Regulations on the Protection of Traditional Knowledge in Traditional Chinese Medicine of China (the PRC)

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Unofficial English translation prepared for reference only. The official Chinese text prevails.

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Article 1 — These Regulations are formulated in accordance with the Law of the People's Republic of China on Traditional Chinese Medicine for the purpose of protecting traditional knowledge in traditional Chinese medicine, promoting the inheritance and development of traditional knowledge in traditional Chinese medicine, and carrying forward the culture of traditional Chinese medicine.

Article 2 — For the purposes of these Regulations, "traditional knowledge in traditional Chinese medicine" means the theories, techniques and methods of traditional Chinese medicine, and the related forms in which they are expressed, that have been formed through the long-term practical accumulation and generational inheritance and development of the Chinese nation, including:

(1) traditional theories, techniques and methods of prevention, health care, diagnosis, treatment and rehabilitation in traditional Chinese medicine;

(2) classical famous formulas and proven formulas of traditional Chinese medicine;

(3) traditional techniques for the variety breeding, cultivation, collection and identification of Chinese medicinal materials, and traditional techniques and processes for the processing of prepared slices of Chinese medicinal materials and the preparation of traditional Chinese medicine preparations;

(4) ancient books and documents on traditional Chinese medicine, and traditional marks and symbols unique to traditional Chinese medicine; and

(5) other traditional knowledge in traditional Chinese medicine.

Article 3 — The protection of traditional knowledge in traditional Chinese medicine shall follow the law of the development of traditional Chinese medicine, adhere to inheriting the essence while upholding integrity and pursuing innovation, and adhere to giving priority to protection and combining protection with utilization.

Activities for the protection of traditional knowledge in traditional Chinese medicine shall comply with laws and administrative regulations and shall not harm the interests of the State, the public interest of society, or the lawful rights and interests of others.

Article 4 — The competent department of traditional Chinese medicine under the State Council shall be responsible for the protection of traditional knowledge in traditional Chinese medicine nationwide.

The competent departments of traditional Chinese medicine of the local people's governments at or above the county level shall be responsible for the protection of traditional knowledge in traditional Chinese medicine within their respective administrative regions.

Other relevant departments of the people's governments at or above the county level shall, within the scope of their respective duties, be responsible for the work related to the protection of traditional knowledge in traditional Chinese medicine.

Article 5 — The competent department of traditional Chinese medicine under the State Council shall, together with other relevant departments under the State Council, establish a mechanism for sharing

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information related to traditional knowledge in traditional Chinese medicine and strengthen work coordination.

Article 6 — The competent departments of traditional Chinese medicine of the people's governments at or above the provincial level shall incorporate the protection of traditional knowledge in traditional Chinese medicine into relevant plans, strengthen the inheritance, dissemination, promotion and application of traditional knowledge in traditional Chinese medicine and scientific and technological research thereon, and provide necessary support.

The competent departments of traditional Chinese medicine of the people's governments at or above the county level shall encourage and guide social forces to participate in the protection of traditional knowledge in traditional Chinese medicine through donations, voluntary services and other means.

Article 7 — The State encourages and supports news media, public cultural institutions and other entities in carrying out activities such as the publicity, display and experience of traditional knowledge in traditional Chinese medicine in accordance with their respective business scope.

Activities such as the publicity, display and experience of traditional knowledge in traditional Chinese medicine shall comply with the relevant provisions of the State, and shall not involve false or exaggerated publicity or the seeking of improper benefits.

Article 8 — The State supports foreign exchanges and cooperation relating to traditional knowledge in traditional Chinese medicine and promotes the international dissemination and application of traditional knowledge in traditional Chinese medicine.

The administration of foreign investment, outbound investment and technology export involving traditional knowledge in traditional Chinese medicine shall be carried out in accordance with the Foreign Investment Law of the People's Republic of China, the Foreign Trade Law of the People's Republic of China, the Provisions of the State Council on Outbound Investment, the Regulations of the People's Republic of China on the Administration of Technology Import and Export, and other laws, administrative regulations and relevant provisions of the State.

Article 9 — The competent department of traditional Chinese medicine under the State Council shall, together with other relevant departments under the State Council, strengthen the cultivation of talents in traditional knowledge in traditional Chinese medicine.

Organizations and individuals that have made outstanding contributions to the protection of traditional knowledge in traditional Chinese medicine shall be rewarded in accordance with the relevant provisions of the State.

Article 10 — Where the protection of traditional knowledge in traditional Chinese medicine involves State secrets, work secrets, trade secrets, personal privacy or personal information, the relevant provisions of laws and administrative regulations shall be complied with.

Article 11 — The competent department of traditional Chinese medicine under the State Council shall strengthen the overall coordination of the arrangement and selection of ancient books and documents on traditional Chinese medicine and of investigations into traditional knowledge in traditional Chinese medicine.

Article 12 — The competent department of traditional Chinese medicine under the State Council shall establish a database for the protection of traditional knowledge in traditional Chinese medicine and exercise categorized administration over the traditional knowledge in traditional Chinese medicine included in the protection database. The specific measures for the administration of the protection database shall be formulated by the competent department of traditional Chinese medicine under the State Council.

Article 13 — The competent department of traditional Chinese medicine under the State Council shall organize professional institutions to arrange and select ancient books and documents on traditional Chinese

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medicine; the ancient books and documents so selected, and the traditional knowledge in traditional Chinese medicine recorded therein, shall be included in the protection database after confirmation by the competent department of traditional Chinese medicine under the State Council.

Article 14 — The competent departments of traditional Chinese medicine of the people's governments at the provincial level shall be responsible for organizing and carrying out investigations into traditional knowledge in traditional Chinese medicine within their respective administrative regions; the traditional knowledge in traditional Chinese medicine discovered through such investigations shall be included in the protection database after confirmation by the competent department of traditional Chinese medicine under the State Council.

Medical institutions, institutions of higher education, scientific research institutions, enterprises, societies, industry associations and chambers of commerce, among others, may be enlisted to participate in investigations into traditional knowledge in traditional Chinese medicine.

Foreign organizations and individuals shall not conduct investigations into traditional knowledge in traditional Chinese medicine within the territory of China.

The specific measures for investigations into traditional knowledge in traditional Chinese medicine shall be formulated by the competent department of traditional Chinese medicine under the State Council.

Article 15 — When conducting investigations into traditional knowledge in traditional Chinese medicine, the consent of the subjects of the investigation shall be obtained, their customs and habits shall be respected, and their lawful rights and interests shall not be harmed; the physical objects and materials obtained during the investigation shall be properly preserved so as to prevent damage or loss.

With respect to traditional knowledge in traditional Chinese medicine that is on the verge of disappearing and is discovered through investigations or other means, the competent departments of traditional Chinese medicine of the people's governments at the provincial level shall immediately record it and collect the relevant physical objects and materials, or take other rescue protection measures.

Article 16 — The State encourages organizations and individuals to declare the traditional knowledge in traditional Chinese medicine that they hold to the competent department of traditional Chinese medicine of the people's government at the provincial level of their locality; the declared traditional knowledge in traditional Chinese medicine shall be included in the protection database after preliminary review by the competent department of traditional Chinese medicine of the people's government at the provincial level and confirmation by the competent department of traditional Chinese medicine under the State Council.

Article 17 — The competent department of traditional Chinese medicine under the State Council shall publish the relevant information on the traditional knowledge in traditional Chinese medicine included in the protection database.

The competent department of traditional Chinese medicine under the State Council shall, together with the culture and tourism departments and other departments under the State Council, use digital technology to collect and record traditional knowledge in traditional Chinese medicine, so as to facilitate its preservation and use and to facilitate public access.

Article 18 — Holders of traditional knowledge in traditional Chinese medicine shall enjoy the right to inherit and use the traditional knowledge in traditional Chinese medicine that they hold, and shall enjoy the rights of informed consent and benefit sharing with respect to others' acquisition and use of the traditional knowledge in traditional Chinese medicine that they hold.

The State supports the reasonable utilization of traditional knowledge in traditional Chinese medicine that is in the public domain and publicly accessible, such as the traditional theories, techniques and methods and classical famous formulas recorded in ancient books on traditional Chinese medicine, and the competent department of traditional Chinese medicine under the State Council shall perform the duties of the holder

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thereof. The specific measures shall be formulated by the competent department of traditional Chinese medicine under the State Council.

Article 19 — The competent department of traditional Chinese medicine under the State Council shall establish a catalogue for the protection of traditional knowledge in traditional Chinese medicine, and include in the protection catalogue the traditional knowledge in traditional Chinese medicine in the protection database that is representative, distinctive and of important protection value. The specific measures for the administration of the protection catalogue shall be formulated by the competent department of traditional Chinese medicine under the State Council.

Article 20 — The competent department of traditional Chinese medicine under the State Council shall establish an expert review group for the protection catalogue to select, from the protection database, the traditional knowledge in traditional Chinese medicine to be included in the protection catalogue. The competent department of traditional Chinese medicine under the State Council shall publicize the selected traditional knowledge in traditional Chinese medicine and publish the protection catalogue based on the results of such publicity.

The competent departments of traditional Chinese medicine of the people's governments at the provincial level may recommend to the competent department of traditional Chinese medicine under the State Council the traditional knowledge in traditional Chinese medicine to be included in the protection catalogue.

Where the traditional knowledge in traditional Chinese medicine included in the protection catalogue no longer meets the relevant conditions, it shall be removed after confirmation by the expert review group organized by the competent department of traditional Chinese medicine under the State Council, and the removal shall be announced to the public in a timely manner.

Article 21 — The local people's governments at or above the county level may, based on actual circumstances, provide necessary support for the inheritance and dissemination of the traditional knowledge in traditional Chinese medicine included in the protection catalogue.

Article 22 — The culture and tourism department under the State Council shall, together with the cultural relics, traditional Chinese medicine and other competent departments under the State Council, strengthen the protection, restoration, reasonable utilization and inheritance of the ancient books on traditional Chinese medicine included in the protection catalogue.

Article 23 — The competent departments of traditional Chinese medicine of the people's governments at or above the county level shall, based on the needs of the protection of traditional knowledge in traditional Chinese medicine and relying on high-level medical institutions, promote the promotion and application of the traditional knowledge in traditional Chinese medicine included in the protection catalogue through the following means:

(1) collecting and arranging the relevant physical objects and materials;

(2) carrying out clinical application;

(3) carrying out application research so as to enhance the level of standardization and normalization of clinical application;

(4) carrying out master-apprentice education and training so as to cultivate successors; and

(5) holding activities such as demonstrations of techniques and methods and academic seminars and exchanges.

Article 24 — The competent department of traditional Chinese medicine under the State Council shall, together with the industry and information technology, drug administration and other departments under the State Council, relying on enterprises producing prepared slices of Chinese medicinal materials, medical institutions and others, conduct research on and promote the application of the traditional techniques and

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processes for processing prepared slices of Chinese medicinal materials included in the protection catalogue, and support the application of such traditional techniques and processes to enhance the quality of prepared slices of Chinese medicinal materials.

Article 25 — The competent department of traditional Chinese medicine under the State Council shall, together with the agriculture and rural affairs, drug administration and other departments under the State Council, promote the application of the traditional techniques for the variety breeding, cultivation, collection and identification of Chinese medicinal materials included in the protection catalogue.

Article 26 — The State encourages and supports research on traditional knowledge in traditional Chinese medicine using traditional Chinese medicine research methods and modern science and technology, encourages medical institutions, institutions of higher education, scientific research institutions, enterprises, societies, industry associations and chambers of commerce, among others, to cooperate in research, strengthens research on basic theories, mechanisms of action and clinical application, and promotes the inheritance and innovation of traditional Chinese medicine theories, techniques and methods.

Article 27 — The competent departments of traditional Chinese medicine of the people's governments at or above the provincial level shall, based on the needs of the protection of traditional knowledge in traditional Chinese medicine, organize institutions of higher education, scientific research institutions and others to conduct scientific and technological research on the traditional knowledge in traditional Chinese medicine included in the protection catalogue through the following means:

(1) collecting and arranging the relevant physical objects and materials;

(2) tracing the sources of theories, techniques and methods and conducting textual research on key information; and

(3) carrying out development and utilization and the transformation of research results.

Article 28 — Where the competent departments of traditional Chinese medicine and other relevant departments of the people's governments at or above the county level fail to perform their duties for the protection of traditional knowledge in traditional Chinese medicine in accordance with these Regulations, they shall be ordered by the people's government at the same level or the relevant department of the people's government at the next higher level to make corrections within a specified time limit; where the circumstances are serious, the leading personnel and directly responsible persons shall be given sanctions in accordance with law.

Article 29 — Where anyone conducts an investigation into traditional knowledge in traditional Chinese medicine in violation of paragraph 3 of Article 14 of these Regulations, the competent department of traditional Chinese medicine of the people's government at or above the county level shall order the cessation of the illegal act, give a warning, confiscate the illegal gains and the physical objects and materials obtained in the investigation, and may concurrently impose a fine of not less than 50,000 yuan and not more than 500,000 yuan.

Article 30 — Where a violation of these Regulations causes damage to holders of traditional knowledge in traditional Chinese medicine or others, civil liability shall be borne in accordance with law; where a crime is constituted, criminal liability shall be pursued in accordance with law.

Article 31 — Where traditional knowledge in traditional Chinese medicine constitutes cultural relics or intangible cultural heritage items, it shall also be protected in accordance with the relevant provisions of the Law of the People's Republic of China on the Protection of Cultural Relics and the Intangible Cultural Heritage Law of the People's Republic of China.

Article 32 — These Regulations shall come into force on January 1, 2027.

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