

# DRUG ADMINISTRATION LAW OF THE PEOPLE'S REPUBLIC OF CHINA

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### Chapter I

#### General Provisions

**Article 1** This Law is enacted to strengthen drug administration, to ensure drug quality and safety for human beings, to protect the health of people and their legitimate rights and interests in the use of drugs.

**Article 2** All institutions and individuals engaged in research, production, distribution, use, or drug administration in the People's Republic of China shall abide by this Law.

**Article 3** The State develops both modern and traditional medicines to give full play to their role in prevention and treatment of diseases and in maintenance of health.

The State protects the resources of natural crude drugs and encourages the cultivation of Chinese crude drugs.

**Article 4** The State encourages research and development of new drugs and protects the legitimate rights and interests of citizens, legal bodies and other institutions engaged in this field of endeavor.

**Article 5** The drug regulatory department under the State Council shall be responsible for drug administration nationwide. The relevant departments under the State Council shall be responsible for the related administrative work within the limits of their duties.

The drug regulatory departments of the people's governments of provinces, autonomous regions, and municipalities directly under the Central Government shall be responsible for drug regulation in their administrative areas. The relevant departments of the said people's governments shall be responsible for the related regulatory work within the limits of their duties.

The drug regulatory department under the State Council shall cooperate with the competent departments for comprehensive economic administration under the State Council in implementing pharmaceutical development programs and policies formulated by the State for the pharmaceutical industry.

**Article 6** The drug testing institutes established or designated by drug regulatory departments shall undertake the responsibility for drug testing required for conducting drug review and approval and controlling drug quality in accordance with law.

## Chapter II

### Control over Drug Manufacturers

**Article 7** The establishment of a drug manufacturer shall be subject to approval by the local drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government and be granted the Drug Manufacturing Certificate, and, with the certificate, the manufacturer shall be registered with the administrative department for industry and commerce. No one may manufacture drugs without the certificate.

The valid term and the scope of manufacturing shall be indicated in the Drug Manufacturing Certificate. For renewal of the certificate on expiration, reexamination is required.

When giving approval to the establishment of a new manufacturer, the drug regulatory department shall see to it that, apart from the requirements specified by the provisions in Article 8 of this Law that should be met, the pharmaceutical development programs and policies formulated by the State for the pharmaceutical industry are conformed to and prevent duplicate construction.

**Article 8** A drug manufacturer to be established shall meet the following requirements:

- (1) having legally qualified pharmaceutical and engineering professionals, and the necessary technical workers;
- (2) having the premises, facilities, and hygienic environment required for drug manufacturing;
- (3) having the institutions and personnel capable of quality control and testing for drugs to be produced and the necessary instruments and equipment; and
- (4) having rules and regulations to ensure the quality of drugs.

**Article 9** Drug manufacturers shall conduct production according to the Good Manufacturing Practice for Pharmaceutical Products (GMP) formulated by the drug regulatory department under the State Council on the basis of this Law. The drug regulatory department shall inspect a drug manufacturer as to its compliance with the GMP requirements and issue a certificate to the manufacturer passing the inspection.

The specific measures and schedule for implementing the GMP shall be formulated by the drug regulatory department under the State Council.

**Article 10** With the exception of the processing of prepared slices of Chinese crude drugs, a drug shall be produced in conformity with the National Drug Standard and with the production processes approved by the drug regulatory department under the State Council, and the production records shall be complete and accurate. When drug manufacturers make any change in the production process that may affect the drug quality, they shall submit the matter for examination and approval to the original approval authority.

Prepared slices of Chinese crude drugs shall be processed in conformity with the national drug standards. Those not covered by the national drug standards shall be produced according to the processing procedures formulated by the drug regulatory department of the people's government of the province, autonomous regions, or municipality directly under the Central Government. The said processing procedures shall be submitted to the drug regulatory department under the State Council for the record.

**Article 11** The drug substances and excipients for the manufacture of pharmaceutical products shall meet the requirements for medicinal use.

**Article 12** Drug manufacturers shall perform quality test of the drugs produced; no drugs that do not meet the national drug standards or that are not produced according to the

processing procedures for the prepared slices of Chinese crude drugs formulated by the drug regulatory department of the people's government of the province, autonomous region, or municipality directly under the Central Government may be released.

**Article 13** A drug manufacturer may accept contract production of drugs upon approval by the drug regulatory department under the State Council, or by the drug regulatory department of the people's government of a province, autonomous region, or municipality directly under the Central Government authorized by the drug regulatory department under the State Council.

### **Chapter III Control over Drug Distributors**

**Article 14** The establishment of a drug wholesaler shall be subject to approval of the local drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government and be granted the Drug Supply Certificate; the establishment of a drug retailer shall be subject to approval and be granted the said certificate by the local drug regulatory department at or above the country level. With the certificate, the wholesaler and the retailer shall be registered with the administrative department for industry and commerce. No one may distribute drugs without the certificate.

The valid term and the scope of business shall be indicated in the Drug Supply Certificate. For renewal of the certificate upon expiration, reexamination is required.

When giving approval to the establishment of a new distributor, the drug regulatory department shall see to it that, apart from the requirement specified by the provisions in Article 15 of this Law that should be met, the principles of appropriate location and convenient purchase of drugs by the people are adhered to.

**Article 15** A drug distributor to be established shall meet the following requirements:

- (1) having legally qualified pharmaceutical professionals;
- (2) having the business operation premises, equipment, warehouses and hygienic environment required for drug distribution;
- (3) having the units or personnel for quality control over the drugs to be distributed; and
- (4) having rules and regulations to ensure the quality of the drugs to be distributed.

**Article 16** Drug distributors shall conduct business according to the Good Supply Practice for Pharmaceutical Products (GSP) formulated by the drug regulatory department under the State Council on the basis of this Law. The drug regulatory department shall inspect a drug distributor as to its compliance with the GSP requirements, and issue a certificate to the distributor passing the inspection.

The specific measures and schedule for implementing the GSP shall be formulated by the drug regulatory department under the State Council.

**Article 17** For purchasing drugs, drug distributors shall establish and apply an examination and acceptance system, and check the certificate of drug quality, labels and other marks; no drugs that do not meet the requirements may be purchased.

**Article 18** Drug distributors shall keep authentic and complete records when purchasing and selling drugs. In the record shall be indicated the adopted name in China, dosage form, strength or size, batch number, date of expiry, manufacturer, purchase( or sale) unit, amount of the drug purchased (or sold), purchase or sale price, date of purchase (or sale), and other items specified by the drug regulatory department under the State Council.

**Article 19** Drug distributors shall sell drugs properly and make correct description of usage, dosage and cautions; prescription for dispensing shall be checked, and no drugs listed in the prescription may be changed or substituted without authorization. They shall refuse to dispense incompatible or over-dose prescriptions; when necessary, they may do the dispensing only after corrections or re-signing is made by the prescribing physician.

Drug distributors shall indicate the origin of the Chinese crude drugs to be sold.

**Article 20** A drug distributor shall establish and apply a system for drug storage, and take necessary measures to ensure quality, such as cold storage, protection against freeze and humidity and avoidance of insects and rodents.

An examination system shall be applied for placing drugs in and releasing them from storage.

**Article 21** Chinese crude drugs may be sold at town and country fairs, except those otherwise specified by the State Council.

No drugs other than the Chinese crude drugs may be sold at town and country fairs, but drug retailers holding the Drug Supply Certificate may, within the specified business scope, sell such drugs at stores they set up at the fairs. Specific measures shall be formulated by the State Council.

#### **Chapter IV**

##### **Control over Pharmaceuticals in Medical Institutions**

**Article 22** A medical institution shall be staffed with legally qualified pharmaceutical professionals. No one who is not a pharmaceutical professional may directly engage in technical work in pharmacy.

**Article 23** To dispense pharmaceutical preparations, a medical institution shall be subject to examination and permission by the administrative department for health of the people's government of the province, autonomous region or municipality directly under the Central Government, and upon approval by the drug regulatory department of the said people's government, a Pharmaceutical Preparation Certificate for Medical Institution shall be issued to it by the said drug regulatory department. No one may dispense pharmaceutical preparations without the certificate.

The valid term shall be indicated in the certificate. For renewal of the certificate upon expiration, reexamination is required.

**Article 24** To dispense pharmaceutical preparations, the medical institution shall possess the facilities, management system, testing instruments and hygienic conditions for ensuring their quality.

**Article 25** The pharmaceutical preparations to be dispensed by the medical institutions shall be ones that are to meet the clinic need of the institution but are not available on the market and shall be subject to approval in advance by the local drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government. The quality of the dispensed pharmaceutical preparations shall be subject to test according to regulations; those passing the testing may be used within the institution on the basis of the physician's prescription. In special cases, the pharmaceutical preparations dispensed by a medical institution may be used by other designated medical institutions, upon approval by the

drug regulatory department under the State Council or by the drug regulatory department of the people's government of a province, autonomous region or municipality directly under the Central Government.

No pharmaceutical preparations dispensed by medical institutions may be marketed.

**Article 26** For purchasing drugs, medical institutions shall establish and apply an examination and acceptance system, and check the certificate of drug quality, labels and other marks; no drugs that do not meet the specified requirements may be purchased or used.

**Article 27** Prescriptions dispensed by pharmacists of medical institutions shall be checked, and on drugs listed in the prescriptions may be changed or substituted without authorization. The pharmacists shall refuse to dispense incompatible or over-dose prescriptions; when necessary, they may do the dispensing only after corrections or re-signing is made by the prescribing physician.

**Article 28** A medical institution shall establish and apply a system for drug storage, and take necessary measures to ensure drug quality, such as cold storage, protection against freeze and humidity and avoidance of insects and rodents.

## **Chapter V Control over Drugs**

**Article 29** The dossier on a new drug research and development including the manufacturing process, quality specifications, results of pharmacological and toxicological study, and the related data and the samples shall, in accordance with the regulations of the drug regulatory department under the State Council, be truthfully submitted to the said department for approval, before clinical trial is conducted. Measures for verifying the qualifications of clinical study institutions for drugs shall be formulated jointly by the drug regulatory department and the administrative department for health under the State Council.

When a new drug has gone through clinical trials and passed the evaluation, a New Drug Certificate shall be issued upon approval by the drug regulatory department under the State Council.

**Article 30** The institutions for non-clinical safety evaluation and study and clinical study institutions shall respectively implement the Good Laboratory Practice for Non-Clinical Laboratory Studies (GLP) and Good Clinical Practice (GCP).

The GLP and GCP shall be formulated by the department designated by the State Council.

**Article 31** Production of a new drug or a drug admitted by national drug standards shall be subject to approval by the drug regulatory department under the State Council, and a drug approval number shall be issued for it, with the exception of the Chinese crude drugs and the prepared slices of Chinese crude drugs which where no control by approval number is exercised. The list of the Chinese crude drugs and the prepared slices of the Chinese crude drugs to be controlled by the approval number shall be compiled by the drug regulatory department under the State Council, in conjunction with the administrative department for traditional Chinese medicine under the State Council. A drug manufacturer may produce the drug only after an approval number is granted to it.

**Article 32** Drugs shall meet the national drug standards. The provisions in the second paragraph of Article 10 of this Law shall be applicable to the prepared slices of Chinese crude drugs.

The Pharmacopoeia of the People's Republic of China and the drug standards issued by the drug regulatory department under the State Council shall serve as the national drug standards.

The drug regulatory department under the State Council shall organize a pharmacopoeia commission, which shall be responsible for formulating and revising the national drug standards.

The drug testing institution affiliated to the drug regulatory department under the State Council is responsible for defining the national drug standard substance and reference substance.

**Article 33** The drug regulatory department under the State Council shall organize experts in pharmaceutical, medical and other fields to evaluate new drugs and re-evaluate the drugs already approved for production.

**Article 34** Drug manufacturers, drug distributors and medical institutions shall purchase drugs from pharmaceutical enterprises, which are qualified for production or distribution,



with the exception of the Chinese crude drugs where no control by approval number is exercised.

**Article 35** The State exercises special control over narcotic drugs, psychotropic substances, medicinal toxic drugs and radioactive pharmaceuticals. Measures for the control in this respect shall be formulated by the State Council.

**Article 36** The State adopts a protection system for certain traditional Chinese medicine preparations. The specific measures shall be formulated by the State Council.

**Article 37** The State adopts a classification system for prescription and non-prescription drugs. The specific measures shall be formulated by the State Council.

**Article 38** The importation of drugs with uncertain therapeutic efficacy, serious adverse reaction, or other factors harmful to human health is prohibited.

**Article 39** Evaluation of drugs to be imported shall be organized by the drug regulatory department under the State Council. A drug may be imported only upon approval granted after the fact that it conforms to the quality specifications and is safe and effective is affirmed through examination, and an import drug license shall be issued.

As to small amounts of drugs to be imported for urgent clinical need of medical institutions or for personal medication, formalities for import shall be completed in accordance with the relevant regulations of the State.

**Article 40** Drugs shall be imported via the ports where drug importation is permitted, and be registered by the drug importers with the local drug regulatory departments for the record. The customs shall release the drugs on the basis of the Drug Import Note issued by the said departments, and may not release those drugs for which no Drug Import Note is issued.

The drug regulatory department in the place where the port is located shall notify the drug testing institutions to conduct sampling and testing of the drugs to be imported according to the regulations of the drug regulatory department under the State Council, and sampling fees shall be charged in accordance with the provisions of the second paragraph of Article 41 of this Law.

The ports where drugs may be imported shall be proposed by the drug regulatory department under the State Council together with the General Administration of Customs and submitted to the State Council for approval.

**Article 41** The drug regulatory department under the State Council shall designate drug testing institutions to test the following drugs before they are marketed or at the time they are imported; no drugs that fail to pass the testing may be marketed or imported;

(1) biological products specified by the drug regulatory department under the State Council;

(2) drugs to be marketed in China for the first time; and

(3) other drugs specified by the State Council.

The testing items to be charged for the drugs listed in the preceding paragraph and the rates of fees shall be decided on and publicized by the financial department together with the competent pricing department under the State Council. Measures for collecting fees for testing shall be formulated and announced by the financial department together with the drug regulatory department under the State Council.

**Article 42** The drug regulatory department under the State Council shall organize investigations of the drugs to the production or importation of which it has granted approval; it shall withdraw the approval number or Import Drug License issued to drugs with uncertain therapeutic efficacy, serious adverse reaction, or other factors harmful to human health.

No drugs whose approval numbers or import drug licenses have been withdrawn may be produced, distributed or used. Those already produced or imported shall be destroyed or disposed of under the supervision of the local drug regulatory department.

**Article 43** The State adopts a system for drug reserve.

When major disasters, epidemic situations or other emergencies occur in the country, the department specified by the State Council may transfer drugs from the enterprises to meet the urgent need.

**Article 44** The State Council shall have the power to restrict or prohibit the exportation of the drugs which are in short supply within the country.

**Article 45** Anyone who wishes to import or export narcotic drugs and psychotropic substances that fall within the scope specified by the State shall produce the Import License or Export License issued by the drug regulatory department under the State Council.

**Article 46** The newly-discovered crude drugs or cultivated crude drugs introduced from abroad may be marketed only after examination and approval by the drug regulatory department under the State Council.

**Article 47** Measures for the control over the folk crude drugs customarily used in certain regions shall be formulated by the drug regulatory department together with the administrative department for traditional Chinese medicines under the State Council.

**Article 48** Production (including dispensing, the same below) and distribution of counterfeit drugs are prohibited.

A drug is a counterfeit drug in any of the following cases:

- (1) the ingredients in the drug are different from those specified by the national drug standards; or
- (2) a non-drug substance is simulated as a drug or one drug is simulated as another.

A drug shall be treated as a counterfeit drug in any of the following cases:

- (1) its use is prohibited by the regulations of the drug regulatory department under the State Council;
- (2) it is produced or imported without approval, or marketed without being tested, as required by this Law;
- (3) it is deteriorated;
- (4) it is contaminated;
- (5) it is produced by using drug substances without approval number as required by this Law; or
- (6) the indications or functions indicated are beyond the specified scope.

**Article 49** Production and distribution of substandard drugs are prohibited.

A drug with content not up to the national drug standards is a substandard drug.

A drug shall be treated as a substandard drug in any of the following cases;

- (1) the date of expiry is not indicated or is altered;
- (2) the batch number is not indicated or is altered;
- (3) it is beyond the date of expiry;
- (4) no approval is obtained for the immediate packaging material or container;
- (5) colorants, preservatives, spices, flavorings or other excipients are added without authorization; or
- (6) other cases where the drug standard are not conformed.

**Article 50** A drug name listed in the national drug standard is an adopted name in China. Such an adopted name may not be used as a trademark.

**Article 51** Staff members of drug manufacturers, drug distributors and medical institutions who are in direct contact with drugs shall undergo health checkup annually. No one who suffers from infectious diseases or any other diseases which may cause contamination to drugs may engage in any work in direct contact with drugs.

## **Chapter VI**

### **Control over Drug Packaging**

**Article 52** Immediate packaging materials and containers shall meet the requirements for medicinal use and the standards for ensuring human health and safety. They shall, along with the drugs, be subject to examination and approval by the drug regulatory department.

No drug manufacturers may use immediate packaging materials and containers for which no approval is obtained.

If the immediate packaging materials and containers are not up to standard, the drug regulatory department shall give orders stopping the use of such materials and containers.

**Article 53** Drug packaging shall conform to drug quality requirements and be convenient for storage, transportation and medical use.

Chinese crude drugs shall be packed for transportation. On each package shall be indicated the name of the drug, the origin of production, the date and the name of the consignor, with a quality certification mark attached.

**Article 54** A label shall be printed or stuck on the drug package together with an insert sheet, as required by regulations.

In the label or insert sheet shall be indicated the adopted name of the drug in China, its ingredients, strength, manufacturer, approval number, product batch number, production date, date of expiry, indications or functions, usage, dosage, contraindications, adverse drug reactions, and precautions.

Specified marks shall be printed in the label of narcotic drugs, psychotropic substances, toxic drugs for medical use, radioactive pharmaceuticals, drugs for topical use, and non-prescription drugs.

## Chapter VII

### Control over Drug Pricing and Advertising

**Article 55** For drugs the prices of which are fixed or guided by the government according to law, the competent pricing department of the government shall, on the pricing principle stipulated in the Pricing Law of the People's Republic of China and on the basis of average social cost, supply and demand in the market, and public affordability, rationally fix and adjust the prices, in order to ensure that price is commensurate with quality, eliminate excessively high price, and protect the legitimate interests of users.

Drug manufacturers, drug distributors and medical institutions shall implement prices fixed or guided by the government. No one may raise prices in any matter without authorization.

Drug manufacturers shall provide the truthful manufacturing and operating cost to the competent pricing department of the government. No one may refuse to or falsely or deceptively report the cost.

**Article 56** For drugs the prices of which are adjustable with the market according to law, drug manufacturers, drug distributors and medical institutions shall fix the prices on the principles of fairness, rationality, good faith and commensuration of price with quality, in order to provide the users with drugs of reasonable prices.

When fixing and indicating retailing prices, drug manufacturers, drug distributors and medical institutions shall abide by the regulations on control over drug prices formulated by the competent pricing department under the State Council. Usurious profits and fraud in pricing that harms the users' interests are prohibited.

**Article 57** Drug manufacturers, drug distributors and medical institutions shall provide the actual buying and selling prices and quantity of the drugs purchased and sold, and other related data to the competent pricing department of the government.

**Article 58** Medical institutions shall provide the patients with a list of drug prices; and the medical institutions designated by medical insurance provider shall truthfully publicize the prices of drugs in common use in compliance with the specified measures, in order to ensure reasonable use of drugs. Specific measures shall be formulated by the administrative department for health under the state Council.

**Article 59** Drug manufacturers, drug distributors and medical institutions are prohibited from offering or accepting, in private, off-the-book rake-offs or other benefits in the course of purchasing and selling drugs.

Drug manufacturers, drug distributors or their agents are prohibited from offering, under any pretences, money or things of value or other benefits to leading members, drug purchasers, physicians, or other related persons of the medical institutions where their drugs are used. Leading members of medical institutions, drug purchasers, physicians, or other related persons, on their part, are prohibited from accepting, under any pretences, money or things of value or other benefits offered by drug manufacturers and drug distributors or their agents.

**Article 60** Drug advertisements shall be subject to approval by the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government where the enterprise is located, an approval number of drug advertisement shall be issued. No one may launch advertisements without the approval number.

Prescription drugs may be introduced in the medical or pharmaceutical professional publications jointly designated by the administrative department for health and the drug regulatory department under the State Council, but their advertisements may not be released by mass media or disseminated to the general public by other means.

**Article 61** The content of drug advertisements shall be truthful and lawful, and the insert sheet approved by the drug regulatory department under the State Council shall be taken as the basis, and no false content may be contained in them.

No unscientific, categorical assertion or warranty of described function may be contained in drug advertisements; no names or images of government departments, medical or pharmaceutical research institutions, academic institutions, or experts, scholars, physicians and patients may be used as evidence for drug advertising.

No-drug advertisements may not deal with drug promotion.

**Article 62** Drug regulatory departments of the people's governments of provinces, autonomous regions or municipalities directly under the Central Government shall inspect the drug advertisements approved by them, and inform the advertisement regulatory authority of those advertisements that violate this Law or the Advertisement Law of the

People's Republic of China, and put forward suggestions for their handling, and the said authority shall deal with such cases according to law.

**Article 63** Where drug pricing and advertising are not governed by the provisions of this Law, the provisions of the Pricing Law of the People's Republic of China and the Advertisement Law of the People's Republic of China shall be applicable.

## **Chapter VIII**

### **Inspection of Drugs**

**Article 64** Drug regulatory departments shall have the power to supervise and inspect, according to law and administrative regulations, matters related to drug research and development, which it has given approval, to drug production and distribution, and to the use of drugs by medical institutions. No institutions or individuals concerned may resist the supervision and inspection or conceal any facts.

When people from drug regulatory departments conduct supervision and inspection, they shall show their identification documents, and they shall keep confidential the technical and business secrets of the persons under inspection which they come to know in the course of supervision and inspection.

**Article 65** Drug regulatory departments may conduct selective testing of drug quality in light of the need of supervision and inspection. Sampling for selective testing shall be carried out according to relevant regulations, and no fees whatever may be charged for sampling or testing. The necessary expenses shall be listed and covered in accordance with the regulations of the State Council.

The drug regulatory department shall take administrative enforcement measures to seal or seize the drugs and related materials that are proved to be potentially harmful to human health and shall, within seven days, make an administrative decision on the matter in question. Where it is necessary to test such drugs, it shall, within 15 days from the date the testing report is issued, make the administrative decision.

**Article 66** The drug regulatory department under the State Council and the drug regulatory departments of the people's governments of provinces, autonomous regions and municipalities directly under the Central Government shall regularly announce the results of selective testing of drug quality. Where the announcement is improper, it shall be corrected within the scope in which the original announcement is made.

**Article 67** Where the party has objection to the results of testing conducted by the drug testing institution, it may, within seven days from the date it receives the testing results, apply for re-testing to the said drug testing institution, or to such an institution established or designated by the drug regulatory department at the next higher level, and it may also directly apply to the drug testing institution established or designated by the drug regulatory department under the State Council. The drug testing institution that accepts the application shall, within the time limit specified by the drug regulatory department under the State Council, draw a conclusion from the re-test.

**Article 68** Drug regulatory departments shall, in accordance with regulations and on the basis of the GMP and GSP, make follow-up inspections on the certified drug manufacturers and distributors.

**Article 69** With regard to the drugs produced according to the provisions of this Law by drug manufacturers not located in the region, no local people's government or drug regulatory department may, by means of demanding drug testing or approval, restrict or deny their access to the region.

**Article 70** No drug regulatory department, or drug testing institution established by the department, or the institution specially engaged in drug testing designated by the department may be involved in production or distribution of drugs, or recommend drugs in its name or have the supervisor for drug production or sale named after it .

No staff members of drug regulatory departments, of drug testing institutions established by the departments or of institutions specially engaged in drug testing designated by the departments may be involved in drug production or distribution.

**Article 71** The State applies a system of report on adverse drug reaction. Drug manufacturers, drug distributors and medical institutions shall make constant investigations into quality, therapeutic efficacy and reactions of the drugs produced, distributed and used by them. When serious adverse drug reactions possibly induced by drug use are discovered, they shall, without delay, report the matter to the local drug regulatory departments and administrative departments for health of the people's governments of provinces, autonomous regions and municipalities directly under the Central Government. Specific measures shall be formulated by the drug regulatory department under the State Council together with the administrative department for health under the State Council.



With regard to drugs with confirmed serious adverse reactions, the drug regulatory department under the State Council or the drug regulatory department of the people's government of province, autonomous region or municipality directly under the Central Government may take urgent control measures to suspend their production, distribution and use, and it shall, within five days, arrange for assessment and, within 15 days from the date the conclusion is drawn, make an administrative decision on how to deal with the case.

**Article 72** Drug testing sections of the drug manufacturers, drug distributors and medical institutions and their staff members shall accept technical instructions given by drug testing institutions set up by the local drug regulatory departments.

## **Chapter IX**

### **Legal Liabilities**

**Article 73** Any drug manufacturer or distributor that, without obtaining Drug Manufacturing Certificate, Drug Supply Certificate or Pharmaceutical Preparation Certificate for Medical Institution, manufactures or distributes drugs shall be banned, the drugs illegally produced or sold and the illegal gains there from shall be confiscated, and they shall also be fined not less than two times but not more than five times the value of the drugs(including the drugs sold and not sold, the same below). If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

**Article 74** Where counterfeit drugs are produced or sold, the drugs illegally produced or sold and the illegal gains shall be confiscated, and a fine not less than two times but not more than five times the value of the said drugs shall be imposed. The approval documents, if any, shall be withdrawn and an order shall be given to suspend production or business operation for rectification. If the circumstances are serious, the Drug Manufacturing Certificate, Drug Supply Certificate or Pharmaceutical Preparation Certificate for Medical Institution shall be revoked. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

**Article 75** Where substandard drugs are produced or sold, the drugs illegally produced or sold and the illegal gains shall be confiscated, and a fine not less than, but not more than three times, the value of the said drugs shall also be imposed. If the circumstances are serious, an order shall be given to suspend production or business operation for rectification, or the drug approval documents shall be withdrawn and the Drug

Manufacturing Certificate, the Drug supply Certificate, or the Pharmaceutical Preparation Certificate for Medical Institution shall be revoked. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

**Article 76** Where enterprises or other institutions are engaged in production or sale of counterfeit or substandard drugs, if the circumstances are serious, the persons directly in charge and the other persons directly responsible shall be prohibited from engaging in the drug production or distribution within 10 years.

The drug substances, excipients, packaging materials and manufacturing equipment specially used for producing counterfeit or substandard drugs by any producer shall be confiscated.

**Article 77** Anyone who knows or should know that the drugs are counterfeit or substandard drugs provides conveniences such as transportation, keeping or storage of the drugs, all the earnings therefrom shall be confiscated, and a fine not less than 50 per cent of, but not more than 3 times, the amount of the illegal earnings shall also be imposed. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

**Article 78** The quality testing results provided by the drug testing institution shall be contained in the penalty notification regarding counterfeit and substandard drugs, except in cases specified in the provisions of Subparagraphs (1), (2), (5) and (6) of the third paragraph of Article 48 and the third paragraph of Article 49 of this Law.

**Article 79** Any drug manufacturer, drug distributor, institution for non-clinical safety study, or institution for drug clinical trial that does not implement the GMP, GSP, GLP or GCP according to regulations shall be given a disciplinary warning and shall be instructed to rectify within a time limit. If it fails to do so, it shall be instructed to suspend production or business operation or other work for rectification and shall also be fined not less than RMB5,000 yuan but not more than RMB20,000 yuan. If the circumstances are serious, the Drug Manufacturing Certificate, Drug Supply Certificate or the qualifications of the institution for drug clinical trial shall be annulled.

**Article 80** Any drug manufacturer, drug distributor or medical institution that, in violation of the provisions of Article 34 of this Law, purchases drugs from the enterprises without Drug Manufacturing Certificate or Drug Supply Certificate shall be instructed to rectify, the drugs illegally purchased shall be confiscated, and it shall be fined not less than two times but not more than five times the value of the drugs purchased; the illegal gains, if

any, shall be confiscated. If the circumstances are serious, the Drug Manufacturing Certificate, Drug Distribution Certificate, or the license for the medical institution shall be revoked.

**Article 81** If any enterprise that imports drugs to which import drug license has been granted fails to register, in accordance with the provisions of this Law, for the record with the drug regulatory department in the place where the port is located and drug importation is permitted, it shall be given a disciplinary warning and be instructed to rectify within a time limit; if it fails to do so, the import drug license shall be revoked.

**Article 82** If anyone falsifies, alters, trades in, rents out or lends the certificates or drug approval documents, the illegal gains shall be confiscated and a fine not less than, but not more than three times, the amount of the illegal gains shall be imposed; if there are no illegal gains, a fine not less than RMB 20, 000 yuan but not more than RMB 100,000 yuan shall be imposed. If the circumstances are serious, the Drug Manufacturing Certificate, Drug Supply Certificate or Pharmaceutical Preparation Certificate for Medical Institution of the party that sells, rents out or lends it shall be revoked. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

**Article 83** If anyone, in violation of the provisions of this Law, obtains the Drug Manufacturing Certificate, Drug Distribution Certificate, Pharmaceutical Preparation Certificate for Medical Institution, or drug approval documents by providing false certificates, documents and data, or samples, or by other fraudulent means, the said certificates shall be revoked and the documents shall be withdrawn, his applications for such certificates or approval documents shall be rejected within five years, and a fine not less than RMB 10, 000 yuan but more than RMB 30, 000 yuan shall also be imposed.

**Article 84** Any medical institution that sells its own dispensed pharmaceutical preparations on the market shall be instructed to rectify, the preparations for illegal sale shall be confiscated, and a fine not less than, but not more than three times, the value of the said preparations shall be imposed, and the illegal gains, if any, shall be confiscated.

**Article 85** Any drug distributor that violates the provisions of Article 18 and 19 of this Law shall be instructed to rectify and be given a disciplinary warning. If the circumstances are serious, the Drug Supply Certificate shall be revoked.

**Article 86** Where the drugs with labels or marks are not in conformity with the provisions of Article 54 of this Law, except for those treated as counterfeit or substandard drugs, an

instruction for rectification and a disciplinary warning shall be given. If the circumstances are serious, the approval documents for the drugs shall be withdrawn.

**Article 87** Where a drug testing institution issues a false testing report, if it constitutes a crime, criminal liabilities shall be investigated in accordance with law; if it does not constitute a crime, the institution shall be instructed to rectify and be given a disciplinary warning, and also be fined not less than RMB30, 000 yuan but not more than RMB 50, 000 yuan. The persons directly in charge and the other person directly responsible shall, in accordance with law, be punished with demotion, dismissal, or expulsion and also be fined not more than RMB 30, 000 yuan. The illegal gains, if any, shall be confiscated. If the circumstances are serious, the qualification for testing shall be annulled. If the testing result issued by the drug testing institution is not true to fact and losses are thus occasioned, the institution shall bear corresponding liability of compensation for losses.

**Article 88** The administrative sanctions prescribed in Article 73 through Article 87 of this Law shall be determined by the drug regulatory departments at or above the county level according to the division of responsibility defined by the drug regulatory department under the State Council. Revocation of the Drug Manufacturing Certificate, Drug Supply Certificate and Pharmaceutical Preparation Certificate for Medical Institution or withdrawal of the drug approval documents shall be determined by the department that issued the certificate or the approval documents.

**Article 89** Any violation of the provision of Article 55, 56 or 57 of this Law governing the control over drug pricing shall be punished pursuant to the provisions of the Pricing Law of the People's Republic of China.

**Article 90** Drug manufacturers, drug distributors or medical institutions that offer or accept, in private, the rake-offs or other benefits in the course of purchasing and selling drugs or drug manufacturers, drug distributors or their agents that offer money or things of value or other benefits to leading members, drug purchasers, physicians, or other related persons of the medical institutions where their drugs are used shall be fined not less than RMB 10, 000 yuan but not more than RMB 200, 000 yuan by the administrative department for industry and commerce, and the illegal gains, if any, shall be confiscated. If the circumstances are serious, the said department shall revoke the business licenses of the drug manufacturers or drug distributors and inform the drug regulatory department of the matter, which shall revoke their Drug Manufacturing Certificate, or Drug Distribution Certificate. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

**Article 91** Any leading members, purchasers or other related persons of drug manufacturers or distributors that, in the course of drug purchasing or selling, accept money or things of value or other benefits offered by other manufacturers, distributors or their agents shall be given sanctions according to law, and the illegal gains shall be confiscated. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

Leading members, drug purchasers, physicians or other related persons of medical institutions who accept money or things of value or other benefits offered by drug manufacturers, drug distributors or their agents shall be given sanctions by the administrative department for health or the institutions to which they belong, and the illegal gains shall be confiscated. With regard to licensed physicians who seriously violate laws, the administrative department for health shall revoke their licenses for medical practice. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

**Article 92** Any violation of the provisions of this Law related to the control over drug advertising shall be punished pursuant to the provisions of the Advertisement Law of the People's Republic of China, the drug regulatory department that issues the advertisement approval number shall withdraw it and shall, within one year, reject any application for approval of advertising for the drug in question. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

Where a drug regulatory department does not perform its duty of drug advertisement examination in accordance with law and the advertisement approved for issuance contains false information or other content violating laws or administrative regulations, administrative sanctions shall, in accordance with law, be given to the persons directly in charge and the other persons directly responsible. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

**Article 93** Drug manufacturers, drug distributors or medical institutions that violate the provisions of this Law and thus cause harm and losses to users of drugs shall bear the liability of compensation in accordance with law.

**Article 94** Any drug regulatory department that violates the provisions of this Law and commits one of the following acts shall be instructed by the competent authority at the next higher level or the supervisory body to recall the certificates unlawfully issued or to withdraw the drug approval documents, and administrative sanctions shall be given to the persons directly in charge and the other persons directly responsible in accordance with

law. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

(1) issuing the GMP and GSP certificates to the enterprises that do not comply with the corresponding requirements, failing to perform, in accordance with regulations, the duty of follow-up inspections in respect of the enterprises that have obtained the certificates, or failing to instruct, in accordance with law, the enterprises not complying with the requirements to rectify or withdraw their certificates;

(2) issuing the Drug Manufacturing Certificate, Drug Supply Certificate or Pharmaceutical Preparation Certificate for Medical Institution to the enterprises or institutions that do not comply with the statutory requirements;

(3) issuing an Import Drug License to the drug that does not comply with the requirements for import; or

(5) granting approval for conducting a clinical trial, issuing a New Drug Certificate or a drug approval number, where the requirements for clinical trial or drug production are not fulfilled.

**Article 95** If any drug regulatory department, drug testing institution established by the department or institutions specially engaged in drug testing designated by the department is involved in drug production or distribution, it shall be instructed by the authority at the next high level or the supervisory body to rectify, and the illegal gains, if any, shall be confiscated. If the circumstances are serious, administrative sanctions shall be given to the persons directly in charge and the other persons directly responsible in accordance with law. Any staff member of the drug regulatory department, drug testing institution established by the department or institution specially engaged in drug testing designated by the department who is involved in drug production or distribution shall be given an administrative sanction in accordance with law.

**Article 96** If any drug regulatory department or drug testing institution established or designated by the department, in violation of law, collects testing fees for supervision over drug testing shall be instructed by the relevant government department to return the fees, and administrative sanctions shall be given to the persons directly in charge and the other persons directly responsible in accordance with law. Any drug testing institution that collects testing fees in violation of law, if the circumstances are serious, shall be disqualified for drug testing.

**Article 97** Drug regulatory departments shall, in accordance with law, perform their duties of supervision and inspection and shall see to it that the enterprises holding the Drug Manufacturing Certificate or Drug Supply Certificate engage in drug production or drug distribution in accordance with the provisions of this Law.

Where enterprises holding the Drug Manufacturing Certificate or Drug Supply Certificate produce or sell counterfeit or substandard drugs, the legal liabilities of such enterprises shall be investigated and, in addition, the persons directly in charge and the other persons directly responsible of the drug regulatory departments who neglect their duty or commit dereliction of duty shall be given administrative sanctions in accordance with law. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

**Article 98** The drug regulatory department shall instruct the drug regulatory department at a lower level to put right, within a time limit, the administrative action taken in violation of this Law, and it shall have the power to alter or annual the action which is not put right within the time limit.

**Article 99** Anyone responsible for drug regulation who abuses his power, engages in malpractice for personal gain or neglects his duty, if it constitutes a crime, shall be investigated for criminal liabilities in accordance with law; if it is not serious enough to constitute a crime, he shall be given administrative sanctions in accordance with law.

**Article 100** Where a Drug Manufacturing Certificate or Drug Distribution Certificate is revoked in accordance with this Law, the drug regulatory department shall notify the administrative department for industry and commerce to alter or cancel the registration.

**Article 101** The value of products mentioned in this Chapter shall be calculated on the basis of the marked prices of the drugs illegally produced or sold; where there is no marked price, the value shall be calculated according to the market prices of drugs of the same kind.

## Chapter X Supplementary Provisions

**Article 102** The terms used in this Law are defined as follows:

Drugs refer to articles which are used in the prevention, treatment and diagnosis of human diseases and intended for the regulation of the physiological functions of human beings, for which indications, usage and dosage are established, including Chinese

crude drugs, prepared slices of Chinese crude drugs, traditional Chinese medicine preparations, chemical drugs substances and their preparations, antibiotics, biochemical drugs, radioactive pharmaceuticals, serum, vaccines, blood products and diagnostic agents.

Excipients refer to the vehicles and additives used for drug production and prescription dispensing.

Drug manufacturers refer to enterprises exclusively or partly engaged in drug production.

Drug distributors refer to enterprises exclusively or partly engaged in drug distribution.

**Article 103** Measures for control over the cultivation, collection and breeding of Chinese crude drugs shall be separately formulated by the State Council.

**Article 104** The State exercises special control over the circulation of preventive biological products. Specific measures shall be formulated by the State Council.

**Article 105** Specific measures for enforcement of this Law by the Chinese People's Liberation Army shall be formulated by the State Council and Central Military Commission in accordance with this Law.

**Article 106** This Law shall go into effect as of December 1, 2001.