Regulations on Administrative Protection for Pharmaceuticals

REGULATIONS ON ADMINISTRATIVE PROTECTION FOR PHARMACEUTICALS

Approved by the State Council on December 12, 1992 and promulgated by the State Pharmaceutical Administration on December 19, 1992.

CHAPTER I GENERAL PROVISIONS

Article 1. These Regulations are enacted with a view to expanding economic and technological cooperation and exchange with foreign countries, providing Administrative Protection to the lawful rights and interests of the owners of the exclusive right of foreign pharmaceuticals.

Article 2. The "pharmaceuticals", as mentioned in these Regulations, refers to medicines for human beings.

Article 3. Enterprises and other organizations and individuals from the country or the region, which has concluded bilateral treaty or agreement with the Peoples Republic of China on administrative protection for pharmaceuticals, may apply for Administrative Protection for Pharmaceuticals in accordance with these Regulations.

Article 4. The competent authorities for the production and distribution of pharmaceuticals under the State Council receives and examines applications for Administrative Protection for Pharmaceuticals, grants Administrative Protection to the pharmaceuticals which conform with the provisions of these Regulations, and issues the Certificate for Administrative Protection for Pharmaceuticals to the applicants.

CHAPTER II APPLICATION FOR ADMINISTRATIVE PROTECTION

Article 5. A pharmaceutical which can be applied for Administrative Protection shall meet the following requirements:

(1) Was not subject to protection by exclusive rights in accordance with the provisions of the Chinas Patent Law prior to January 1, 1993;

(2) Is subject to an exclusive right to prohibit others from making, using or selling it in the country to which the applicant belongs, which was granted after January 1, 1986 and before January 1, 1993;

(3) Has not been marketed in China prior to the date of filing the application for administrative protection.

Article 6. The right of applying for Administrative Protection for Pharmaceuticals belongs to the owner of the exclusive right of the pharmaceutical.

Article 7. Where an owner of the exclusive right of a foreign pharmaceutical applies for Administrative Protection, he or it shall appoint an agency designated by the competent authorities for the production and distribution of pharmaceuticals under the State Council to act as his or its agent.

Article 8. An applicant shall provide the following documents both in Chinese and the original:
(1) An Application for Administrative Protection for Pharmaceuticals;
(2) A copy of the certificate issued by the competent authorities of country to which the applicant belongs granting such exclusive right;
(3) A copy of the document issued by the competent authorities of the country to which the applicant belongs for the approval for manufacture or marketing of such pharmaceutical;
(4) A copy of a contract for the manufacture and / or marketing formally entered into between the applicant and a Chinese enterprise as legal person (including wholly foreign capital enterprises , Chinese - foreign joint venture enterprises, or Chinese - foreign cooperative enterprises), which has obtained approval for manufacture or marketing of pharmaceuticals in accordance with the relevant Chinese laws and regulations , with respect to the manufacture and / or marketing of the pharmaceutical in China.

Article 9. Prior to or after applying for the Administrative Protection, the owner of the exclusive right of a foreign pharmaceutical shall apply to the administrative department of health under the State Council for going through the procedures of approval for manufacturing or marketing of the pharmaceutical in China, in accordance with the provisions of the Pharmaceutical Administration Law of the Peoples Republic of China.

CHAPTER III EXAMINATION AND APPROVAL OF APPLICATION FOR ADMINISTRATIVE PROTECTION

Article 10. Within 15 days from the date of receipt of the application documents for Administrative Protection, the competent authorities for the production and distribution of pharmaceuticals of the State Council, upon preliminary examination, shall make the following decisions according to different conditions:
(1) Where the application documents are in conformity with the pro-visions of Article 8 of these Regulations, issue the notice of acceptance and announce it;
(2) Where the application documents are not in conformity with the provisions of Article 8 of these Regulations, request the applicant to complement within a definite time; if the time limit for making complement is not met, the application shall be deemed to have not been filed.

Article 11. The competent authorities for the production and distribution of pharmaceuticals under the State Council shall finish the examination within six months from the date of receipt of the

application documents, or from the date of receipt of the complementary documents stipulated in Article 10(2) of these Regulations. If, under special circumstances, the examination cannot be finished within six months, the competent authorities for the production and distribution of pharmaceuticals under the State Council shall promptly notify the applicant, inform the reason and properly prolong the examination time.

After examination, where the application is in conformity with the provisions of these Regulations, Administrative Protection shall be granted; Where the application is not in conformity with the provisions of these Regulations, no Administrative Protection shall be granted and the reason shall be informed.

Article 12. Where a pharmaceutical is granted with Administrative Protection, the competent authorities for the production and distribution of pharmaceuticals under the State Council shall issue the Certificate for Administrative Protection for Pharmaceuticals and make an announcement.

CHAPTER IV DURATION, CESSATION, REVOCATION AND EFFECT OF ADMINISTRATIVE PROTECTION

Article 13. The term of Administrative Protection begins from the date on which the Certificate for Administrative Protection for Pharmaceuticals is issued and remains in force for seven years and six months.

Article 14. The owner of the exclusive right of a foreign pharmaceutical shall pay an annual fee beginning with the year in which the Certificate for Administrative Protection for Pharmaceuticals is issued.

Article 15. In any of the following cases, Administrative Protection shall cease before the expiration of its duration:

(1) Where the exclusive right of a pharmaceutical had been invalid or had lost efficacy in the country to which the applicant belongs;

(2) Where the owner of the exclusive right of a pharmaceutical does not pay an annual fee as prescribed;

(3) Where the owner of the exclusive right of a pharmaceutical abandons the administrative protection by a written declaration;

(4) Where the owner of the exclusive right of a pharmaceutical does not apply to the administrative department of health under the State Council for going through the procedures of approval for manufacture or marketing of this pharmaceutical in China within a year from the date on which the Certificate for Administrative Protection for Pharmaceuticals is issued.

Article 16. Where, after the Certificate for Administrative Protection for Pharmaceuticals has been issued, any organization or individual thinks that the grant of Administrative Protection to the subject pharmaceutical is not in conformity with the provisions of these Regulations, it or he may request the competent authorities for the production and distribution of pharmaceuticals under the State Council

to revoke the Administrative Protection of the subject pharmaceutical. Where the owner of the exclusive right of the pharmaceutical is not satisfied with the revocation decision made by the competent authorities for the production and distribution of pharmaceuticals under the State Council, it or he may institute legal proceedings in the people's court.

Article 17. The cessation or revocation of Administrative Protection for Pharmaceuticals shall be announced by the competent authorities for the production and distribution of pharmaceuticals under the State Council.

Article 18. For the pharmaceuticals which have obtained Administrative Protection, without the authorization of the owners of the exclusive right of the pharmaceuticals, the administrative department of health under the State Council and the administrative departments of health of provinces, autonomous regions or municipalities directly under the Central Government shall not ratify others to manufacture or sell them.

Article 19. Where there is any manufacture or marketing of a pharmaceutical without authorization of the owner of the exclusive right of the pharmaceutical who has obtained Administrative Protection, the owner of the exclusive right of the pharmaceutical may request the competent authorities for the production and distribution of pharmaceuticals under the State Council to stop the infringing act; if the owner of the exclusive right of the pharmaceutical requests for economic compensation, he or it may institute legal proceedings in the people's court.

CHAPTER V SUPPLEMENTARY PROVISIONS

Article 20. The competent authorities for the production and distribution of pharmaceuticals under the State Council shall take measures to keep secret all the materials provided by applicants which requires to be kept secret.

Article 21. Any application for Administrative Protection for Pharmaceuticals filed with, and any other relevant proceedings before, the competent authorities for the production and distribution of pharmaceuticals under the State Council shall be subject to the payment of a fee as prescribed.

Article 22. The rules for the implementation of these Regulations shall be formulated by the competent authorities for the production and distribution of pharmaceuticals under the State Council.

Article 23. The competent authorities for the production and distribution of pharmaceuticals under the State Council shall be responsible for the interpretation of these Regulations.

Article 24. These Regulations shall enter into force on January 1, 1993.