|  |  |  |
| --- | --- | --- |
| 发文机关  Promulgator | ：  : | 全国人民代表大会常务委员会  The Standing Committee of the National People's Congress |
| 发布日期  Date of Issue | ：  : | 2015.04.24  2015.04.24 |
| 生效日期  Effective Date | ：  : | 2015.04.24  2015.04.24 |
| 时效性  Effectiveness | ：  : | 现行有效  Current |

# 中华人民共和国药品管理法（2015修订）

# Drug Administration Law of the People's Republic of China (Revision 2015)

中华人民共和国药品管理法（2015修订）

Drug Administration Law of the People's Republic of China (Revision 2015)

(1984年9月20日第六届全国人民代表大会常务委员会第七次会议通过 2001年2月28日第九届全国人民代表大会常务委员会第二十次会议修订根据 2013年12月28日第十二届全国人民代表大会常务委员会第六次会议《关于修改等七部法律的决定》第一次修正 根据2015年4月24日第十二届全国人民代表大会常务委员会第十四次会议《关于修改的决定》第二次修正)

(Adopted at the 7th Meeting of the Standing Committee of the 6th National People's Congress on September 20, 1984; revised at the 20th Meeting of the Standing Committee of the 9th National People's Congress on February 28, 2001; amended for the first time according to the Decision on Amending Seven Laws passed at the 6th Meeting of the Standing Committee of the 12th National People's Congress on December 28, 2013; and amended for the second time according to the Decision on Amending Seven Laws passed at the 14th Meeting of the Standing Committee of the 12th National People's Congress on April 24, 2015)

　　第一章　总则

Chapter 1 General Provisions

　　第二章　药品生产企业管理

Chapter 2 Administration of Pharmaceutical Producing Enterprises

　　第三章　药品经营企业管理

Chapter 3 Administration of Pharmaceutical Trading Enterprises

　　第四章　医疗机构的药剂管理

Chapter 4 Control over Pharmaceuticals in Medical Institutions

　　第五章　药品管理

Chapter 5 Administration over Drugs

　　第六章　药品包装的管理

Chapter 6 Drug Packaging Management

　　第七章　药品价格和广告的管理

Chapter 7 Drug Pricing and Advertising Management

　　第八章　药品监督

Chapter 8 Drug Supervision

　　第九章　法律责任

Chapter 9 Legal Liabilities

　　第十章　附则

Chapter 10 Supplementary Provisions

第一章 总则

Chapter 1 General Provisions

第一条   为加强药品监督管理，保证药品质量，保障人体用药安全，维护人民身体健康和用药的合法权益，特制定本法。

Article 1. This Law is formulated in order to strengthen drug control and administration, ensure the quality of drugs, guarantee safe drug use for human beings and safeguard the health of the people and their legal rights and interests in drug use.

第二条   在中华人民共和国境内从事药品的研制、生产、经营、使用和监督管理的单位或者个人，必须遵守本法。

Article 2 All entities and individuals engaged in research, production, distribution and use of, and supervision and administration over, drugs within the territory of the People's Republic of China shall comply with the Law.

第三条   国家发展现代药和传统药，充分发挥其在预防、医疗和保健中的作用。

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

国家保护野生药材资源，鼓励培育中药材。

The State protects the resources of wild medicinal materials and encourages the cultivation of Chinese traditional medicinal materials.

第四条   国家鼓励研究和创制新药，保护公民、法人和其他组织研究、开发新药的合法权益。

The State encourages the research and development of new drugs and protects the legal rights and interests of citizens, legal persons and other organisations in the research and development of new drugs.

第五条   国务院药品监督管理部门主管全国药品监督管理工作。国务院有关部门在各自的职责范围内负责与药品有关的监督管理工作。

Article 5 The drug regulatory department under the State Council is responsible for drug supervision and administration nationwide. Other relevant departments under the State Council are responsible for the supervision and control of pharmaceuticals related to the scope of their functions.

省、自治区、直辖市人民政府药品监督管理部门负责本行政区域内的药品监督管理工作。省、自治区、直辖市人民政府有关部门在各自的职责范围内负责与药品有关的监督管理工作。

The drug control and administration departments of the people's governments of a province, autonomous region or centrally administered municipality are responsible for drug control and administration within their administrative regions. The relevant departments of the people's governments of provinces, autonomous regions, and municipalities directly under the Central Government are responsible for the supervision and control of pharmaceuticals related to the scope of their functions.

国务院药品监督管理部门应当配合国务院经济综合主管部门，执行国家制定的药品行业发展规划和产业政策。

The drug regulatory department under the State Council shall cooperate with the comprehensive economic department under the State Council in implementing the pharmaceutical development plan and industrial policies formulated by the State.

第六条   药品监督管理部门设置或者确定的药品检验机构，承担依法实施药品审批和药品质量监督检查所需的药品检验工作。

Article 6 The pharmaceutical inspection institutions established or designated by the pharmaceutical supervisory and administrative departments shall be responsible for the examination and approval of pharmaceuticals and the supervision and inspection of pharmaceutical quality in accordance with laws.

第二章 药品生产企业管理

Chapter 2 Administration of Pharmaceutical Producing Enterprises

第七条   开办药品生产企业，须经企业所在地省、自治区、直辖市人民政府药品监督管理部门批准并发给《药品生产许可证》。无《药品生产许可证》的，不得生产药品。

Article 7. The establishment of a drug -producing enterprise must be approved by, and the Drug Production Licence shall be issued by, the drug control and administrative department of the people's government of a province, autonomous region or centrally administered municipality in which the enterprise is located. No drug production is permitted without the Drug Production Licence.

《药品生产许可证》应当标明有效期和生产范围，到期重新审查发证。

The Pharmaceutical Production License shall bear the scope of production and a period of validity, and upon expiration a new license shall be issued after examination for its renewal.

药品监督管理部门批准开办药品生产企业，除依据本法第八条规定的条件外，还应当符合国家制定的药品行业发展规划和产业政策，防止重复建设。

Apart from the provisions in Article 8 of this Law, the approval of the establishment of a drug-producing enterprise by the drug control and administration department shall be in accordance with the development plans for the drug industry and the industrial policies stipulated by the State and shall avoid duplication.

第八条   开办药品生产企业，必须具备以下条件:

Article 8 To establish a pharmaceutical producing enterprise, the following requirements must be met:

（一）具有依法经过资格认定的药学技术人员、工程技术人员及相应的技术工人；

1. having legally qualified pharmaceutical professionals, engineering professionals, and the corresponding technical workers;

（二）具有与其药品生产相适应的厂房、设施和卫生环境；

(II) having plant, facilities and sanitary environment suitable for its pharmaceutical production;

（三）具有能对所生产药品进行质量管理和质量检验的机构、人员以及必要的仪器设备；

(III) having the organization, personnel and necessary instruments and equipment capable of quality control and inspection for the drugs produced;

（四）具有保证药品质量的规章制度。

4. having rules and regulations to ensure the quality of drugs.

第九条   药品生产企业必须按照国务院药品监督管理部门依据本法制定的《药品生产质量管理规范》组织生产。药品监督管理部门按照规定对药品生产企业是否符合《药品生产质量管理规范》的要求进行认证；对认证合格的，发给认证证书。

Article 9. Drug-producing enterprises must organise their production in accordance with the Standards for Quality Control of Drug Production stipulated by the drug control and administrative department of the State Council on the basis of this Law. The drug control and administrative departments shall, in accordance with the regulations, conduct assessment in regard to whether or not a drug-producing enterprise meets the requirements of the Standards for Quality Control of Drug Production and shall issue assessment certificates to those which pass the assessment.

《药品生产质量管理规范》的具体实施办法、实施步骤由国务院药品监督管理部门规定。

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

第十条   除中药饮片的炮制外，药品必须按照国家药品标准和国务院药品监督管理部门批准的生产工艺进行生产，生产记录必须完整准确。药品生产企业改变影响药品质量的生产工艺的，必须报原批准部门审核批准。

Article 10 Except for the preparation of Chinese medicines into ready-to-use forms, pharmaceuticals must be produced in accordance with the national pharmaceutical standard and the technological procedures approved by the supervisory and administrative departments of pharmaceuticals under the State Council, and the record of production must be complete and accurate. If a drug-producing enterprise makes changes in the technological processes affecting the quality of the drugs, the enterprise must submit the changes for examination and approval to the original approval authorities.

中药饮片必须按照国家药品标准炮制；国家药品标准没有规定的，必须按照省、自治区、直辖市人民政府药品监督管理部门制定的炮制规范炮制。省、自治区、直辖市人民政府药品监督管理部门制定的炮制规范应当报国务院药品监督管理部门备案。

The prepared slices of traditional Chinese drugs shall be processed in conformity with the national drug standards. Those not covered by the national drug standards shall be processed in accordance with the processing standards formulated by the drug regulatory departments of the people's governments of the provinces, autonomous regions and municipalities directly under the Central Government. The said processing norms shall be submitted to the drug regulatory department under the State Council for the record.

第十一条   生产药品所需的原料、辅料，必须符合药用要求。

Article 11 The raw and supplementary materials used for the production of pharmaceuticals must conform to the requirements for medicinal use.

第十二条   药品生产企业必须对其生产的药品进行质量检验；不符合国家药品标准或者不按照省、自治区、直辖市人民政府药品监督管理部门制定的中药饮片炮制规范炮制的，不得出厂。

Article 12. Drug-producing enterprises must conduct quality tests on the drugs they produce. Where the drugs do not comply with the state drug standards or the processing standards for the processing of Chinese medicinal liquids and tablets stipulated by the drug control and administrative department of the people's government of a province, autonomous region or centrally administered municipality, the drugs must not leave the factory.

第十三条   经省、自治区、直辖市人民政府药品监督管理部门批准，药品生产企业可以接受委托生产药品。

Article 13. With the approval of the drug control and administrative department of the people's government of a province, autonomous region or centrally administered municipality, drug-producing enterprises may accept commissions to produce drugs.

第三章 药品经营企业管理

Chapter 3 Administration of Pharmaceutical Trading Enterprises

第十四条   开办药品批发企业，须经企业所在地省、自治区、直辖市人民政府药品监督管理部门批准并发给《药品经营许可证》；开办药品零售企业，须经企业所在地县级以上地方药品监督管理部门批准并发给《药品经营许可证》。无《药品经营许可证》的，不得经营药品。

Article 14. The establishment of a drug - wholesaling enterprise must be approved by the drug control and administrative department of the people's government of a province, autonomous region or centrally administered municipality where the enterprise is located, and must obtain the Drug-trading Licence. The establishment of a drug retailing enterprise must be approved by the local drug control and administrative department at county level or above where the enterprise is located, and the Drug-trading Licence must be obtained. No one is allowed to distribute drugs without a Drug Distribution Certificate.

《药品经营许可证》应当标明有效期和经营范围，到期重新审查发证。

A Pharmaceutical Trade License shall bear a scope of business and a period of validity, and upon expiration a new license shall be issued after examination for its renewal.

药品监督管理部门批准开办药品经营企业，除依据本法第十五条规定的条件外，还应当遵循合理布局和方便群众购药的原则。

Apart from the provisions in Article 15 of this Law, the approval of the establishment of a pharmaceutical trading enterprise by the pharmaceutical supervisory and administrative departments shall follow the principle of rational location and convenience for buying of pharmaceuticals by the people.

第十五条   开办药品经营企业必须具备以下条件:

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

（一）具有依法经过资格认定的药学技术人员；

1. having legally qualified pharmaceutical professionals;

（二）具有与所经营药品相适应的营业场所、设备、仓储设施、卫生环境；

(II) It shall have business premises, equipment, warehouse facilities and sanitary conditions suitable for the pharmaceuticals in which it trades.

（三）具有与所经营药品相适应的质量管理机构或者人员；

(III) It shall have a quality control organ or personnel suitable for the pharmaceuticals in which it trades.

（四）具有保证所经营药品质量的规章制度。

(IV) It shall have rules and regulations designed to ensure the quality of pharmaceuticals in which it trades.

第十六条   药品经营企业必须按照国务院药品监督管理部门依据本法制定的《药品经营质量管理规范》经营药品。药品监督管理部门按照规定对药品经营企业是否符合《药品经营质量管理规范》的要求进行认证；对认证合格的，发给认证证书。

Article 16 Drug distributors shall conduct drug distribution in accordance with the Good Distribution Practice for Drugs formulated by the drug regulatory department under the State Council based on the Law. The drug regulatory departments shall inspect a drug distributor for its compliance with the requirements of the Good Distribution Practice for Drugs, and issue a certificate to the distributor passing the inspection.

《药品经营质量管理规范》的具体实施办法、实施步骤由国务院药品监督管理部门规定。

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

第十七条   药品经营企业购进药品，必须建立并执行进货检查验收制度，验明药品合格证明和其他标识；不符合规定要求的，不得购进。

Article 17. On purchasing drugs, a drug-trading enterprise must establish and implement a system of stock inspection and acceptance. Quality certificates and other labels of the drugs must be verified. Where drugs do not satisfy the stipulated requirements, they may not be purchased.

第十八条   药品经营企业购销药品，必须有真实完整的购销记录。购销记录必须注明药品的通用名称、剂型、规格、批号、有效期、生产厂商、购（销）货单位、购（销）货数量、购销价格、购（销）货日期及国务院药品监督管理部门规定的其他内容。

Article 18 Pharmaceutical trading enterprises shall keep accurate and complete records of purchased pharmaceuticals. Purchase and sale records shall indicate the generic name of the drug, dosage form, specification, batch number, expiry date, manufacturer, purchasing (selling) unit, purchasing (selling) quantity, purchasing and selling price, purchasing (selling) date and other items specified by the drug regulatory department under the State Council.

第十九条   药品经营企业销售药品必须准确无误，并正确说明用法、用量和注意事项；调配处方必须经过核对，对处方所列药品不得擅自更改或者代用。对有配伍禁忌或者超剂量的处方，应当拒绝调配；必要时，经处方医师更正或者重新签字，方可调配。

Article 19. Drugs sold by a drug-trading enterprise must be presented correctly; the method of use, dosage and points to note must be explained precisely. In making up prescriptions, checks must be carried out; the drugs itemised in the prescription must not be altered or substituted without authorisation. Where a prescription contains ingredients that are incompatible or amounts of ingredients in excess of the proper dosage, a request to make up the prescription shall be refused; if necessary, after the prescribing doctor has corrected it or signed it again, it may be made up.

药品经营企业销售中药材，必须标明产地。

When traditional Chinese medicinal materials are offered for sale by pharmaceutical trading enterprises, their origin must be indicated.

第二十条   药品经营企业必须制定和执行药品保管制度，采取必要的冷藏、防冻、防潮、防虫、防鼠等措施，保证药品质量。

Article 20 Rules for storage of pharmaceuticals shall be formulated and implemented by pharmaceutical trading enterprises, which must adopt necessary measures to facilitate cold storage and protection against freeze, moisture, insects and rodents to ensure pharmaceutical quality.

药品入库和出库必须执行检查制度。

An inspection system shall be carried out in relation to drugs which are brought into or removed from the warehouse.

第二十一条   城乡集市贸易市场可以出售中药材，国务院另有规定的除外。

Article 21. Chinese medicinal materials may be sold at urban or rural fairs, except as otherwise stipulated by the State.

城乡集市贸易市场不得出售中药材以外的药品，但持有《药品经营许可证》的药品零售企业在规定的范围内可以在城乡集市贸易市场设点出售中药材以外的药品。具体办法由国务院规定。

No drugs other than the traditional Chinese drugs may be sold at urban or rural trade markets, but drug retailers holding a Drug Distribution Certificate may, within the specified scope, sell such drugs at stores they set up at urban or rural trade markets. The specific measures shall be formulated by the State Council.

第四章 医疗机构的药剂管理

Chapter 4 Control over Pharmaceuticals in Medical Institutions

第二十二条   医疗机构必须配备依法经过资格认定的药学技术人员。非药学技术人员不得直接从事药剂技术工作。

Article 22 A medical institution shall be staffed with legally qualified pharmaceutical professionals. No one other than a pharmaceutical technician may directly engage in technical work in pharmacy.

第二十三条   医疗机构配制制剂，须经所在地省、自治区、直辖市人民政府卫生行政部门审核同意，由省、自治区、直辖市人民政府药品监督管理部门批准，发给《医疗机构制剂许可证》。无《医疗机构制剂许可证》的，不得配制制剂。

Article 23 To dispense pharmaceutical preparations, a medical institution shall be subject to examination and approval by the administrative department for health of the people's government of the province, autonomous region or municipality directly under the Central Government where the medical institution is located, 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 the medical institution. No medicinal preparations shall be made without a Dispensing Permit for Medical Organizations.

《医疗机构制剂许可证》应当标明有效期，到期重新审查发证。

The valid term shall be indicated in a Pharmaceutical Preparation Certificate for Medical Institution. For renewal of the certificate upon expiration, reexamination is required.

第二十四条   医疗机构配制制剂，必须具有能够保证制剂质量的设施、管理制度、检验仪器和卫生条件。

Article 24 To dispense pharmaceutical preparations, a medical institution shall have the facilities, management system, testing instruments and sanitary conditions for ensuring their quality.

第二十五条   医疗机构配制的制剂，应当是本单位临床需要而市场上没有供应的品种，并须经所在地省、自治区、直辖市人民政府药品监督管理部门批准后方可配制。配制的制剂必须按照规定进行质量检验；合格的，凭医师处方在本医疗机构使用。特殊情况下，经国务院或者省、自治区、直辖市人民政府的药品监督管理部门批准，医疗机构配制的制剂可以在指定的医疗机构之间调剂使用。

Article 25 The pharmaceutical preparations to be dispensed by a medical institution shall be those meeting the clinical need of the institution but not available on the market and shall be subject to prior approval 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 medicinal preparations made by medical organizations must be inspected in accordance with relevant regulations. Those preparations conforming to standard can be used as the doctor prescribes. Under special circumstances, with the approval of the pharmaceutical supervisory and administrative departments of the State Council or of the provinces, autonomous regions and municipalities directly under the central government, the pharmaceutical preparations dispensed by medical organizations can be used by other designated medical organizations.

医疗机构配制的制剂，不得在市场销售。

No pharmaceutical preparations dispensed by medical institutions may be marketed.

第二十六条   医疗机构购进药品，必须建立并执行进货检查验收制度，验明药品合格证明和其他标识；不符合规定要求的，不得购进和使用。

Article 26 When purchasing pharmaceuticals, medical organizations must establish and implement a system of quality inspection and check the certificates and other marks of pharmaceuticals. Those pharmaceuticals that do not meet the requirements of relevant regulations must not be purchased and used.

第二十七条   医疗机构的药剂人员调配处方，必须经过核对，对处方所列药品不得擅自更改或者代用。对有配伍禁忌或者超剂量的处方，应当拒绝调配；必要时，经处方医师更正或者重新签字，方可调配。

Article 27 Prescriptions being dispensed by pharmacists of medical institutions shall be checked, and no drug listed therein may be changed or substituted without authorization. Where a prescription contains ingredients that are incompatible or amounts of ingredients in excess of the proper dosage, a request to make up the prescription shall be refused; if necessary, after the prescribing doctor has corrected it or signed it again, it may be made up.

第二十八条   医疗机构必须制定和执行药品保管制度，采取必要的冷藏、防冻、防潮、防虫、防鼠等措施，保证药品质量。

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

第五章 药品管理

Chapter 5 Administration over Drugs

第二十九条   研制新药，必须按照国务院药品监督管理部门的规定如实报送研制方法、质量指标、药理及毒理试验结果等有关资料和样品，经国务院药品监督管理部门批准后，方可进行临床试验。药物临床试验机构资格的认定办法，由国务院药品监督管理部门、国务院卫生行政部门共同制定。

Article 29. Where a new drug has been researched and developed, in accordance with the regulations set down by the drug control and administrative department of the State Council, a report must be submitted, together with samples, giving details of the method of research and development, quality norms, results of pharmacological and toxicological tests and other relevant data. A clinical test can be carried out only after approval has been obtained from the drug control and administrative department of the State Council. Measures for verifying the qualifications of clinical drug trial institutions shall be jointly formulated by the drug regulatory department and the administrative department for health under the State Council.

完成临床试验并通过审批的新药，由国务院药品监督管理部门批准，发给新药证书。

Where a new drug has completed its clinical tests and passed the examination and approval, a new drug certificate shall be issued upon approval by the drug control and administrative department of the State Council.

第三十条   药物的非临床安全性评价研究机构和临床试验机构必须分别执行药物非临床研究质量管理规范、药物临床试验质量管理规范。

Article 30 Institutions for non-clinical safety evaluation and research of drugs and institutions for clinical trial of drugs shall respectively implement quality management standards for non-clinical drug research and quality management standards for clinical drug trials.

药物非临床研究质量管理规范、药物临床试验质量管理规范由国务院确定的部门制定。

The good practices of non-clinical drug research and good practices of clinical drug trials shall be formulated by the department designated by the State Council.

第三十一条   生产新药或者已有国家标准的药品的，须经国务院药品监督管理部门批准，并发给药品批准文号；但是，生产没有实施批准文号管理的中药材和中药饮片除外。实施批准文号管理的中药材、中药饮片品种目录由国务院药品监督管理部门会同国务院中医药管理部门制定。

Article 31 A new medicine or medicine standardized by the State can be put into production only after the pharmaceutical supervisory and administrative department under the State Council has approved it and issued a registered document of approval, with the exception of the traditional Chinese medicines and the prepared slices of traditional Chinese medicines over which no control by registered document of approval is exercised. The drug regulatory department under the State Council shall, in concert with the administrative department for traditional Chinese medicines under the State Council, formulate the catalogue of varieties of traditional Chinese medicinal materials and Chinese herbal medicines subject to approval number control.

药品生产企业在取得药品批准文号后，方可生产该药品。

A drug manufacturer may produce the drug only after an approval number is obtained.

第三十二条   药品必须符合国家药品标准。中药饮片依照本法第十条第二款的规定执行。

Article 32 Pharmaceuticals must meet the pharmaceutical standards of the State. The provisions of paragraph 2 of Article 10 of the Law apply to the prepared slices of traditional Chinese drugs.

国务院药品监督管理部门颁布的《中华人民共和国药典》和药品标准为国家药品标准。

The Pharmacopoeia of the People's Republic of China and the pharmaceutical standards promulgated by the pharmaceutical supervisory and administrative department under the State Council shall be the State pharmaceutical standards.

国务院药品监督管理部门组织药典委员会，负责国家药品标准的制定和修订。

The pharmaceutical supervisory and administrative department under the State Council shall organize the Pharmacopoeia Committee which shall be responsible for the formulation and revision of the state pharmaceutical standards.

国务院药品监督管理部门的药品检验机构负责标定国家药品标准品、对照品。

The drug testing institutions of the drug regulatory department under the State Council are responsible for defining the national drug standard substance and reference substance.

第三十三条   国务院药品监督管理部门组织药学、医学和其他技术人员，对新药进行审评，对已经批准生产的药品进行再评价。

Article 33. The drug control and administrative department of the State Council shall organise pharmaceutical, medical and other technical personnel to evaluate new drugs and re-evaluate drugs which have already been approved for production.

第三十四条   药品生产企业、药品经营企业、医疗机构必须从具有药品生产、经营资格的企业购进药品；但是，购进没有实施批准文号管理的中药材除外。

Article 34. Drug-producing enterprises, drug-trading enterprises and medical organisations must purchase drugs from enterprises which are qualified to produce and trade drugs. However, the purchase of the Chinese medicinal materials which are not controlled under the approval number system is excepted.

第三十五条   国家对麻醉药品、精神药品、医疗用毒性药品、放射性药品，实行特殊管理。管理办法由国务院制定。

Article 35 The State exercises special control over narcotic drugs, psychotropic substances, toxic drugs for medical use and radioactive drugs. Administrative measures shall be formulated by the State Council.

第三十六条   国家实行中药品种保护制度。具体办法由国务院制定。

Article 36 The State adopts a protection system for certain traditional Chinese medicines. Specific measures shall be formulated by the State Council.

第三十七条   国家对药品实行处方药与非处方药分类管理制度。具体办法由国务院制定。

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

第三十八条   禁止进口疗效不确、不良反应大或者其他原因危害人体健康的药品。

Article 38 Import of medicines whose curative effects are uncertain or poor, or which produce adverse reactions or have other harmful effects on human health shall be prohibited.

第三十九条   药品进口，须经国务院药品监督管理部门组织审查，经审查确认符合质量标准、安全有效的，方可批准进口，并发给进口药品注册证书。

Article 39 The import of medicines must go through examinations organized by the pharmaceutical supervisory and administrative department under the State Council. Those confirmed to conform to quality standards to be safe and effective can be approved to be imported and shall be issued a registered certificate for import.

医疗单位临床急需或者个人自用进口的少量药品，按照国家有关规定办理进口手续。

Medicines to be imported in small quantities for urgent clinical needs by medical institutions or for personal use shall go through import formalities in accordance with the relevant regulations of the State.

第四十条   药品必须从允许药品进口的口岸进口，并由进口药品的企业向口岸所在地药品监督管理部门登记备案。海关凭药品监督管理部门出具的《进口药品通关单》放行。无《进口药品通关单》的，海关不得放行。

Article 40 Drugs shall be imported via the ports where drug importation is permitted, and registered for the record by the drug importers with the drug regulatory departments in the places where the ports are located. The customs shall release the drugs based on the Drug Import Note issued by the said departments. Those without the Import Pharmaceuticals Customs Form shall not be permitted to pass through Customs.

口岸所在地药品监督管理部门应当通知药品检验机构按照国务院药品监督管理部门的规定对进口药品进行抽查检验，并依照本法第四十一条第二款的规定收取检验费。

The pharmaceutical supervisory and administrative departments where the ports are located shall notify the pharmaceutical inspection institutions to carry out selective examinations and inspections on the imported pharmaceuticals according to the regulations stipulated by the pharmaceutical supervisory and administrative department under the State Council, and shall charge inspection fees according to Article 41 (2) of this Law.

允许药品进口的口岸由国务院药品监督管理部门会同海关总署提出，报国务院批准。

The ports which are permitted to import drugs shall be jointly nominated by the drug control and administrative department of the State Council and the General Administration of Customs, and approved by the State Council.

第四十一条   国务院药品监督管理部门对下列药品在销售前或者进口时，指定药品检验机构进行检验；检验不合格的，不得销售或者进口:

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:

（一）国务院药品监督管理部门规定的生物制品；

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

（二）首次在中国销售的药品；

(II) Drugs to be sold in China for the first time; or

（三）国务院规定的其他药品。

(III) other pharmaceuticals prescribed by the State Council.

前款所列药品的检验费项目和收费标准由国务院财政部门会同国务院价格主管部门核定并公告。检验费收缴办法由国务院财政部门会同国务院药品监督管理部门制定。

The testing items to be charged for the drugs listed in the preceding paragraph and the charging rates shall be ratified and announced by the financial department under the State Council in concert with the competent price department under the State Council. The measures for collecting inspection fees shall be formulated by the financial department under the State Council jointly with the drug regulatory department under the State Council.

第四十二条   国务院药品监督管理部门对已经批准生产或者进口的药品，应当组织调查；对疗效不确、不良反应大或者其他原因危害人体健康的药品，应当撤销批准文号或者进口药品注册证书。

Article 42 The pharmaceutical supervisory and administrative department under the State Council shall organize investigations on medicines which have been approved for production or importation. It shall revoke the registered documents of approval or the registered certificate of import if it discovers that the medicines' curative effects are uncertain or poor, that they produce serious adverse reactions, or that for other reasons they are harmful to people's health.

已被撤销批准文号或者进口药品注册证书的药品，不得生产或者进口、销售和使用；已经生产或者进口的，由当地药品监督管理部门监督销毁或者处理。

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

第四十三条   国家实行药品储备制度。

Article 43 The State adopts a system for drug reserve.

国内发生重大灾情、疫情及其他突发事件时，国务院规定的部门可以紧急调用企业药品。

In case of serious disasters, epidemic situations and other emergencies, the department prescribed by the State Council may transfer drugs from enterprises to meet such emergencies.

第四十四条   对国内供应不足的药品，国务院有权限制或者禁止出口。

Article 44. The State Council has the power to restrict or prohibit the export of drugs in insufficient supply for the domestic market.

第四十五条   进口、出口麻醉药品和国家规定范围内的精神药品，必须持有国务院药品监督管理部门发给的《进口准许证》、《出口准许证》。

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.

第四十六条   新发现和从国外引种的药材，经国务院药品监督管理部门审核批准后，方可销售。

Article 46 Newly discovered domestic medicinal plants or medicinal plants introduced from abroad may be sold only after they have been examined and approved by the pharmaceutical regulatory department under the State Council.

第四十七条   地区性民间习用药材的管理办法，由国务院药品监督管理部门会同国务院中医药管理部门制定。

Article 47 Administrative measures for the folk crude drugs customarily used in certain regions shall be formulated by the drug regulatory department under the State Council in concert with the administrative department for traditional Chinese medicines under the State Council.

第四十八条   禁止生产（包括配制，下同）、销售假药。

Article 48 Production (including dispensing, hereinafter the same) and sale of counterfeit drugs are prohibited.

有下列情形之一的，为假药:

A fake medicine has any one of the following characteristics:

（一）药品所含成份与国家药品标准规定的成份不符的；

1. the ingredients in the drug are inconsistent with those specified by the national drug standards;

（二）以非药品冒充药品或者以他种药品冒充此种药品的。

(II) a non-drug substance is passed off as a drug, or one drug is passed off as another.

有下列情形之一的药品，按假药论处:

A medicine shall be handled as fake medicine in any of the following cases:

（一）国务院药品监督管理部门规定禁止使用的；

1. the use is prohibited by the provisions of the drug regulatory department under the State Council;

（二）依照本法必须批准而未经批准生产、进口，或者依照本法必须检验而未经检验即销售的；

(II) Producing or importing goods or selling goods without being approved or inspected as required by this Law;

（三）变质的；

(III) it has deteriorated;

（四）被污染的；

(IV) being polluted;

（五）使用依照本法必须取得批准文号而未取得批准文号的原料药生产的；

(V) it is produced by using crude drugs without approval numbers as required by the Law; and

（六）所标明的适应症或者功能主治超出规定范围的。

(VI) The indications or functions indicated are beyond the specified scope.

第四十九条   禁止生产、销售劣药。

Article 49. It is prohibited to produce or sell inferior drugs.

药品成份的含量不符合国家药品标准的，为劣药。

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

有下列情形之一的药品，按劣药论处:

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

（一）未标明有效期或者更改有效期的；

1. the expiration date is not indicated or is altered;

（二）不注明或者更改生产批号的；

2. the batch number is not indicated or is altered;

（三）超过有效期的；

3. the medicine has passed its expiry date;

（四）直接接触药品的包装材料和容器未经批准的；

(IV) the packaging materials or containers in direct contact with drugs have not been approved;

（五）擅自添加着色剂、防腐剂、香料、矫味剂及辅料的；

(V) colorants, preservatives, spices, flavorings and accessories are added without authorization;

（六）其他不符合药品标准规定的。

(VI) The medicine fails to meet the prescribed standards in other respects.

第五十条   列入国家药品标准的药品名称为药品通用名称。已经作为药品通用名称的，该名称不得作为药品商标使用。

Article 50 The names of the drugs listed in the national drug standards shall be the generic names of the drugs. Such a common name may not be used as a trademark of the drug.

第五十一条   药品生产企业、药品经营企业和医疗机构直接接触药品的工作人员，必须每年进行健康检查。患有传染病或者其他可能污染药品的疾病的，不得从事直接接触药品的工作。

Article 51 Personnel in pharmaceutical producing or trading enterprises and in medical organizations who have direct contact with medicines must undergo an annual medical examination. Those who suffer from infectious diseases or other diseases that may contaminate drugs may not engage in work involving direct contact with drugs.

第六章 药品包装的管理

Chapter 6 Drug Packaging Management

第五十二条   直接接触药品的包装材料和容器，必须符合药用要求，符合保障人体健康、安全的标准，并由药品监督管理部门在审批药品时一并审批。

Article 52 Packaging materials and containers in direct contact with drugs shall meet the requirements for medicinal use and the standards for ensuring human health and safety, and shall, along with the drugs, be subject to examination and approval by the drug regulatory departments.

药品生产企业不得使用未经批准的直接接触药品的包装材料和容器。

Drug-producing enterprises must not use unapproved packing materials or containers which have direct contact with drugs.

对不合格的直接接触药品的包装材料和容器，由药品监督管理部门责令停止使用。

The drug control and administrative department shall order suspension of the use of rejected packaging materials and containers which have direct contact with drugs.

第五十三条   药品包装必须适合药品质量的要求，方便储存、运输和医疗使用。

Article 53 Packaging must meet the specific quality requirements of the pharmaceuticals and facilitate their storage, transportation and medical use.

发运中药材必须有包装。在每件包装上，必须注明品名、产地、日期、调出单位，并附有质量合格的标志。

Traditional Chinese medicines must be packaged before transportation. On each package, the name of the product, its place of origin, the date and the consignor must be indicated and a sign for compliance with the quality standards must be marked.

第五十四条   药品包装必须按照规定印有或者贴有标签并附有说明书。

Article 54 Packages of drugs shall be labeled and instructions attached as required.

标签或者说明书上必须注明药品的通用名称、成份、规格、生产企业、批准文号、产品批号、生产日期、有效期、适应症或者功能主治、用法、用量、禁忌、不良反应和注意事项。

The label or directions must indicate the generic name of the medicine, ingredients, specifications, the producer, approval number, batch number of the product, production date, expiry date, indications or functions, directions for use, dosage, contraindications, adverse reactions and precautions.

麻醉药品、精神药品、医疗用毒性药品、放射性药品、外用药品和非处方药的标签，必须印有规定的标志。

The labels of narcotic drugs, psychotropic drugs, toxic drugs for medical use, radioactive drugs, drugs for external use only and non-prescription drugs must bear the prescribed mark.

第七章 药品价格和广告的管理

Chapter 7 Drug Pricing and Advertising Management

第五十五条   依法实行市场调节价的药品，药品的生产企业、经营企业和医疗机构应当按照公平、合理和诚实信用、质价相符的原则制定价格，为用药者提供价格合理的药品。

Article 55. With regard to the drugs with market regulated prices, the drug-producing enterprises, drug-trading enterprises and medical organisations shall set the drug prices in accordance with the principles of being fair, reasonable, honest and trustworthy, and of matching the price with the quality so as to provide drug-users with reasonably priced drugs.

药品的生产企业、经营企业和医疗机构应当遵守国务院价格主管部门关于药价管理的规定，制定和标明药品零售价格，禁止暴利和损害用药者利益的价格欺诈行为。

Pharmaceutical producing enterprises, trading enterprises and medical organizations shall abide by the regulations concerning the control on prices of pharmaceuticals prescribed by the competent authority of pricing under the State Council, shall fix and mark the retail prices of pharmaceuticals, and shall avoid sudden excessive profits and deceptive acts on pricing which will harm the interests of the users of the pharmaceuticals.

第五十六条   药品的生产企业、经营企业、医疗机构应当依法向政府价格主管部门提供其药品的实际购销价格和购销数量等资料。

Article 56. Drug-producing enterprises, drug-trading enterprises and medical organisations shall provide the responsible government department of price control with information concerning the actual purchase or sale prices of drugs and the quantities of purchases and sales.

第五十七条   医疗机构应当向患者提供所用药品的价格清单；医疗保险定点医疗机构还应当按照规定的办法如实公布其常用药品的价格，加强合理用药的管理。具体办法由国务院卫生行政部门规定。

Article 57. Medical organisations shall provide patients with detailed price lists of the drugs the patients are prescribed; designated medical organisations covered by medical insurance shall also publish the prices of the frequently used drugs in a way stipulated by regulations, and shall strengthen the administration of drug use in a reasonable way. The specific measures in this regard shall be formulated by the health administration department under the State Council.

第五十八条   禁止药品的生产企业、经营企业和医疗机构在药品购销中帐外暗中给予、收受回扣或者其他利益。

Article 58. Drug-producing enterprises, drug-trading enterprises and medical organisations are prohibited from giving or accepting commissions or other benefits when purchasing or selling drugs.

禁止药品的生产企业、经营企业或者其代理人以任何名义给予使用其药品的医疗机构的负责人、药品采购人员、医师等有关人员以财物或者其他利益。禁止医疗机构的负责人、药品采购人员、医师等有关人员以任何名义收受药品的生产企业、经营企业或者其代理人给予的财物或者其他利益。

Pharmaceutical producing enterprises, trading enterprises or their agents are prohibited to give any property or other benefits under any name to the principals, buyers of pharmaceuticals, physicians and other relevant persons in the medical organizations where their pharmaceuticals are used. Leading members, drug purchasers, physicians, or other related persons of medical institutions are prohibited from accepting, in any name, money or things of value or other benefits offered by drug-producing enterprises, drug- trading enterprises or their agents.

第五十九条   药品广告须经企业所在地省、自治区、直辖市人民政府药品监督管理部门批准，并发给药品广告批准文号；未取得药品广告批准文号的，不得发布。

Article 59. Drug advertisements must be approved by the drug control and administrative department of the people's government of a province, autonomous region or centrally administered municipality and an approval number for a drug advertisement must then be obtained. Where an approval number for a drug advertisement is not obtained, the advertisement must not be made public.

处方药可以在国务院卫生行政部门和国务院药品监督管理部门共同指定的医学、药学专业刊物上介绍，但不得在大众传播媒介发布广告或者以其他方式进行以公众为对象的广告宣传。

Prescription pharmaceuticals may be introduced in the medical or pharmaceutical journals jointly designated by the administrative department of health of the State Council and the drug regulatory department of the State Council, provided that they are not advertised in mass media or publicized to the public in any other form.

第六十条   药品广告的内容必须真实、合法，以国务院药品监督管理部门批准的说明书为准，不得含有虚假的内容。

Article 60. The contents of a drug advertisement must be authentic and legal, based on the instructions for use approved by the drug control and administrative department of the State Council. False contents must not be included.

药品广告不得含有不科学的表示功效的断言或者保证；不得利用国家机关、医药科研单位、学术机构或者专家、学者、医师、患者的名义和形象作证明。

Drug advertisements shall not contain unscientific assertions or assurances in terms of effectiveness; and shall not use the names and images of government departments, pharmaceutical research units, academic institutions, experts, scholars, physicians and patients as supporting evidence.

非药品广告不得有涉及药品的宣传。

Non- drug advertisements must not include drug-related publicity.

第六十一条   省、自治区、直辖市人民政府药品监督管理部门应当对其批准的药品广告进行检查，对于违反本法和《中华人民共和国广告法》的广告，应当向广告监督管理机关通报并提出处理建议，广告监督管理机关应当依法作出处理。

Article 61. The drug control and administrative department of the people's government of a province, autonomous region or centrally administered municipality shall examine the drug advertisements to be approved. Where an advertisement violates this Law and the Law of Advertising of the People's Republic of China, it shall be reported to the authorities responsible for the supervision and control of advertising and suggestions to handle the matter shall be made; the authorities responsible for the supervision and control of advertising shall deal with the matter in accordance with the law.

第六十二条   药品价格和广告，本法未规定的，适用《中华人民共和国价格法》、《中华人民共和国广告法》的规定。

Article 62. With regard to matters in relation to prices or advertisements of drugs that have not been stipulated in this Law, the Price Law of the People's Republic of China and the Law of Advertising of the People's Republic of China shall apply.

第八章 药品监督

Chapter 8 Drug Supervision

第六十三条   药品监督管理部门有权按照法律、行政法规的规定对报经其审批的药品研制和药品的生产、经营以及医疗机构使用药品的事项进行监督检查，有关单位和个人不得拒绝和隐瞒。

Article 63. The drug control and administrative departments have the right to conduct supervision and examination, in accordance with the provisions of the law and administrative regulations, in respect to the research on drugs and drug production and business operations submitted for approval, as well as issues regarding the use of drugs by medical organisations. The relevant units or individuals must not refuse to cooperate, or conceal anything.

药品监督管理部门进行监督检查时，必须出示证明文件，对监督检查中知悉的被检查人的技术秘密和业务秘密应当保密。

When conducting supervision and inspection, the drug control and administrative departments must produce identification and shall keep confidential the technical and business secrets of the persons under inspection coming to their knowledge in the course of supervision and inspection.

第六十四条   药品监督管理部门根据监督检查的需要，可以对药品质量进行抽查检验。抽查检验应当按照规定抽样，并不得收取任何费用。所需费用按照国务院规定列支。

Article 64. If necessary, the drug control and administrative department may carry out random testing of the quality of drugs. Sampling for random sampling inspection shall be carried out pursuant to the provisions, and no fees shall be collected. The cost shall be listed and paid in accordance with the regulations of the State Council.

药品监督管理部门对有证据证明可能危害人体健康的药品及其有关材料可以采取查封、扣押的行政强制措施，并在七日内作出行政处理决定；药品需要检验的，必须自检验报告书发出之日起十五日内作出行政处理决定。

Pharmaceutical supervisory and administrative departments may take administrative coercive measures including sequestration and attachment against pharmaceuticals and related materials which have been proven to be potentially harmful to human health, and shall make decisions regarding the handling of the cases within seven days. For pharmaceuticals which need to be tested, decisions regarding the handling of the cases shall be made within 15 days from the date of issue of the testing reports.

第六十五条   国务院和省、自治区、直辖市人民政府的药品监督管理部门应当定期公告药品质量抽查检验的结果；公告不当的，必须在原公告范围内予以更正。

Article 65. The drug control and administrative department of the people's government of a province, autonomous region or centrally administered municipality shall produce a public notice with regard to the results of any random tests of drug quality at regular intervals. Where the public notice is not properly produced, corrections must be made within the scope of the original public notice.

第六十六条   当事人对药品检验机构的检验结果有异议的，可以自收到药品检验结果之日起七日内向原药品检验机构或者上一级药品监督管理部门设置或者确定的药品检验机构申请复验，也可以直接向国务院药品监督管理部门设置或者确定的药品检验机构申请复验。受理复验的药品检验机构必须在国务院药品监督管理部门规定的时间内作出复验结论。

Article 66. Where the parties concerned disagree with the results of a test conducted by the drug testing authorities, within seven (7) days of the receipt of the result of the drug test the parties concerned may apply for a review to the original drug testing authorities or the drug testing authorities established or designated by the drug control and administrative departments at a higher level, or apply for a review directly to the drug testing authorities established or designated by the drug control and administrative department of the State Council. The inspection institution which accepts the re-inspection shall conclude the re-inspection within the time limit prescribed by the pharmaceutical supervisory and administrative department under the State Council.

第六十七条   药品监督管理部门应当按照规定，依据《药品生产质量管理规范》、《药品经营质量管理规范》，对经其认证合格的药品生产企业、药品经营企业进行认证后的跟踪检查。

Article 67. On the basis of the Standards for Quality Control of Drug Production and the Standards for Quality Control of Drug-trading, the drug control and administrative departments shall conduct follow-up tests of the drug-producing enterprises and drug-trading enterprises after they have been authenticated by the departments.

第六十八条   地方人民政府和药品监督管理部门不得以要求实施药品检验、审批等手段限制或者排斥非本地区药品生产企业依照本法规定生产的药品进入本地区。

Article 68. The drug control and administrative department of a local people's government must not, by way of requiring a drug test or examination and approval etc., restrict or exclude any drugs produced in accordance with the provisions of this Law from being introduced into a local region by drug-producing enterprises which do not belong to the region.

第六十九条   药品监督管理部门及其设置的药品检验机构和确定的专业从事药品检验的机构不得参与药品生产经营活动，不得以其名义推荐或者监制、监销药品。

Article 69. Drug control and administrative departments and the drug-testing authorities set up by these departments, as well as designated organisations engaging in professional drug testing must not participate in drug production or drug-trading activities and must not recommend, or supervise the production or sale of drugs in their names.

药品监督管理部门及其设置的药品检验机构和确定的专业从事药品检验的机构的工作人员不得参与药品生产经营活动。

The staff of drug control and administrative departments and the drug-testing authorities set up by these departments, as well as the designated authorities engaging in drug testing must not participate in drug production and operations.

第七十条   国家实行药品不良反应报告制度。药品生产企业、药品经营企业和医疗机构必须经常考察本单位所生产、经营、使用的药品质量、疗效和反应。发现可能与用药有关的严重不良反应，必须及时向当地省、自治区、直辖市人民政府药品监督管理部门和卫生行政部门报告。具体办法由国务院药品监督管理部门会同国务院卫生行政部门制定。

Article 70 The state adopts the pharmaceutical side effect reporting system. Drug manufacturers, drug distributors and medical institutions shall make constant investigations into quality, therapeutic efficacy and reactions of the drugs produced, distributed and used thereby. When serious adverse reactions possibly related to the use of the pharmaceuticals are discovered, they must be promptly reported to the pharmaceutical supervisory and administrative departments and the administrative departments of health of the provinces, autonomous regions and municipalities directly under the central government. Specific measures therefor shall be formulated by the drug regulatory department under the State Council in concert with the administrative department for health under the State Council.

对已确认发生严重不良反应的药品，国务院或者省、自治区、直辖市人民政府的药品监督管理部门可以采取停止生产、销售、使用的紧急控制措施，并应当在五日内组织鉴定，自鉴定结论作出之日起十五日内依法作出行政处理决定。

. Where there are drugs which have been confirmed to have serious side-effects, the drug control and administrative department of the State Council or the drug control and administrative department of the people's government of a province, autonomous region or centrally administered municipality may adopt emergency control measures to stop the production, sale and use of the drugs. An evaluation must be organised within five (5) days and an administrative handling decision must be made within 15 days of the conclusion of the evaluation.

第七十一条   药品生产企业、药品经营企业和医疗机构的药品检验机构或者人员，应当接受当地药品监督管理部门设置的药品检验机构的业务指导。

Article 71. Drug-testing organisations of drug-producing enterprises, drug-trading enterprises and medical organisations and their staff shall receive professional guidance from the drug-testing authorities set up by the local drug control and administrative departments.

第九章 法律责任

Chapter 9 Legal Liabilities

第七十二条   未取得《药品生产许可证》、《药品经营许可证》或者《医疗机构制剂许可证》生产药品、经营药品的，依法予以取缔，没收违法生产、销售的药品和违法所得，并处违法生产、销售的药品（包括已售出的和未售出的药品，下同）货值金额二倍以上五倍以下的罚款；构成犯罪的，依法追究刑事责任。

Article 72. Production or trading of drugs without a Drug Production Licence, Drug-trading Licence or Dispensing Licence must be banned in accordance with the law. Drugs produced or sold in violation of the law and any illegal earnings must be confiscated. A fine of between two (2) to five (5) times the value of the illegally produced or sold drugs (including sold or unsold drugs) shall be imposed. Where a crime is constituted, criminal liability shall be pursued.

第七十三条   生产、销售假药的，没收违法生产、销售的药品和违法所得，并处违法生产、销售药品货值金额二倍以上五倍以下的罚款；有药品批准证明文件的予以撤销，并责令停产、停业整顿；情节严重的，吊销《药品生产许可证》、《药品经营许可证》或者《医疗机构制剂许可证》；构成犯罪的，依法追究刑事责任。

Article 73. Where spurious drugs are produced or sold, the illegally produced or sold drugs and the illegal earnings shall be confiscated. A fine of between two (2) to five (5) times the value of the illegally produced or sold spurious drugs shall be imposed. Where a drug approval certificate has been issued, the certificate shall be cancelled, and the parties involved shall be ordered to stop production or stop operations for rectification. Where the situation is serious, the Drug Production Licence, Drug-trading Licence or Dispensing Licence may be revoked. Where a crime is constituted, criminal liability shall be pursued.

第七十四条   生产、销售劣药的，没收违法生产、销售的药品和违法所得，并处违法生产、销售药品货值金额一倍以上三倍以下的罚款；情节严重的，责令停产、停业整顿或者撤销药品批准证明文件、吊销《药品生产许可证》、《药品经营许可证》或者《医疗机构制剂许可证》；构成犯罪的，依法追究刑事责任。

Article 74. Where inferior drugs are produced or sold, the illegally produced or sold drugs and the illegal earnings shall be confiscated. A fine of between two (2) to three (3) times the value of the illegally produced or sold inferior drugs shall be imposed. Where a drug approval certificate is issued, the certificate shall be cancelled, and the parties involved shall be ordered to stop production or stop operations for rectification. Where the situation is serious, the Drug Production Licence, Drug-trading Licence or Dispensing Licence may be revoked. Where a crime is constituted, criminal liability shall be pursued.

第七十五条   从事生产、销售假药及生产、销售劣药情节严重的企业或者其他单位，其直接负责的主管人员和其他直接责任人员十年内不得从事药品生产、经营活动。

Article 75. Where there are serious cases of enterprises or other units engaging in the production and sale of spurious drugs or in the production and sale of inferior drugs, the directly responsible personnel and other directly responsible personnel must not engage in drug producing or drug trading activities within the next ten years.

对生产者专门用于生产假药、劣药的原辅材料、包装材料、生产设备，予以没收。

The crude materials, accessories, packaging materials and manufacturing equipment used by manufacturers to produce counterfeit or substandard drugs shall be confiscated.

第七十六条   知道或者应当知道属于假劣药品而为其提供运输、保管、仓储等便利条件的，没收全部运输、保管、仓储的收入，并处违法收入百分之五十以上三倍以下的罚款；构成犯罪的，依法追究刑事责任。

Article 76. Where any parties who have the knowledge, or should have the knowledge, that drugs are spurious or inferior, still provide the convenience of transport, preservation or storage, the earnings from the transport, preservation and storage of the drugs shall all be confiscated. A fine of between fifty per cent and three (3) times the illegal earnings shall be imposed. Where a crime is constituted, criminal liability shall be pursued.

第七十七条   对假药、劣药的处罚通知，必须载明药品检验机构的质量检验结果；但是，本法第四十八条第三款第（一）、（二）、（五）、（六）项和第四十九条第三款规定的情形除外。

Article 77. The penalty notice for spurious or inferior drugs shall bear the results of the quality examination of the drug-testing authorities. However, the circumstances listed in Items 1, 2, 5 and 6 in paragraph 3 of Article 48 and the provisions in paragraph 3 of Article 49 of this Law are excepted.

第七十八条   药品的生产企业、经营企业、药物非临床安全性评价研究机构、药物临床试验机构未按照规定实施《药品生产质量管理规范》、《药品经营质量管理规范》、药物非临床研究质量管理规范、药物临床试验质量管理规范的，给予警告，责令限期改正；逾期不改正的，责令停产、停业整顿，并处五千元以上二万元以下的罚款；情节严重的，吊销《药品生产许可证》、《药品经营许可证》和药物临床试验机构的资格。

Article 78. Where drug-producing enterprises, drug- trading enterprises, research institutions of non-clinical drug safetyappraisal, or clinical drug testing organisations fail to implement the Standards for Quality Control of Drug Production, Standards for Quality Control of Drug-trading, quality control standards for non-clinical drug research, or quality control standards for clinical drug testing, warnings and orders shall be issued for corrective measures to be taken within a time limit. Where no corrective measures have been taken when the time limit has passed, orders must be issued to stop production or operations for rectification, and a fine of between 5,000 yuan and 20,000 yuan shall be imposed. Where the situation is serious, the Drug Production Licence, Drug-trading Licence or qualifications as a clinical drug-testing body shall be revoked.

第七十九条   药品的生产企业、经营企业或者医疗机构违反本法第三十四条的规定，从无《药品生产许可证》、《药品经营许可证》的企业购进药品的，责令改正，没收违法购进的药品，并处违法购进药品货值金额二倍以上五倍以下的罚款；有违法所得的，没收违法所得；情节严重的，吊销《药品生产许可证》、《药品经营许可证》或者医疗机构执业许可证书。

Article 79. Where drug-producing enterprises, drug- trading enterprises or medical organisation, in violation of the provisions in Article 34 of this Law, purchase drugs from enterprises which do not have a Drug Production Licence or Drug-trading Licence, they shall be ordered to make corrections. Illegally purchased drugs shall be confiscated. A fine of between two (2) times and five (5) times the value of the illegally purchased drugs shall be imposed. Where there are illegal earnings, they shall be confiscated. Where the situation is serious, Drug Production Licences, Drug-trading Licences or the operation licences of medical organisations shall be revoked.

第八十条   进口已获得药品进口注册证书的药品，未按照本法规定向允许药品进口的口岸所在地的药品监督管理部门登记备案的，给予警告，责令限期改正；逾期不改正的，撤销进口药品注册证书。

Article 80. Where the import of drugs which have been granted a registration certificate for drug import has not been registered for the record, in accordance with the provisions of this Law, with the drug control and administrative departments at the place where the port permitted to import the drugs is located, warnings shall be issued. The parties involved shall be ordered to make corrections within a time limit. Where no correction is made when the time limit has passed, the registration certificate for the drug import shall be revoked.

第八十一条   伪造、变造、买卖、出租、出借许可证或者药品批准证明文件的，没收违法所得，并处违法所得一倍以上三倍以下的罚款；没有违法所得的，处二万元以上十万元以下的罚款；情节严重的，并吊销卖方、出租方、出借方的《药品生产许可证》、《药品经营许可证》、《医疗机构制剂许可证》或者撤销药品批准证明文件；构成犯罪的，依法追究刑事责任。

Article 81. Where licences or drug approval documents are forged, altered, purchased or sold, leased or lent, the illegal earnings shall be confiscated. A fine of between two (2) times and three (3) times the illegal earnings shall be imposed. Where there are no illegal earnings, a fine of between 20,000 yuan and 100,000 yuan shall be imposed. Where the situation is serious, the Drug Production Licences, Drug-trading licences, or Dispensing Licences shall be revoked, or drug approval documents shall be cancelled. Where a crime is constituted, criminal liability shall be pursued.

第八十二条   违反本法规定，提供虚假的证明、文件资料、样品或者采取其他欺骗手段取得《药品生产许可证》、《药品经营许可证》、《医疗机构制剂许可证》或者药品批准证明文件的，吊销《药品生产许可证》、《药品经营许可证》、《医疗机构制剂许可证》或者撤销药品批准证明文件，五年内不受理其申请，并处一万元以上三万元以下的罚款。

Article 82. Where Drug Production Licences, Drug-trading Licences, Dispensing Licences, or drug approval documents are obtained by way of providing false certificates, documents and materials or samples or by other deceptive means, the Drug Production Licences, Drug-trading Licences, Dispensing Licences shall be revoked, or drug approval documents shall be cancelled. No re-applications shall be accepted within the next five (5) years. A fine of between 10,000 yuan and 30,000 yuan shall be imposed.

第八十三条   医疗机构将其配制的制剂在市场销售的，责令改正，没收违法销售的制剂，并处违法销售制剂货值金额一倍以上三倍以下的罚款；有违法所得的，没收违法所得。

Article 83. Where a medical organisation sells in the market medicine made up by itself, the medical organisation shall be ordered to rectify the situation. Medicine sold illegally shall be confiscated. A fine between of two (2) times and three (3) times the value of the illegally sold medicine shall be imposed. Where there are illegal earnings, the illegal earnings shall be confiscated.

第八十四条   药品经营企业违反本法第十八条、第十九条规定的，责令改正，给予警告；情节严重的，吊销《药品经营许可证》。

Article 84. Where drug-trading enterprises violate the provisions in Article 18 and Article 19 of this Law, they shall be ordered to rectify the situation. Where the situation is serious, Drug-trading Licences shall be revoked.

第八十五条   药品标识不符合本法第五十四条规定的，除依法应当按照假药、劣药论处的外，责令改正，给予警告；情节严重的，撤销该药品的批准证明文件。

Article 85. Where drug labels do not comply with the provisions in Article 54 of this Law, except where punishment is required to be imposed for spurious or inferior drugs in accordance with law, an order shall be issued to rectify the situation and a warning shall be issued. Where the situation is serious, the approval documents of the said drug shall be cancelled.

第八十六条   药品检验机构出具虚假检验报告，构成犯罪的，依法追究刑事责任；不构成犯罪的，责令改正，给予警告，对单位并处三万元以上五万元以下的罚款；对直接负责的主管人员和其他直接责任人员依法给予降级、撤职、开除的处分，并处三万元以下的罚款；有违法所得的，没收违法所得；情节严重的，撤销其检验资格。药品检验机构出具的检验结果不实，造成损失的，应当承担相应的赔偿责任。

Article 86. Where a drug-testing body issues a false examination report, thus constituting a crime, criminal liability shall be pursued. Where no crime is constituted, the drug-testing body shall be ordered to rectify the situation and a warning shall be issued. A fine of between 30,000 yuan and 50,000 yuan shall be imposed. Disciplinary actions of demotion, dismissal or expulsion shall be imposed upon the directly responsible leading personnel and other directly responsible personnel. A fine of up to 30,000 yuan shall be imposed. Where there are illegal earnings, the illegal earnings shall be confiscated. Where the situation is serious, the qualifications for drug testing shall be cancelled. If an inspection institution produces false inspection reports and causes serious consequences, it shall bear corresponding liabilities for compensation.

第八十七条   本法第七十二条至第八十六条规定的行政处罚，由县级以上药品监督管理部门按照国务院药品监督管理部门规定的职责分工决定；吊销《药品生产许可证》、《药品经营许可证》、《医疗机构制剂许可证》、医疗机构执业许可证书或者撤销药品批准证明文件的，由原发证、批准的部门决定。

Article 87. The administrative penalties in the provisions from Article 72 to Article 86 of this Law shall be determined by the drug control and administrative departments at county level or above in accordance with the duties stipulated by the drug control and administrative department of the State Council. Where Drug Production Licences, Drug-trading Licences, Dispensing Licences, Business Licences of Medical Bodies, or drug approval documents are revoked, the decisions shall be made by the original departments which issued the licences or gave the approval.

第八十八条   违反本法第五十五条、第五十六条关于药品价格管理的规定的，依照《中华人民共和国价格法》的规定处罚。

Article 88. Where there are violations of the provisions on the management of drug prices in Articles 55 and 56 of this Law, penalties shall be imposed in accordance with the Price Law of the People's Republic of China.

第八十九条   药品的生产企业、经营企业、医疗机构在药品购销中暗中给予、收受回扣或者其他利益的，药品的生产企业、经营企业或者其代理人给予使用其药品的医疗机构的负责人、药品采购人员、医师等有关人员以财物或者其他利益的，由工商行政管理部门处一万元以上二十万元以下的罚款，有违法所得的，予以没收；情节严重的，由工商行政管理部门吊销药品生产企业、药品经营企业的营业执照，并通知药品监督管理部门，由药品监督管理部门吊销其《药品生产许可证》、《药品经营许可证》；构成犯罪的，依法追究刑事责任。

Article 89. Where in the purchase or sale of drugs, drug-producing enterprises, drug- trading enterprises, or medical organisations offer or accept commissions or other benefits in secret, or drug-producing enterprises, drug- trading enterprises or their agents offer money, goods or other benefits to the responsible persons of medical organisations, drug purchasing personnel, doctors or other related personnel who use their drugs, the administrative authorities responsible for industry and commerce shall impose a fine of between 10,000 yuan and 200,000 yuan. Where there are illegal earnings, the illegal earnings shall be confiscated. Where the situation is serious, the administrative authorities responsible for industry and commerce shall revoke the business licences of the drug-producing and drug-trading enterprises, and notify the drug control and administrative department to revoke the Drug Production Licences and Drug-trading Licences. Where a crime is constituted, criminal liability shall be pursued.

第九十条   药品的生产企业、经营企业的负责人、采购人员等有关人员在药品购销中收受其他生产企业、经营企业或者其代理人给予的财物或者其他利益的，依法给予处分，没收违法所得；构成犯罪的，依法追究刑事责任。

Article 90. Where in the purchase or sale of drugs, the responsible personnel or drug purchasing personnel of drug-producing or drug- trading enterprises receive money, goods or other benefits offered by other drug- producing enterprises, drug- trading enterprises or their agents, penalties shall be imposed in accordance with the law and illegal earnings shall be confiscated. Where a crime is constituted, criminal liability shall be pursued.

医疗机构的负责人、药品采购人员、医师等有关人员收受药品生产企业、药品经营企业或者其代理人给予的财物或者其他利益的，由卫生行政部门或者本单位给予处分，没收违法所得；对违法行为情节严重的执业医师，由卫生行政部门吊销其执业证书；构成犯罪的，依法追究刑事责任。

If the directors, buyers, physicians or other relevant persons in medical organizations receive any property or other interests from pharmaceutical producing enterprises, pharmaceutical trading enterprises or their agents, they shall be disciplined by the administrative departments of health or the work units to which they belong, and the unlawful gains shall be confiscated.

第九十一条   违反本法有关药品广告的管理规定的，依照《中华人民共和国广告法》的规定处罚，并由发给广告批准文号的药品监督管理部门撤销广告批准文号，一年内不受理该品种的广告审批申请；构成犯罪的，依法追究刑事责任。

Article 91 Where the provisions of this Law on the control of drug advertising are violated, penalties shall be imposed in accordance with the provisions in the Law of Advertising of the People's Republic of China; and the drug control and administrative departments which issued approval numbers for advertisements shall cancel the approval numbers of the advertisements. A re-application for an approval number for advertising of the said drugs shall not be accepted within one (1) year. Where a crime is constituted, criminal liability shall be pursued.

药品监督管理部门对药品广告不依法履行审查职责，批准发布的广告有虚假或者其他违反法律、行政法规的内容的，对直接负责的主管人员和其他直接责任人员依法给予行政处分；构成犯罪的，依法追究刑事责任。

Where a drug control and administrative department does not fulfil its duties to examine drug advertisements, and where the approved advertisements contain false or other contents that violate the law or administrative regulations, the directly responsible leading personnel and other directly responsible personnel shall have administrative sanctions imposed in accordance with the law. Where a crime is constituted, criminal liability shall be pursued.

第九十二条   药品的生产企业、经营企业、医疗机构违反本法规定，给药品使用者造成损害的，依法承担赔偿责任。

Article 92. Where drug-producing enterprises, drug- trading enterprises or medical organisations violate the provisions of this Law and cause damage to drug users, they shall assume liability for compensation.

第九十三条   药品监督管理部门违反本法规定，有下列行为之一的，由其上级主管机关或者监察机关责令收回违法发给的证书、撤销药品批准证明文件，对直接负责的主管人员和其他直接责任人员依法给予行政处分；构成犯罪的，依法追究刑事责任:

Article 93 Any drug regulatory department that violates the provisions of the Law and commits any of the following acts shall be ordered by the competent authority at the next higher level or the supervisory body to withdraw 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 liable in accordance with the law. If a crime is constituted, criminal liabilities shall be prosecuted in accordance with the law:

（一）对不符合《药品生产质量管理规范》、《药品经营质量管理规范》的企业发给符合有关规范的认证证书的，或者对取得认证证书的企业未按照规定履行跟踪检查的职责，对不符合认证条件的企业未依法责令其改正或者撤销其认证证书的；

1. issuing the certificates proving the compliance with the Good Manufacturing Practice for Drugs or the Good Distribution Practice for Drugs to the enterprises that do not meet the corresponding requirements, failing to perform, as required, the duty of follow-up inspections in respect of the enterprises that have obtained the certificates, or failing to order, in accordance with the law, the enterprises not meeting the requirements to make corrections or failing to revoke their certificates; or

（二）对不符合法定条件的单位发给《药品生产许可证》、《药品经营许可证》或者《医疗机构制剂许可证》的；

(II) issuing a Drug Manufacturing Certificate, Drug Distribution Certificate or Pharmaceutical Preparation Certificate for Medical Institution to the entities that do not meet the statutory requirements;

（三）对不符合进口条件的药品发给进口药品注册证书的；

(III) issue a registration certificate of import to a drug that does not meet the requirements for import;

（四）对不具备临床试验条件或者生产条件而批准进行临床试验、发给新药证书、发给药品批准文号的。

(IV) granting approval for conducting a clinical trial, issuing a new drug certificate or a drug approval number, where the requirements for clinical trial or production are not met.

第九十四条   药品监督管理部门或者其设置的药品检验机构或者其确定的专业从事药品检验的机构参与药品生产经营活动的，由其上级机关或者监察机关责令改正，有违法收入的予以没收；情节严重的，对直接负责的主管人员和其他直接责任人员依法给予行政处分。

Article 94. Where a drug control and administrative department, a drug-testing institution set up by this department, or an institution specialising in drug testing designated by this department participates in drug production and operations, it shall be ordered by the higher authorities or supervising authorities to rectify the situation. Where there are illegal earnings, they shall be confiscated. Where the situation is serious, the directly responsible leading personnel and other directly responsible personnel shall have administrative sanctions imposed in accordance with the law.

药品监督管理部门或者其设置的药品检验机构或者其确定的专业从事药品检验的机构的工作人员参与药品生产经营活动的，依法给予行政处分。

If a staff member in a pharmaceutical supervisory and administrative department, or in an inspection institution it has established, or in an institution exclusively engaged in pharmaceutical inspection it has appointed, participates in the production and trade of pharmaceuticals, he or she shall be subject to administrative sanction.

第九十五条   药品监督管理部门或者其设置、确定的药品检验机构在药品监督检验中违法收取检验费用的，由政府有关部门责令退还，对直接负责的主管人员和其他直接责任人员依法给予行政处分。对违法收取检验费用情节严重的药品检验机构，撤销其检验资格。

Article 95. Where in the supervision and testing of drugs, a drug control and administrative department or a drug-testing institution set up or designated by this department charges fees for the testing, in violation of the law, the relevant government department shall be ordered to refund the fees. The directly responsible leading personnel and other directly responsible personnel shall have administrative sanctions imposed in accordance with the law. Where a drug testing institution has seriously violated the law by charging testing fees, its testing qualification shall be revoked.

第九十六条   药品监督管理部门应当依法履行监督检查职责，监督已取得《药品生产许可证》、《药品经营许可证》的企业依照本法规定从事药品生产、经营活动。

Article 96. The drug control and administrative departments shall fulfil their duties of supervision and examination in accordance with the law and shall supervise the enterprises which have obtained Drug Production Licences or Drug-trading Licences as they engage in drug production and trade in accordance with the provisions of this Law.

已取得《药品生产许可证》、《药品经营许可证》的企业生产、销售假药、劣药的，除依法追究该企业的法律责任外，对有失职、渎职行为的药品监督管理部门直接负责的主管人员和其他直接责任人员依法给予行政处分；构成犯罪的，依法追究刑事责任。

If an enterprise which has obtained a Pharmaceutical Production License or a Pharmaceutical Trade License produces and sells fake medicines and medicines of inferior quality, the enterprise shall be investigated for legal liabilities according to laws and regulations. In addition, the directly liable person in charge and other responsible personnel in the pharmaceutical supervisory and administrative departments who have neglected or have been derelict in their duties shall be subject to administrative sanctions. If a crime is constituted, they shall be investigated for criminal liabilities according to laws and regulations.

第九十七条   药品监督管理部门对下级药品监督管理部门违反本法的行政行为，责令限期改正；逾期不改正的，有权予以改变或者撤销。

Article 97. Where a lower drug control and administrative department is responsible for administrative conduct in violation of this Law, the drug control and administrative department shall order it to rectify the situation within a time limit. Where no actions are taken within the time limit, the drug control and administrative department has the right to make alterations or cancellations.

第九十八条   药品监督管理人员滥用职权、徇私舞弊、玩忽职守，构成犯罪的，依法追究刑事责任；尚不构成犯罪的，依法给予行政处分。

Article 98. Where the personnel of a drug control and administration department abuse their power, practise favouritism or neglect their duties and thus commit crimes, criminal liability shall be pursued. Where no crime is constituted, administrative penalties shall be imposed.

第九十九条   本章规定的货值金额以违法生产、销售药品的标价计算；没有标价的，按照同类药品的市场价格计算。

Article 99. In this chapter, the value of the goods is calculated with reference to the marked prices of the illegally produced or sold drugs. Where there are no marked prices, the calculations are made with reference to the market prices of drugs of the same type.

第十章 附则

Chapter 10 Supplementary Provisions

第一百条   本法下列用语的含义是:

Article 100 For the purpose of this Law, the definitions of the following terms are:

药品，是指用于预防、治疗、诊断人的疾病，有目的地调节人的生理机能并规定有适应症或者功能主治、用法和用量的物质，包括中药材、中药饮片、中成药、化学原料药及其制剂、抗生素、生化药品、放射性药品、血清、疫苗、血液制品和诊断药品等。

Drugs refer to substances which are used in the prevention, treatment and diagnosis of human diseases, and intended to regulate human physiological functions, for which indications or major functions, usage and dosage are specified, including traditional Chinese medicinal materials, traditional Chinese medicine decoction pieces, traditional Chinese patent medicines, chemical raw material medicines and their preparations, antibiotics, biochemical drugs, radioactive drugs, serums, vaccines, blood products and diagnostic drugs.

辅料，是指生产药品和调配处方时所用的赋形剂和附加剂。

Supplementary materials shall mean excipients and additives used for drug production and formulation.

药品生产企业，是指生产药品的专营企业或者兼营企业。

Pharmaceutical producing enterprise "means an enterprise exclusively or partly engaged in the production of pharmaceuticals.

药品经营企业，是指经营药品的专营企业或者兼营企业。

Pharmaceutical trading enterprise "means an enterprise exclusively or partly engaged in the trading of pharmaceuticals.

第一百零一条   中药材的种植、采集和饲养的管理办法，由国务院另行制定。

Article 101 The administrative measures for the cultivation and collection of raw materials for Chinese medicines or the raising of animals in relation to Chinese medicines shall be separately formulated by the State Council.

第一百零二条   国家对预防性生物制品的流通实行特殊管理。具体办法由国务院制定。

Article 102 The State exercises special administration over the circulation of preventive biological products. Specific measures shall be formulated by the State Council.

第一百零三条   中国人民解放军执行本法的具体办法，由国务院、中央军事委员会依据本法制定。

Article 103 Specific measures for implementation of this Law by the Chinese People's Liberation Army shall be formulated by the State Council and the Central Military Commission in accordance with this Law.

第一百零四条   本法自2001年12月1日起施行。

Article 104 This Law shall go into effect as of December 1, 2001.