prescribed by the state for such establishment, and shall establish a clinical teaching base conforming to the standards prescribed by the state.

The standards for the establishment of educational institutions of traditional Chinese medicines shall be made by the administrative department of health under the State Council jointly with the administrative department of education under the State Council; the standards for clinical teaching bases of educational institutions of traditional Chinese medicines shall be made by the administrative department of health under the State Council.

Article 16 The state encourages the succession of academic experiences and technical specialties of traditional Chinese medicine experts, and educates senior clinical talents of traditional Chinese medical science and technical talents of traditional Chinese medicines.

Article 17 A tutor who undertakes the instruction of succession of academic experiences and technical specialties of traditional Chinese medicine experts shall meet the following conditions:

- (a) having high academic level and rich practicing experiences, technical specialties and good occupational virtues;
- (b) having worked in the field of traditional Chinese medicines for no less than 30 years and have held a senior professional post for no less than 10 years.

Article 18 A successor who is to succeed the academic experiences and technical specialties of traditional Chinese medicine experts shall meet the following conditions:

- (a) having the academic qualification of regular course education or above in a higher educational institution and have good occupational virtues;
- (b) being employed by a medical and sanitary institution or by an educational or scientific research institution of medical science to work in the field of traditional Chinese medicines, and to hold a professional post of intermediate level or above.

Article 19 The measures on the administration of the tutors and successors for the succession of academic experiences and technical specialties of traditional Chinese medicine experts shall be formulated by the administrative department for traditional Chinese medicines under the State Council jointly with other relevant departments.

Article 20 The department responsible for the administration of traditional Chinese medicines under the people's government of the province, autonomous region or municipality directly under the Central Government shall, in accordance with the relevant provisions of the state, improve the system in its own region for the continuing education of persons in the field of traditional Chinese medicines, and make plans on training such persons.

The department responsible for the administration of traditional Chinese medicines under the local people's government at or above the county level shall, upon the requirements of the planning on training persons in the field of traditional Chinese medicines, hold trainings of basic

knowledge and skills on traditional Chinese medicines for persons providing urban and rural sanitary services at the basic level.

A medical institution shall create conditions for the professionals of traditional Chinese medicines to accept the continuing education.

Article 21 The state develops the science and technology of traditional Chinese medicines, includes them into the scientific and technological development planning, and strengthens the construction of key scientific research institutions of traditional Chinese medicines.

The local people's government at or above the county level shall make full use of the resources of traditional Chinese medicines, stress the scientific research and technical development of traditional Chinese medicines, take measures to develop, extend and apply technical achievements of traditional Chinese medicines, and promote the scientific and technological development of traditional Chinese medicines.

Article 22 For the scientific research of traditional Chinese medicines, it shall be stressed that both traditional and modern ways shall be used to carry out the basic theory research and clinical research of traditional Chinese medicines, and that traditional Chinese medical theories and modern science and technology shall be used to carry out the research on prevention and treatment of common diseases, frequently occurring diseases, as well as difficult and complicated diseases.

The scientific research institutions, higher educational institutions and medical institutions of traditional Chinese medicines shall make efforts at tackling the key problems in the scientific research of traditional Chinese medicines and extending and applying scientific and technological achievements of traditional Chinese medicines, and educate the academic leaders and middle-aged and young technical backbones of traditional Chinese medicines.

Article 23 Those who donate diagnostic and treatment methods of traditional Chinese medicines as well as literatures, esoteric recipes and proved recipes of traditional Chinese medicines, which are of great significance to the scientific and technological development of traditional Chinese medicines, shall be granted awards with reference to the Regulation on Scientific and Technological Awards of the State.

Article 24 The state supports the foreign exchange and cooperation in respect of traditional Chinese medicines, and enhances the international dissemination of traditional Chinese medicines.

The extension, transfer, foreign exchange of major scientific research achievements of traditional Chinese medicines, and the Chinese-foreign cooperative research of traditional Chinese medical technologies, shall be approved by the department responsible for the administration of traditional Chinese medicines under the people's government at or above the provincial level, so as to prevent the loss of major traditional Chinese medical resources.

If any scientific research achievement of traditional Chinese medicines belongs to the scientific

and technological secrets of the state but is indeed necessary for transfer or foreign exchange, the provisions in laws, administrative regulations and departmental rules on maintenance of state secrets shall be abided by.

#### Chapter IV Guaranty Measures

Article 25 The local people's government at or above the county level shall, in light of the needs in the development of the undertaking of traditional Chinese medicines and the situation of the local national economic and social development, gradually increase the input to the undertaking of traditional Chinese medicines, and shall support the development of the undertaking of traditional Chinese medicines.

No entity or individual shall misappropriate the expenses for the undertaking of traditional Chinese medicines for other use.

The state encourages domestic and overseas organizations and individuals to support the development of the undertaking of traditional Chinese medicines by means of donating or contributing investments, etc..

Article 26 Non-profit medical institutions of traditional Chinese medicines may, in accordance with the relevant provisions of the state, enjoy fiscal subsidies, tax reduction and exemption, and other preferential policies.

Article 27 The medical institutions designated and determined by the administrative department for labor security under the local people's government at or above the county level to treat patients of urban and town employees enjoying basic medical insurances, shall include the qualified medical institutions of traditional Chinese medicines.

The medical institutions of traditional Chinese medicines qualified for the designation shall provide basic medical treatment services as prescribed to those who enjoy the insurances.

Article 28 The people's governments at or above the county level shall take measures to strengthen the collection, neatening, research and protection of the literatures of traditional Chinese medicines.

The relevant entities and medical institutions of traditional Chinese medicines shall strengthen the management, protection and utilization of important literatures of traditional Chinese medicines.

Article 29 The state protects wild resources of traditional Chinese medicinal materials, supports the research, development and utilization of artificial substitutes of endangered animal and plant of traditional Chinese medicinal materials.

The local people's government at or above the county level shall strengthen the reasonable development and utilization of traditional Chinese medicinal materials, encourage the establishment of bases for planting and cultivating traditional Chinese medicinal materials, and

promote the development and production of scarce traditional Chinese medicinal materials.

Article 30 The evaluating and appraising activities related to traditional Chinese medicines shall embody the characteristics of traditional Chinese medicines, and follow the development law of the traditional Chinese medicines.

For the purpose of appraising the qualification for holding the professional posts of traditional Chinese medicines, appraising and evaluating traditional Chinese medical treatment institutions, or educational or scientific research institutions of traditional Chinese medicines, initiating projects of or appraising achievements on scientific research topics of traditional Chinese medicines, a special appraising and evaluating organization of traditional Chinese medicines shall be established, or the experts of traditional Chinese medicines shall participate in the appraisal and evaluation.

## Chapter V Legal Liabilities

Article 31 If any functionary in the department responsible for the administration of traditional Chinese medicines violates the present regulation in his administration of traditional Chinese medicines, by taking advantage of his post to accept the properties of others or to obtain other's benefits, by abusing his power or neglecting his duty, or by failing to investigate the illegal acts he has found, and thus causing severe consequences, if a crime has been constituted, he shall be investigated for criminal liabilities in accordance with the law; if the consequences are not serious enough for criminal punishment, he shall be imposed upon the administrative sanction of demotion or dismissal from his post in accordance with the law.

Article 32 If a medical institution of traditional Chinese medicines violates the present regulation and is under any of the following circumstances, it shall be ordered by the department responsible for the administration of traditional Chinese medicines under the local people's government at or above the county level to make a correction within a time limit; if it fails to make a correction before the expiry of the time limit, it shall be ordered to cease its business for rectification, or its practicing permit of medical institution shall be revoked and its qualification as a medical institution designated to treat patients of urban and town employees enjoying basic medical insurances shall be cancelled by the original approving organ, and the liable persons in charge and other directly liable persons shall be imposed upon disciplinary sanctions in accordance with the law:

(a) it does not meet the standards for the establishment of medical institutions of traditional Chinese medicines;

(b) it has acquired the qualifications as a medical institution designated to treat patients of urban and town employees enjoying basic medical insurances, but fails to provide those who have bought insurances with basic medical treatment services as prescribed.

Article 33 Whoever, without authorization, opens a medical institution of traditional Chinese medicines without the approval or engages in the traditional Chinese medical treatment activities by failing to pass the examination for the qualification of practicing physician or practicing

assistant physician as prescribed to obtain the practicing permit, shall be punished in accordance with the relevant provisions in the Law of the People's Republic of China on Practicing Physicians and the Regulation on the Administration of Medical Institutions.

Article 34 If an educational institution of traditional Chinese medicines violates the present regulation and is under any of the following circumstances, it shall be ordered by the department responsible for the administration of traditional Chinese medicines under the local people's government at or above the county level to make a correction within a time limit; if it fails to make a correction before the expiry of the time limit, it shall be revoked by the original approving organ:

- (a) it does not meet the prescribed standards for the establishment;
- (b) it has not established a clinical teaching base conforming to the prescribed standards.

Article 35 Whoever violates the present regulation, and thus causing heavy losses to the resources of traditional Chinese medicines or divulging scientific and technological secrets of the state, and the case is severe, and a crime is constituted, he shall be investigated for criminal liabilities in accordance with the law; if the consequences are not serious enough for criminal punishment, he shall be ordered by the department responsible for the administration of traditional Chinese medicines under the local people's government at or above the county level to make a correction, and the liable persons in charge and other directly liable persons shall be imposed upon disciplinary sanctions in accordance with the law.

Article 36 Whoever violates the present regulation by damaging or destroying the literatures of traditional Chinese medicines shall be ordered by the department responsible for the administration of traditional Chinese medicines under the local people's government at or above the county level to make a correction, and the liable persons in charge and other directly liable persons shall be imposed upon disciplinary sanctions in accordance with the law; whoever damages or destroys the literatures of traditional Chinese medicines which belong to cultural relics under protection of the state, and the case is severe, and a crime is constituted, he shall be investigated for criminal liabilities in accordance with the law.

Article 37 If any medical institution of traditional Chinese medicines alters the approved contents in an advertisement of traditional Chinese medical treatment, its registered document of approval for advertisements shall be revoked by the original approving department, and its application for approval of advertisements shall not be accepted within 1 year.

The department responsible for the administration of traditional Chinese medicines shall, after revoking the registered document of approval for advertising traditional Chinese medical treatment, notify the supervisory and administrative organ for advertisements within 5 working days as of the date when it makes the decision on administrative disposal. The supervisory and administrative organ for advertisements shall, within 15 working days as of the receipt of the notification from the department responsible for the administration of traditional Chinese medicines, investigate and deal with the matter in accordance with the relevant provisions in the Advertising Law of the People's Republic of China.

## Chapter VI Supplementary Provisions

Article 38 The medical institutions of traditional Chinese medicines mentioned in the present regulation shall mean the hospitals and clinics of traditional Chinese medicines or those of traditional Chinese medicines in combination with Western medicines, which have obtained the practicing permit of medical institution in accordance with the law.

The administration of national minorities medicines shall be implemented with reference to the present regulation.

Article 39 The present regulation shall come into force on October 1, 2003.