Medicinal Product Administration Law of the People's Republic of China (2019 Revision)

中华人民共和国药品管理法(2019修订)

Document Number: Order No. 31 of the President of the People's Republic of China
Area of Law: Pharmaceutical Administration Epidemic Prevention and Control
Level of Authority: Laws
Date Issued: 08-26-2019
Effective Date: 12-01-2019
Issuing Authority: Standing Committee of the National People's Congress
Status: Effective

2015-2019 Comparison Version 2013-2015 Annotation Version 2001-2013 Annotation Version 1984-2001 Comparison Version

Order of the President of the People's Republic of China

(No. 31)

The Medicinal Product Administration Law of the People's Republic of China, as revised and adopted at the 12th Session of the Standing Committee of the Thirteenth National People's Congress of the People's Republic of China on August 26, 2019, is hereby issued, and shall come into force on December 1, 2019.

Xi Jinping, President of the People's Republic of China

August 26, 2019

Medicinal Product Administration Law of the People's Republic of China

(Adopted at the 7th Session of the Standing Committee of the Sixth National People's Congress on September 20, 1984; revised for the first time at the 20th Session of the Ninth National People's Congress on February 28, 2001; amended for the first time in accordance with the Decision to Amend Seven Laws Including the Marine Environment Protection Law of the People's Republic of China at the 6th Session of the Standing Committee of the Twelfth National People's Congress on December 28, 2013; amended for the second time in accordance with the Decision to Amend the Medicinal Product Administration Law of the People's Republic of China at the 14th Session of the Standing Committee of the Twelfth National People's Congress of the People's Republic of China on April 24, 2015; and revised for the second time at the 12th Session of the Standing Committee of the Thirteenth National People's Congress on August 26, 2019)

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中华人民共和国主席令

（第三十一号）

《中华人民共和国药品管理法》已由中华人民共和国第十三届全国人民代表大会常务委员会第十二次会议于2019年8月26日修订通过，现予公布，自2019年12月1日起施行。

中华人民共和国主席 习近平

2019年8月26日

中华人民共和国药品管理法

（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第一次修订 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〈中华人民共和国海洋环境保护法〉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〈中华人民共和国药品管理法〉的决定》第二次修正 2019年8月26日第十三届全国人民代表大会常务委员会第十二次会议第二次修订）

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Chapter I General Provisions 第一章 总 则

Article 1 This Law is enacted for the purposes of enhancing medicinal product administration, ensuring medicinal product quality, maintaining the medication safety and lawful rights and interests of the public, and protecting and promoting public health.

第一条 为了加强药品管理，保证药品质量，保障公众用药安全和合法权益，保护和促进公众健康，制定本法。

Article 2 This Law shall apply to the research, development, manufacturing, distribution, use, supervision, and administration of medicinal products in the territory of the People's Republic of China.

第二条 在中华人民共和国境内从事药品研制、生产、经营、使用和监督管理活动，适用本法。

For the purposes of this Law, “medicinal product” means a substance for the prevention, treatment, or diagnosis of disease in human beings to effect the intended regulation of human physiological functions with the approved therapeutic indications or actions and indications, usage, and dosage, including but not limited to traditional Chinese medicines, chemical medicines, and biological products.

本法所称药品，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、化学药和生物制品等。

Article 3 Medicinal product administration shall center around people's health, adhere to the principles of risk management, whole process management and control, and social co-governance, and by establishment of a scientific and strict regulatory regime, comprehensively improve medicinal product quality, and guarantee the safety, efficacy, and accessibility of medicinal products.

第三条 药品管理应当以人民健康为中心，坚持风险管理、全程管控、社会共治的原则，建立科学、严格的监督管理制度，全面提升药品质量，保障药品的安全、有效、可及。

Article 4 The state shall develop both modern and traditional medicines to maximize their roles in prevention, medical care, and health protection.

第四条 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。

The state shall protect the natural resources of medicinal materials and the varieties of traditional Chinese medicines, and encourage the cultivation of traditional Chinese medicinal materials of recognized quality and efficacy.

国家保护野生药材资源和中药品种，鼓励培育道地中药材。

Article 5 The state shall encourage the research and invention of new medicinal products, and protect the lawful rights and interests of citizens, legal persons, and other organizations in the research and development of new medicinal products.

第五条 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。

Article 6 In medicinal product administration, the state shall implement a marketing authorization holder system for medicinal products. Marketing authorization holders shall be responsible for the safety, efficacy, and quality controllability of medicinal products during the whole process of research, development, manufacture, distribution, and use of medicinal products in accordance with the law.

第六条 国家对药品管理实行药品上市许可持有人制度。药品上市许可持有人依法对药品研制、生产、经营、使用全过程中药品的安全性、有效性和质量可控性负责。

Article 7 The research, development, manufacture, distribution, and use of medicinal products shall comply with laws, regulations, rules, standards, and specifications, and the authenticity, accuracy, integrity, and traceability of information during the whole process shall be ensured.

第七条 从事药品研制、生产、经营、使用活动，应当遵守法律、法规、规章、标准和规范，保证全过程信息真实、准确、完整和可追溯。

Article 8 The medicinal product regulatory department of the State Council shall be responsible for the national supervision and administration of medicinal products. The other relevant departments of the State Council shall be responsible for supervision and administration related to medicinal products within their respective functions. The medicinal product regulatory department of the State Council shall cooperate with the relevant departments of the State Council in implementing national general plans for pharmaceutical industry development and industry policies.

第八条 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职责范围内负责与药品有关的监督管理工作。国务院药品监督管理部门配合国务院有关部门，执行国家药品行业发展规划和产业政策。

The medicinal product regulatory departments of the people's governments of provinces, autonomous regions, and municipalities directly under the central government shall be responsible for the supervision and administration of medicinal products within their respective administrative regions. The department of a people's government at or above the districted city or the county level charged with the function of supervision and administration of medicinal products ("medicinal product regulatory department") shall be responsible for the supervision and administration of medicinal products within its administrative region. The relevant departments of a local people's government at or above the county level shall be responsible for supervision and administration related to medicinal products within their respective 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。设区的市级、县级人民政府承担药品监督管理职责的部门（以下称药品监督管理部门）负责本行政区域内的药品监督管理工作。县级以上地方人民政府有关部门在各自职责范围内负责与药品有关的监督管理工作。

Article 9 Local people's governments at and above the county level shall be responsible for the supervision and administration of medicinal products within their respective administrative regions, lead, organize, and coordinate in a unified manner the supervision and administration of medicinal products as well as medicinal product safety emergency response work within their respective administrative regions, and establish and improve their supervision and administration working mechanisms and information sharing mechanisms for medicinal products.

第九条 县级以上地方人民政府对本行政区域内的药品监督管理工作负责，统一领导、组织、协调本行政区域内的药品监督管理工作以及药品安全突发事件应对工作，建立健全药品监督管理工作机制和信息共享机制。

Article 10 Local people's governments at and above the county level shall include medicinal product safety work in the national economic and social development plans at their respective levels, list the funding for medicinal product safety work in their respective budgets, strengthen their capacity building for supervision and administration of medicinal products, and provide guarantees for medicinal product safety work.

第十条 县级以上人民政府应当将药品安全工作纳入本级国民经济和社会发展规划，将药品安全工作经费列入本级政府预算，加强药品监督管理能力建设，为药品安全工作提供保障。

Article 11 The specialized technical institutions for medicinal products established or designated by medicinal product regulatory departments shall undertake the evaluation, control, inspection, surveillance, reevaluation, and other work necessary for the implementation of supervision and administration of medicinal products in accordance with the law.

第十一条 药品监督管理部门设置或者指定的药品专业技术机构，承担依法实施药品监督管理所需的审评、检验、核查、监测与评价等工作。

Article 12 The state shall establish and improve a medicinal product traceability system. The medicinal product regulatory department of the State Council shall develop unified medicinal product traceability standards and specifications, advance the interconnection and mutual sharing of medicinal product traceability information, and achieve medicinal product traceability.

第十二条 国家建立健全药品追溯制度。国务院药品监督管理部门应当制定统一的药品追溯标准和规范，推进药品追溯信息互通互享，实现药品可追溯。

The state shall establish a pharmacovigilance system to monitor, identify, assess, and control adverse reactions to medicinal products and other harmful reactions associated with the use of medicinal products.

国家建立药物警戒制度，对药品不良反应及其他与用药有关的有害反应进行监测、识别、评估和控制。

Article 13 The people's governments at all levels and their relevant departments and the pharmaceutical industry associations, among others, shall strengthen publicity and education on medicinal product safety, and widely disseminate medicinal product safety laws and regulations and other knowledge.

第十三条 各级人民政府及其有关部门、药品行业协会等应当加强药品安全宣传教育，开展药品安全法律法规等知识的普及工作。

News media shall, in the public interest, conduct publicity on medicinal product safety laws and regulations and other knowledge, and implement supervision over illegal activities related to medicinal products by public opinion. Publicity and coverage on medicinal products shall be comprehensive, scientific, objective, and fair.

新闻媒体应当开展药品安全法律法规等知识的公益宣传，并对药品违法行为进行舆论监督。有关药品的宣传报道应当全面、科学、客观、公正。

Article 14 Pharmaceutical industry associations shall strengthen industry self-regulation, establish and improve industry norms, advance the building of industry integrity systems, and guide and supervise their members in the lawful manufacture and distribution, among others, of medicinal products.

第十四条 药品行业协会应当加强行业自律，建立健全行业规范，推动行业诚信体系建设，引导和督促会员依法开展药品生产经营等活动。

Article 15 The people's governments at and above the county level and their relevant departments shall, in accordance with the relevant provisions issued by the state, commend and reward entities and individuals which have made outstanding contributions to the research, development, manufacture, distribution, use, supervision, and administration of medicinal products.

第十五条 县级以上人民政府及其有关部门对在药品研制、生产、经营、使用和监督管理工作中做出突出贡献的单位和个人，按照国家有关规定给予表彰、奖励。

Chapter II Research, Development, and Registration of Medicinal Products

第二章 药品研制和注册

Article 16 The state shall support pharmaceutical innovations oriented to clinical value with clear or special therapeutic effects on human diseases, encourage the research and development of new medicinal products which have new therapeutic mechanisms, treat serious life-threatening diseases or rare diseases, or have multi-target systematic regulation and intervention functions for human body, among others, and promote the advancement of pharmaceutical technology.

第十六条 国家支持以临床价值为导向、对人的疾病具有明确或者特殊疗效的药物创新，鼓励具有新的治疗机理、治疗严重危及生命的疾病或者罕见病、对人体具有多靶向系统性调节干预功能等的新药研制，推动药品技术进步。

The state shall encourage the science and technology research on traditional Chinese medicines and the development of pharmaceuticals by using modern science and technology and traditional research methods for traditional Chinese medicines, establish and improve a technical evaluation system conforming to the characteristics of traditional Chinese medicines, and promote traditional Chinese medicine inheritance and innovation.

国家鼓励运用现代科学技术和传统中药研究方法开展中药科学技术研究和药物开发，建立和完善符合中药特点的技术评价体系，促进中药传承创新。

The state shall adopt effective measures to encourage pediatric medicinal product research, development, and innovation, support the development of new varieties, dosage forms, and specifications of pediatric medicinal products which conform to the physiological characteristics of children, and prioritize the evaluation and approval of pediatric medicinal products.

国家采取有效措施，鼓励儿童用药品的研制和创新，支持开发符合儿童生理特征的儿童用药品新品种、剂型和规格，对儿童用药品予以优先审评审批。

Article 17 The research and development of medicinal products shall comply with the good laboratory practice for nonclinical laboratory studies (“GLP”) for pharmaceuticals and the good clinical practice (“GCP”) for pharmaceuticals, and the continuing compliance with the statutory requirements shall be ensured during the whole process of research and development of medicinal products.

第十七条 从事药品研制活动，应当遵守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，保证药品研制全过程持续符合法定要求。

The GLP and GCP shall be developed by the medicinal product regulatory department of the State Council in conjunction with the relevant departments of the State Council.

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药品监督管理部门会同国务院有关部门制定。

Article 18 Nonclinical laboratory studies for pharmaceuticals shall be conducted in compliance with the relevant provisions issued by the state, with the personnel, site, equipment, instruments, and management system appropriate for the study project, and the authenticity of the relevant data, information, and samples shall be ensured.

第十八条 开展药物非临床研究，应当符合国家有关规定，有与研究项目相适应的人员、场地、设备、仪器和管理制度，保证有关数据、资料和样品的真实性。

Article 19 To conduct pharmaceutical clinical trials, the research and development methods, quality indicators, results of pharmacological and toxicological tests, and other relevant data, information, and samples shall be truthfully reported in accordance with the rules of the medicinal product regulatory department of the State Council, and be subject to the approval of the medicinal product regulatory department of the State Council. The medicinal product regulatory department of the State Council shall, within 60 working days of accepting an application for a clinical trial, decide whether to grant the application and notify the sponsor, and shall be deemed to have granted the application if the sponsor is not notified within the time limit. Bioequivalence studies, if any, shall be reported to the medicinal product regulatory department of the State Council for recordation.

第十九条 开展药物临床试验，应当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数据、资料和样品，经国务院药品监督管理部门批准。国务院药品监督管理部门应当自受理临床试验申请之日起六十个工作日内决定是否同意并通知临床试验申办者，逾期未通知的，视为同意。其中，开展生物等效性试验的，报国务院药品监督管理部门备案。

Pharmaceutical clinical trials shall be conducted in clinical trial institutions which meet the corresponding conditions. Pharmaceutical clinical trial institutions shall be subject to recordation management, and the specific measures shall be developed jointly by the medicinal product regulatory department of the State Council and the health department of the State Council.

开展药物临床试验，应当在具备相应条件的临床试验机构进行。药物临床试验机构实行备案管理，具体办法由国务院药品监督管理部门、国务院卫生健康主管部门共同制定。

Article 20 Pharmaceutical clinical trials shall be conducted in conformity with ethical principles, and clinical trial protocols shall be developed, subject to the review and consent of the ethics committee.

第二十条 开展药物临床试验，应当符合伦理原则，制定临床试验方案，经伦理委员会审查同意。

The ethics committee shall establish a working system of ethical review, ensure that the process of ethical review is independent, objective, and fair, oversee the conduct of pharmaceutical clinical trials in a well-regulated manner, protect the lawful rights and interests of human subjects, and safeguard the public interest.

伦理委员会应当建立伦理审查工作制度，保证伦理审查过程独立、客观、公正，监督规范开展药物临床试验，保障受试者合法权益，维护社会公共利益。

Article 21 In the implementation of pharmaceutical clinical trials, the objectives, risks, and other particulars of clinical trials shall be truthfully stated and explained to human subjects or their guardians, informed consent forms voluntarily signed by human subjects or their guardians shall be obtained, and effective measures shall be adopted to protect the lawful rights and interests of human subjects.

第二十一条 实施药物临床试验，应当向受试者或者其监护人如实说明和解释临床试验的目的和风险等详细情况，取得受试者或者其监护人自愿签署的知情同意书，并采取有效措施保护受试者合法权益。

Article 22 Where any safety issue or other risk is discovered during a pharmaceutical clinical trial, the sponsor of the clinical trial shall, in a timely manner, adjust the clinical trial protocol or suspend or terminate the clinical trial, and report to the medicinal product regulatory department of the State Council. When necessary, the medicinal product regulatory department of the State Council may order adjustment of the clinical trial protocol or suspension or termination of the clinical trial.

第二十二条 药物临床试验期间，发现存在安全性问题或者其他风险的，临床试验申办者应当及时调整临床试验方案、暂停或者终止临床试验，并向国务院药品监督管理部门报告。必要时，国务院药品监督管理部门可以责令调整临床试验方案、暂停或者终止临床试验。

Article 23 Pharmaceuticals in clinical trials intended for the treatment of serious life-threatening diseases for which there is no effective means of treatment may, upon review and informed consent, be administered to patients with the same conditions within the institution conducting the clinical trials, provided that such pharmaceuticals may be beneficial as indicated by medical observation and it is in conformity with ethical principles.

第二十三条 对正在开展临床试验的用于治疗严重危及生命且尚无有效治疗手段的疾病的药物，经医学观察可能获益，并且符合伦理原则的，经审查、知情同意后可以在开展临床试验的机构内用于其他病情相同的患者。

Article 24 Medicinal products to be marketed in China shall be subject to the approval of the medicinal product regulatory department of the State Council, and registration certificates shall be obtained for them, except for traditional Chinese medicinal materials and decoction pieces not subject to approval management. The catalogs of traditional Chinese medicinal materials and decoction pieces subject to approval management shall be developed by the medicinal product regulatory department of the State Council in conjunction with the traditional Chinese medicine department of the State Council.

第二十四条 在中国境内上市的药品，应当经国务院药品监督管理部门批准，取得药品注册证书；但是，未实施审批管理的中药材和中药饮片除外。实施审批管理的中药材、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主管部门制定。

To apply for registration of a medicinal product, the applicant shall provide authentic, sufficient, and reliable data, information, and samples, evidencing the safety, efficacy, and quality controllability of the medicinal product.

申请药品注册，应当提供真实、充分、可靠的数据、资料和样品，证明药品的安全性、有效性和质量可控性。

Article 25 For a medicinal product under an application for registration, the medicinal product regulatory department of the State Council shall arrange for pharmaceutical, medical, and other technical personnel to conduct an evaluation to review the safety, efficacy, and quality controllability of the medicinal product and the applicant's capabilities of quality management, risk prevention and control, and payment of damages, among others; and if the prescribed conditions are met, issue a registration certificate for the medicinal product.

第二十五条 对申请注册的药品，国务院药品监督管理部门应当组织药学、医学和其他技术人员进行审评，对药品的安全性、有效性和质量可控性以及申请人的质量管理、风险防控和责任赔偿等能力进行审查；符合条件的，颁发药品注册证书。

In approving medicinal products, the medicinal product regulatory department of the State Council shall concurrently evaluate and approve chemical active pharmaceutical ingredients (APIs), concurrently evaluate the relevant inactive ingredients and packaging materials and containers immediately in contact with medicinal products, and concurrently review and approve the quality standards, manufacturing processes, labels, and package leaflets of medicinal products.

国务院药品监督管理部门在审批药品时，对化学原料药一并审评审批，对相关辅料、直接接触药品的包装材料和容器一并审评，对药品的质量标准、生产工艺、标签和说明书一并核准。

For the purposes of this Law, “inactive ingredients” means excipients and additives used in the manufacture of medicinal products and the dispensing of prescriptions.

本法所称辅料，是指生产药品和调配处方时所用的赋形剂和附加剂。

Article 26 Medicinal products intended for the treatment of serious life-threatening diseases for which there is no effective means of treatment or urgently needed for public health may be conditionally approved with the relevant matters stated in the registration certificates for them, provided that data from pharmaceutical clinical trials have indicated any therapeutic effects and their clinical values are predictable.

第二十六条 对治疗严重危及生命且尚无有效治疗手段的疾病以及公共卫生方面急需的药品，药物临床试验已有数据显示疗效并能预测其临床价值的，可以附条件批准，并在药品注册证书中载明相关事项。

Article 27 The medicinal product regulatory department of the State Council shall improve the working system of evaluation and approval of medicinal products, strengthen capacity building, establish and improve the communication and exchange, expert advice, and other mechanisms, optimize the processes of evaluation and approval, and raise the efficiency of evaluation and approval.

第二十七条 国务院药品监督管理部门应当完善药品审评审批工作制度，加强能力建设，建立健全沟通交流、专家咨询等机制，优化审评审批流程，提高审评审批效率。

The evaluation conclusion and basis for a medicinal product approved for marketing shall be disclosed to the public in accordance with the law to receive supervision by the public. Trade secrets known during evaluation and approval shall be kept confidential.

批准上市药品的审评结论和依据应当依法公开，接受社会监督。对审评审批中知悉的商业秘密应当保密。

Article 28 Medicinal products shall meet the national medicinal product standards. Where any medicinal product quality standards approved by the medicinal product regulatory department of the State Council are higher than the national medicinal product standards, the approved medicinal product quality standards shall prevail; and absent national medicinal product standards, the approved medicinal product quality standards shall be met.

第二十八条 药品应当符合国家药品标准。经国务院药品监督管理部门核准的药品质量标准高于国家药品标准的，按照经核准的药品质量标准执行；没有国家药品标准的，应当符合经核准的药品质量标准。

The Pharmacopoeia of the People's Republic of China and the medicinal product standards promulgated by the medicinal product regulatory department of the State Council shall be the national medicinal product standards.

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 medicinal product regulatory department of the State Council shall, in conjunction with the health department of the State Council, organize a pharmacopoeia committee responsible for the development and revision of the national medicinal product standards.

国务院药品监督管理部门会同国务院卫生健康主管部门组织药典委员会，负责国家药品标准的制定和修订。

The medicinal product control institutions established or designated by the medicinal product regulatory department of the State Council shall be responsible for establishing national biological reference preparations and chemical reference substances for medicinal products.

国务院药品监督管理部门设置或者指定的药品检验机构负责标定国家药品标准品、对照品。

Article 29 The names of medicinal products listed in the national medicinal product standards shall be the generic names of medicinal products. The names which have become the generic names of medicinal products shall not be used as trademarks of medicinal products.

第二十九条 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。

Chapter III Holders of Marketing Authorization for Medicinal Products

第三章 药品上市许可持有人

Article 30 Marketing authorization holders are enterprises or pharmaceutical research and development institutions, among others, which have obtained registration certificates for medicinal products.

第三十条 药品上市许可持有人是指取得药品注册证书的企业或者药品研制机构等。

Marketing authorization holders shall be responsible for the nonclinical laboratory studies, clinical trials, manufacture, distribution, post-market studies, and surveillance, reporting, and disposition of adverse reactions, among others, of medicinal products in accordance with the provisions of this Law. Any other entity or individual engaged in the research and development, manufacture, distribution, storage, transportation, or use, among others, of medicinal products shall assume corresponding responsibility in accordance with the law.

药品上市许可持有人应当依照本法规定，对药品的非临床研究、临床试验、生产经营、上市后研究、不良反应监测及报告与处理等承担责任。其他从事药品研制、生产、经营、储存、运输、使用等活动的单位和个人依法承担相应责任。

The legal representative or the primary person in charge of a marketing authorization holder shall be fully responsible for medicinal product quality.

药品上市许可持有人的法定代表人、主要负责人对药品质量全面负责。

Article 31 A marketing authorization holder shall establish a medicinal product quality assurance system, and employ specialized personnel independently responsible for medicinal product quality management.

第三十一条 药品上市许可持有人应当建立药品质量保证体系，配备专门人员独立负责药品质量管理。

A marketing authorization holder shall regularly review the quality management systems of the authorized manufacturers and distributors of the approved medicinal product, and oversee their continuing capabilities of quality assurance and control.

药品上市许可持有人应当对受托药品生产企业、药品经营企业的质量管理体系进行定期审核，监督其持续具备质量保证和控制能力。

Article 32 A marketing authorization holder may manufacture the registered medicinal product itself or authorize a manufacturer of medicinal products to manufacture the registered medicinal product.

第三十二条 药品上市许可持有人可以自行生产药品，也可以委托药品生产企业生产。

A marketing authorization holder shall obtain a manufacturing permit for medicinal products in accordance with the provisions of this Law if it manufactures the registered medicinal product itself; or if it authorizes a manufacturer of medicinal products to manufacture the registered medicinal product, the authorized manufacturer shall meet the prescribed conditions. The marketing authorization holder and the authorized manufacturer shall enter into an agreement on the authorized manufacture and a quality agreement, and strictly perform their obligations under the agreements.

药品上市许可持有人自行生产药品的，应当依照本法规定取得药品生产许可证；委托生产的，应当委托符合条件的药品生产企业。药品上市许可持有人和受托生产企业应当签订委托协议和质量协议，并严格履行协议约定的义务。

The medicinal product regulatory department of the State Council shall develop the guidance on quality agreements for the authorized manufacture of medicinal products, and guide and oversee the marketing authorization holders and authorized manufacturers in performing their obligations to assure medicinal product quality.

国务院药品监督管理部门制定药品委托生产质量协议指南，指导、监督药品上市许可持有人和受托生产企业履行药品质量保证义务。

Marketing authorization holders may not outsource the manufacture of blood products, narcotic drugs, psychotropic substances, poisonous substances for medical use, and pharmaceutical precursor chemicals, except as otherwise specified by the medicinal product regulatory department of the State Council.

血液制品、麻醉药品、精神药品、医疗用毒性药品、药品类易制毒化学品不得委托生产；但是，国务院药品监督管理部门另有规定的除外。

Article 33 A marketing authorization holder shall establish the rules and procedures for the release of medicinal products to be placed on the market, review the ex-factory medicinal products released by a manufacturer of medicinal products, and grant release only upon signature of the qualified person. Medicinal products in nonconformity with the national medicinal product standards may not be released.

第三十三条 药品上市许可持有人应当建立药品上市放行规程，对药品生产企业出厂放行的药品进行审核，经质量受权人签字后方可放行。不符合国家药品标准的，不得放行。

Article 34 A marketing authorization holder may itself sell the medicinal product for which a registration certificate has been obtained, or authorize a distributor of medicinal products to sell the registered medicinal products. A marketing authorization holder engaged in the retailing of medicinal products shall obtain a distribution permit for medicinal products.

第三十四条 药品上市许可持有人可以自行销售其取得药品注册证书的药品，也可以委托药品经营企业销售。药品上市许可持有人从事药品零售活动的，应当取得药品经营许可证。

A marketing authorization holder shall meet the conditions as set forth in Article 52 of this Law if it sells the registered medicinal product itself; or if it authorizes a distributor of medicinal products to sell the registered medicinal products, the authorized distributor shall meet the prescribed conditions. The marketing authorization holder and the authorized distributor shall enter into an agreement on the authorized distribution, and strictly perform the obligations under the agreement.

药品上市许可持有人自行销售药品的，应当具备本法第五十二条规定的条件；委托销售的，应当委托符合条件的药品经营企业。药品上市许可持有人和受托经营企业应当签订委托协议，并严格履行协议约定的义务。

Article 35 Where a marketing authorization holder or a manufacturer or distributor of medicinal products outsources the storage or transportation of medicinal products, it shall assess the quality assurance and risk management capabilities of the authorized service provider, enter into a storage or transportation agreement with the authorized service provider, covering, among others, the liability for medicinal product quality and the operating rules and procedures, and oversee the authorized service provider.

第三十五条 药品上市许可持有人、药品生产企业、药品经营企业委托储存、运输药品的，应当对受托方的质量保证能力和风险管理能力进行评估，与其签订委托协议，约定药品质量责任、操作规程等内容，并对受托方进行监督。

Article 36 Marketing authorization holders, manufacturers and distributors of medicinal products, and medical institutions shall establish and implement their medicinal product traceability systems, provide traceability information as required, and ensure the traceability of medicinal products.

第三十六条 药品上市许可持有人、药品生产企业、药品经营企业和医疗机构应当建立并实施药品追溯制度，按照规定提供追溯信息，保证药品可追溯。

Article 37 A marketing authorization holder shall establish an annual reporting system, and annually report its manufacture and sale of medicinal products, post-market studies, risk management, and other information to the medicinal product regulatory department of the people's government of the province, autonomous region, or municipality directly under the Central Government as required.

第三十七条 药品上市许可持有人应当建立年度报告制度，每年将药品生产销售、上市后研究、风险管理等情况按照规定向省、自治区、直辖市人民政府药品监督管理部门报告。

Article 38 Where a marketing authorization holder is an overseas enterprise, a corporate enterprise in China designated by it shall perform the obligations of the marketing authorization holder, and assume joint and several liability with the marketing authorization holder.

第三十八条 药品上市许可持有人为境外企业的，应当由其指定的在中国境内的企业法人履行药品上市许可持有人义务，与药品上市许可持有人承担连带责任。

Article 39 A manufacturer of traditional Chinese medicinal decoction pieces shall perform the relevant obligations of a marketing authorization holder, implement the whole process management of the manufacture and sale of decoction pieces, establish a traceability system of decoction pieces, and ensure the safety, efficacy, and traceability of decoction pieces.

第三十九条 中药饮片生产企业履行药品上市许可持有人的相关义务，对中药饮片生产、销售实行全过程管理，建立中药饮片追溯体系，保证中药饮片安全、有效、可追溯。

Article 40 A marketing authorization holder may assign the marketing authorization with the approval of the medicinal product regulatory department of the State Council. The assignee shall have the capabilities of quality management, risk prevention and control, and payment of damages, among others, to ensure the safety, efficacy, and quality controllability of medicinal products, and perform the obligations of a marketing authorization holder.

第四十条 经国务院药品监督管理部门批准，药品上市许可持有人可以转让药品上市许可。受让方应当具备保障药品安全性、有效性和质量可控性的质量管理、风险防控和责任赔偿等能力，履行药品上市许可持有人义务。

Chapter IV Manufacture of Medicinal Products

第四章 药品生产

Article 41 To be engaged in the manufacture of medicinal products, one shall be subject to the approval of the medicinal product regulatory department of the people's government of the province, autonomous region, or municipality directly under the Central Government where it is located, and obtain a manufacturing permit for medicinal products. No medicinal products may be manufactured without a manufacturing permit for medicinal products.

第四十一条 从事药品生产活动，应当经所在地省、自治区、直辖市人民政府药品监督管理部门批准，取得药品生产许可证。无药品生产许可证的，不得生产药品。

A manufacturing permit for medicinal products shall state a period of validity and a scope of manufacture, and upon expiration, shall be reissued after examination.

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。

Article 42 To be engaged in the manufacture of medicinal products, one shall meet the following conditions:

第四十二条 从事药品生产活动，应当具备以下条件：

(1) It has pharmacy technicians, engineering technicians, and corresponding skilled workers, who are qualified in accordance with the law.

（一）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；

(2) It has the factory premises, facilities, and hygienic environment suitable for the manufacture of medicinal products.

（二）有与药品生产相适应的厂房、设施和卫生环境；

(3) It has the institutions and personnel capable of conducting quality management and quality inspection of the medicinal products manufactured as well as necessary instruments and equipment.

（三）有能对所生产药品进行质量管理和质量检验的机构、人员及必要的仪器设备；

(4) It has the rules and regulations to assure quality of medicinal products, and complies with the requirements of the good manufacturing practice ("GMP") for medicinal products developed by the medicinal product regulatory department of the State Council in accordance with this Law.

（四）有保证药品质量的规章制度，并符合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要求。

Article 43 One engaged in the manufacture of medicinal products shall comply with the GMP for medicinal products, establish and improve a quality management system for the manufacture of medicinal products, and ensure the continuing compliance of the whole process of manufacture of medicinal productions with the statutory requirements.

第四十三条 从事药品生产活动，应当遵守药品生产质量管理规范，建立健全药品生产质量管理体系，保证药品生产全过程持续符合法定要求。

The legal representative or the primary person in charge of a manufacturer of medicinal products shall be fully responsible for the enterprise's manufacture of medicinal products.

药品生产企业的法定代表人、主要负责人对本企业的药品生产活动全面负责。

Article 44 Medicinal products shall be manufactured in accordance with the national medicinal product standards and the manufacturing processes reviewed and approved by the medicinal product regulatory department of the State Council. The records of manufacture and inspection shall be complete and accurate, and may not be fabricated.

第四十四条 药品应当按照国家药品标准和经药品监督管理部门核准的生产工艺进行生产。生产、检验记录应当完整准确，不得编造。

Traditional Chinese medicinal decoction pieces shall be processed in accordance with the national medicinal product standards; or in the absence of the national medicinal product standards, be processed in accordance with the processing specifications developed by the medicinal product regulatory department of the province, autonomous region, or municipality directly under the central government. The processing specifications developed by the medicinal product regulatory department of a province, autonomous region, or municipality directly under the central governments shall be filed with the medicinal product regulatory department of the State Council. Decoction pieces which are not processed in accordance with the national medicinal product standards or the processing specifications developed by the medicinal product regulatory department of the people's government of a province, autonomous region, or municipality directly under the Central Government may not leave the factory or be sold.

中药饮片应当按照国家药品标准炮制；国家药品标准没有规定的，应当按照省、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。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炮制规范炮制的，不得出厂、销售。

Article 45 The raw materials and inactive ingredients needed for the manufacture of medicinal products shall satisfy the requirements for medicinal use and the relevant requirements of the GMP for medicinal products.

第四十五条 生产药品所需的原料、辅料，应当符合药用要求、药品生产质量管理规范的有关要求。

In the manufacture of medicinal products, the suppliers of raw materials and inactive ingredients, among others, shall be examined as required to ensure that the raw materials and inactive ingredients, among others, purchased and used satisfy the requirements of the preceding paragraph.

生产药品，应当按照规定对供应原料、辅料等的供应商进行审核，保证购进、使用的原料、辅料等符合前款规定要求。

Article 46 Packaging materials and containers immediately in contact with medicinal products shall satisfy the requirements for medicinal use, and meet the standards for protecting human health and safety.

第四十六条 直接接触药品的包装材料和容器，应当符合药用要求，符合保障人体健康、安全的标准。

The medicinal product regulatory departments shall order cessation of use of noncompliant packaging materials and containers in direct contact with medicinal products.

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。

Article 47 A manufacturer of medicinal products shall conduct quality inspection on its medicinal products. Those in nonconformity with the national medicinal product standards may not leave the factory.

第四十七条 药品生产企业应当对药品进行质量检验。不符合国家药品标准的，不得出厂。

A manufacturer of medicinal products shall establish the rules and procedures for the release of ex-factory medicinal products, and specify the standards and conditions for ex-factory release. Those meeting the standards and conditions may be released upon signature of the qualified person.

药品生产企业应当建立药品出厂放行规程，明确出厂放行的标准、条件。符合标准、条件的，经质量受权人签字后方可放行。

Article 48 The packaging of medicinal products shall conform to the requirements for medicinal product quality, and facilitate storage, transportation, and medical use.

第四十八条 药品包装应当适合药品质量的要求，方便储存、运输和医疗使用。

Traditional Chinese medicinal materials shall be packaged before transportation. The name of product, place of production, date, and supplier shall be indicated on each package, and a quality compliance mark shall be affixed thereto.

发运中药材应当有包装。在每件包装上，应当注明品名、产地、日期、供货单位，并附有质量合格的标志。

Article 49 Labels shall be printed on or glued to the packaging of a medicinal product, accompanied with a package leaflet, as required.

第四十九条 药品包装应当按照规定印有或者贴有标签并附有说明书。

A label or package leaflet shall state a medicinal product's generic name, ingredients, specifications, marketing authorization holder with address, manufacturer with address, approval number, batch number, production date, expiry date, therapeutic indications or actions and indications, usage, dosage, contraindications, adverse reactions, and warnings and precautions. The language on the label and package leaflet shall be clear, and matters such as production date and expiry date shall be marked conspicuously and easily legible.

标签或者说明书应当注明药品的通用名称、成份、规格、上市许可持有人及其地址、生产企业及其地址、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。标签、说明书中的文字应当清晰，生产日期、有效期等事项应当显著标注，容易辨识。

The required marks shall be printed on the labels and package leaflets of narcotic drugs, psychotropic substances, poisonous substances for medical use, radiopharmaceuticals, medicinal products for external use, and non-prescription medicinal products.

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、说明书，应当印有规定的标志。

Article 50 The personnel of marketing authorization holders, manufacturers and distributors of medicinal products, and medical institutions who are immediately in contact with medicinal products shall annually undergo a medical examination. Those suffering from any infectious disease or other disease which may contaminate medicinal products may not work immediately in contact with medicinal products.

第五十条 药品上市许可持有人、药品生产企业、药品经营企业和医疗机构中直接接触药品的工作人员，应当每年进行健康检查。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。

Chapter V Distribution of Medicinal Products

第五章 药品经营

Article 51 To be engaged in the wholesale distribution of medicinal products, one shall be subject to the approval of the medicinal product regulatory department of the people's government of the province, autonomous region, or municipality directly under the Central Government where it is located, and obtain a distribution permit for medicinal products. To be engaged in the retailing of medicinal products, one shall be subject to the approval of the medicinal product regulatory department of the local people's government at or above the county level, and obtain a distribution permit for medicinal products. No medicinal products may be distributed without a distribution permit for medicinal products.

第五十一条 从事药品批发活动，应当经所在地省、自治区、直辖市人民政府药品监督管理部门批准，取得药品经营许可证。从事药品零售活动，应当经所在地县级以上地方人民政府药品监督管理部门批准，取得药品经营许可证。无药品经营许可证的，不得经营药品。

A distribution permit for medicinal products shall state a period of validity and a scope of distribution, and upon expiration, shall be reissued after examination.

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。

In implementing the licensure of distribution of medicinal products, medicinal product regulatory departments shall also follow the principle of convenience for people's purchase of medicinal products, subject to the conditions as set forth in Article 52 of this Law.

药品监督管理部门实施药品经营许可，除依据本法第五十二条规定的条件外，还应当遵循方便群众购药的原则。

Article 52 To be engaged in the distribution of medicinal products, one shall meet the following conditions:

第五十二条 从事药品经营活动应当具备以下条件：

(1) It has pharmacists or other pharmacy technicians, who are qualified in accordance with the law.

（一）有依法经过资格认定的药师或者其他药学技术人员；

(2) It has the business premises, equipment, storage facilities, and hygienic environment suitable for the medicinal products distributed.

（二）有与所经营药品相适应的营业场所、设备、仓储设施和卫生环境；

(3) It has the quality management institutions or personnel suitable for the medicinal products distributed.

（三）有与所经营药品相适应的质量管理机构或者人员；

(4) It has the rules and regulations to assure quality of medicinal products, and complies with the requirements of the good supply practice (“GSP”) for medicinal products developed by the medicinal product regulatory department of the State Council in accordance with this Law.

（四）有保证药品质量的规章制度，并符合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要求。

Article 53 One engaged in the distribution of medicinal products shall comply with the GSP for medicinal products, establish and improve a quality management system for the distribution of medicinal products, and ensure the continuing compliance of the whole process of distribution of medicinal productions with the statutory requirements.

第五十三条 从事药品经营活动，应当遵守药品经营质量管理规范，建立健全药品经营质量管理体系，保证药品经营全过程持续符合法定要求。

The state shall encourage and guide the operations of medicinal product retail chains. The headquarters of enterprises engaged in medicinal product retail chain operations shall establish a unified quality management system, and fulfill the management responsibility for the distribution activities of member retailers.

国家鼓励、引导药品零售连锁经营。从事药品零售连锁经营活动的企业总部，应当建立统一的质量管理制度，对所属零售企业的经营活动履行管理责任。

The legal representative or the primary person in charge of a distributor of medicinal products shall be fully responsible for the enterprise's distribution of medicinal products.

药品经营企业的法定代表人、主要负责人对本企业的药品经营活动全面负责。

Article 54 The state shall implement a prescription and non-prescription classification management of medicinal products. The specific measures shall be developed by the medicinal product regulatory department of the State Council in conjunction with the health department of the State Council.

第五十四条 国家对药品实行处方药与非处方药分类管理制度。具体办法由国务院药品监督管理部门会同国务院卫生健康主管部门制定。

Article 55 Marketing authorization holders, manufacturers and distributors of medicinal products, and medical institutions shall purchase medicinal products from marketing authorization holders or enterprises qualified for the manufacture or distribution of medicinal products; except for the purchase of traditional Chinese medicinal materials not subject to approval management.

第五十五条 药品上市许可持有人、药品生产企业、药品经营企业和医疗机构应当从药品上市许可持有人或者具有药品生产、经营资格的企业购进药品；但是，购进未实施审批管理的中药材除外。

Article 56 Distributors of medicinal products shall establish and implement a purchase inspection system for the purchase of medicinal products, and verify the compliance certificates of medicinal products and other marks; and shall not purchase and sell medicinal products which do not satisfy the prescribed requirements.

第五十六条 药品经营企业购进药品，应当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，不得购进和销售。

Article 57 Distributors of medicinal products shall keep authentic and complete purchase and sale records of the medicinal products purchased and sold. The purchase and sale records shall state a medicinal product's generic name, dosage form, specifications, batch number, expiry date, marketing authorization holder, manufacturer, purchaser or seller, purchase or sales quantity, purchase or sales price, date of purchase or sale, and other matters specified by the medicinal product regulatory department of the State Council.

第五十七条 药品经营企业购销药品，应当有真实、完整的购销记录。购销记录应当注明药品的通用名称、剂型、规格、产品批号、有效期、上市许可持有人、生产企业、购销单位、购销数量、购销价格、购销日期及国务院药品监督管理部门规定的其他内容。

Article 58 Distributors of medicinal products shall retail medicinal products in an accurate and unmistaken manner, and correctly explain the usage, dosage, and warnings and precautions; and when dispensing prescriptions, shall verify each prescription, and may not change or replace any medicinal product listed in the prescription without permission. The dispensing of prescriptions containing incompatible substances or excessive dosages shall be rejected; but when necessary, such a prescription may be dispensed after being corrected or re-signed by the prescribing doctor.

第五十八条 药品经营企业零售药品应当准确无误，并正确说明用法、用量和注意事项；调配处方应当经过核对，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。

Distributors of medicinal products selling traditional Chinese medicinal materials shall mark the origin thereof.

药品经营企业销售中药材，应当标明产地。

Pharmacists or other pharmacy technicians who are qualified in accordance with the law shall be responsible for the medicinal product management, review and dispensing of prescriptions, guidance on rational medication, and other work of the enterprise employing them.

依法经过资格认定的药师或者其他药学技术人员负责本企业的药品管理、处方审核和调配、合理用药指导等工作。

Article 59 Distributors of medicinal products shall develop and implement the rules for the safekeeping of medicinal products, and adopt cooling, freeze-proof, moisture-proof, insect-proof, rodent-proof, and other necessary measures to assure quality of medicinal products.

第五十九条 药品经营企业应当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。

An inspection system of medicinal products entering or leaving warehouses shall be implemented.

药品入库和出库应当执行检查制度。

Article 60 Traditional Chinese medicinal materials may be sold at urban and rural fairs, except as otherwise specified by the State Council.

第六十条 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 61 A marketing authorization holder or a distributor of medicinal products which sells medicinal products online shall comply with the provisions on distribution of medicinal products of this Law. The specific administrative measures shall be developed by the medicinal product regulatory department of the State Council in conjunction with the health and other departments of the State Council.

第六十一条 药品上市许可持有人、药品经营企业通过网络销售药品，应当遵守本法药品经营的有关规定。具体管理办法由国务院药品监督管理部门会同国务院卫生健康主管部门等部门制定。

Vaccines, blood products, narcotic drugs, psychotropic substances, poisonous substances for medical use, radiopharmaceuticals, pharmaceutical precursor chemicals, and other medicinal products under special administration of the state shall not be sold online.

疫苗、血液制品、麻醉药品、精神药品、医疗用毒性药品、放射性药品、药品类易制毒化学品等国家实行特殊管理的药品不得在网络上销售。

Article 62 The provider of a third-party platform for online trading in medicinal products shall, in accordance with the rules of the medicinal product regulatory department of the State Council, undergo recordation with the medicinal product regulatory department of the people's government of the province, autonomous region, or municipality directly under the Central Government where it is located.

第六十二条 药品网络交易第三方平台提供者应当按照国务院药品监督管理部门的规定，向所在地省、自治区、直辖市人民政府药品监督管理部门备案。

The provider of the third-party platform shall, in accordance with the law, examine the qualifications, among others, of marketing authorization holders and distributors of medicinal products which apply for distribution on the platform to ensure their compliance with the statutory requirements, and manage the acts of distribution of medicinal products which occur on the platform.

第三方平台提供者应当依法对申请进入平台经营的药品上市许可持有人、药品经营企业的资质等进行审核，保证其符合法定要求，并对发生在平台的药品经营行为进行管理。

Where the provider of the third-party platform discovers that any marketing authorization holder or distributor of medicinal products engaged in distribution on the platform violates the provisions of this Law, it shall cease in a timely manner and report immediately the violation to the medicinal product regulatory department of the local people's government at the county level; and if any illegal conduct discovered is serious, cease immediately the provision of online trading platform services to the violator.

第三方平台提供者发现进入平台经营的药品上市许可持有人、药品经营企业有违反本法规定行为的，应当及时制止并立即报告所在地县级人民政府药品监督管理部门；发现严重违法行为的，应当立即停止提供网络交易平台服务。

Article 63 Newly discovered medicinal materials and medicinal materials domestically cultivated but introduced from abroad may be sold only with the approval of the medicinal product regulatory department of the State Council.

第六十三条 新发现和从境外引种的药材，经国务院药品监督管理部门批准后，方可销售。

Article 64 Medicinal products shall be imported at a port allowing the import of medicinal products, and enterprises importing medicinal products shall undergo recordation with the medicinal product regulatory department of the place where the port is located. The Customs shall conduct customs clearance based on the customs clearance form for import of medicinal products issued by the medicinal product regulatory department. The Customs shall not release imports without the customs clearance form for import of medicinal products.

第六十四条 药品应当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备案。海关凭药品监督管理部门出具的进口药品通关单办理通关手续。无进口药品通关单的，海关不得放行。

The medicinal product regulatory department of the place where the port is located shall notify the medicinal product control institution regarding the sample testing of the imported medicinal products in accordance with the rules of the medicinal product regulatory department of the State Council.

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。

The ports allowing the import of medicinal products shall be proposed jointly by the medicinal product regulatory department of the State Council and the General Administration of Customs and reported to the State Council for approval.

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。

Article 65 For clinical urgency, a medical institution may import a medicinal product in a limited amount with the approval of the medicinal product regulatory department of the State Council or the people's government of the province, autonomous region, or municipality directly under the Central Government authorized by the State Council. The imported medicinal product shall be used within the designated medical institution for the specific medical purpose.

第六十五条 医疗机构因临床急需进口少量药品的，经国务院药品监督管理部门或者国务院授权的省、自治区、直辖市人民政府批准，可以进口。进口的药品应当在指定医疗机构内用于特定医疗目的。

Medicinal products in a limited amount as personal imports shall be governed by the relevant provisions issued by the state.

个人自用携带入境少量药品，按照国家有关规定办理。

Article 66 Import or export licenses issued by the medicinal product regulatory department of the State Council shall be required for the import or export of narcotic drugs and the psychotropic substances within the scope specified by the state.

第六十六条 进口、出口麻醉药品和国家规定范围内的精神药品，应当持有国务院药品监督管理部门颁发的进口准许证、出口准许证。

Article 67 The import of medicinal products with uncertain therapeutic effects, with significant adverse reactions, or harmful to people's health for other causes shall be prohibited.

第六十七条 禁止进口疗效不确切、不良反应大或者因其他原因危害人体健康的药品。

Article 68 The medicinal product regulatory department of the State Council shall designate medicinal product control institutions to test the following medicinal products before their sale or import; and those untested or failing the test shall not be sold or imported:

第六十八条 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，应当指定药品检验机构进行检验；未经检验或者检验不合格的，不得销售或者进口：

(1) Medicinal products to be sold for the first time in China.

（一）首次在中国境内销售的药品；

(2) Biological products specified by the medicinal product regulatory department of the State Council.

（二）国务院药品监督管理部门规定的生物制品；

(3) Other medicinal products specified by the State Council.

（三）国务院规定的其他药品。

Chapter VI Pharmaceutical Affairs Management of Medical Institutions

第六章　医疗机构药事管理

Article 69 Medical institutions shall have pharmacists or other pharmacy technicians who are qualified in accordance with the law, responsible for the medicinal product management, review and dispensing of prescriptions, guidance on rational medication, and other work of the institution. Persons other than pharmacy technicians may not be directly engaged in pharmaceutical technical work.

第六十九条　医疗机构应当配备依法经过资格认定的药师或者其他药学技术人员，负责本单位的药品管理、处方审核和调配、合理用药指导等工作。非药学技术人员不得直接从事药剂技术工作。

Article 70 A medical institution shall establish and implement a purchase inspection system for the purchase of medicinal products, and verify the compliance certificates of medicinal products and other marks; and shall not purchase and use medicinal products which do not satisfy the prescribed requirements.

第七十条　医疗机构购进药品，应当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 71 A medical institution shall have the premises, equipment, warehousing facility, and hygienic environment suitable for the medicinal products used, develop and implement the rules for the safekeeping of medicinal products, and adopt cooling, freeze-proof, moisture-proof, insect-proof, rodent-proof, and other necessary measures to assure quality of medicinal products.

第七十一条　医疗机构应当有与所使用药品相适应的场所、设备、仓储设施和卫生环境，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 72 A medical institution shall adhere to the principle of safe, effective, economical, and rational medications, use medicinal products rationally by following the principles for guiding clinical application of medicinal products, clinical diagnosis and treatment guidance, and package leaflets, among others, and review the suitability of a doctor's prescriptions and medication advice.

第七十二条　医疗机构应当坚持安全有效、经济合理的用药原则，遵循药品临床应用指导原则、临床诊疗指南和药品说明书等合理用药，对医师处方、用药医嘱的适宜性进行审核。

Entities using medicinal products other than medical institutions shall comply with the provisions of this Law on the use of medicinal products by medical institutions.

医疗机构以外的其他药品使用单位，应当遵守本法有关医疗机构使用药品的规定。

Article 73 A pharmacist or any other pharmacy technician who dispenses a prescription shall verify the prescription, and may not change or replace any medicinal product listed in the prescription without permission. The dispensing of prescriptions containing incompatible substances or excessive dosages shall be rejected; but when necessary, such a prescription may be dispensed after being corrected or re-signed by the prescribing doctor.

第七十三条　依法经过资格认定的药师或者其他药学技术人员调配处方，应当进行核对，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 74 To be engaged in pharmaceutical compounding, a medical institution shall be subject to the approval of the medicinal product regulatory department of the province, autonomous region, or municipality directly under the central government where it is located, and obtain a medical institution compounding permit. No pharmaceutical compounding may be conducted without a medical institution compounding permit.

第七十四条　医疗机构配制制剂，应当经所在地省、自治区、直辖市人民政府药品监督管理部门批准，取得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。

A medical institution compounding permit shall state a period of validity, and upon expiration, shall be reissued after examination.

医疗机构制剂许可证应当标明有效期，到期重新审查发证。

Article 75 A medical institution engaged in pharmaceutical compounding shall have the facilities, management system, testing instruments, and hygienic environment capable of assuring quality of the preparations created.

第七十五条　医疗机构配制制剂，应当有能够保证制剂质量的设施、管理制度、检验仪器和卫生环境。

A medical institution shall conduct pharmaceutical compounding according to the processes reviewed and approved, and the needed raw materials, inactive ingredients, and packaging materials, among others, shall satisfy the requirements for medicinal use.

医疗机构配制制剂，应当按照经核准的工艺进行，所需的原料、辅料和包装材料等应当符合药用要求。

Article 76 The preparations created from pharmaceutical compounding by a medical institution shall be the varieties clinically needed by the institution but not available on the market, and be subject to the approval of the medicinal product regulatory department of the province, autonomous region, or municipality directly under the central government where it is located; except as otherwise required by laws regarding traditional Chinese medicinal preparations.

第七十六条　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，并应当经所在地省、自治区、直辖市人民政府药品监督管理部门批准；但是，法律对配制中药制剂另有规定的除外。

The quality of preparations created from pharmaceutical compounding by a medical institution shall be inspected as required; and compliant preparations may be used upon a doctor's prescription within the institution. With the approval of the medicinal product regulatory department of the State Council or the medicinal product regulatory department of the people's government of a province, autonomous region, or municipality directly under the central government, the preparations created from pharmaceutical compounding by medical institutions may be shared among the designated medical institutions.

医疗机构配制的制剂应当按照规定进行质量检验；合格的，凭医师处方在本单位使用。经国务院药品监督管理部门或者省、自治区、直辖市人民政府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。

Preparations created from pharmaceutical compounding by medical institutions may not be sold on the market.

医疗机构配制的制剂不得在市场上销售。

Chapter VII Post-market Management of Medicinal Products

第七章　药品上市后管理

Article 77 A marketing authorization holder shall develop a post-market risk management plan for medicinal products, proactively conduct post-market studies on medicinal products, further validate the safety, efficacy, and quality controllability of medicinal products, and strengthen the continuing management of the marketed medicinal products.

第七十七条　药品上市许可持有人应当制定药品上市后风险管理计划，主动开展药品上市后研究，对药品的安全性、有效性和质量可控性进行进一步确证，加强对已上市药品的持续管理。

Article 78 For a medicinal product conditionally approved, the marketing authorization holder shall take corresponding risk management measures, and complete relevant studies as required within the prescribed time limit; and if it fails to complete the studies as required within the prescribed time limit or is unable to prove that the benefits of the medicinal product outweigh the risks of it, the medicinal product regulatory department of the State Council shall take action in accordance with the law, and even cancel the registration certificate of the medicinal product.

第七十八条　对附条件批准的药品，药品上市许可持有人应当采取相应风险管理措施，并在规定期限内按照要求完成相关研究；逾期未按照要求完成研究或者不能证明其获益大于风险的，国务院药品监督管理部门应当依法处理，直至注销药品注册证书。

Article 79 Modifications in the process of manufacture of medicinal products shall be managed by classification according to the risks posed by them to the safety, efficacy, and quality controllability of medicinal products and the degrees of their impacts. Significant modifications shall be subject to the approval of the medicinal product regulatory department of the State Council, and any other modification shall undergo recordation or be reported in accordance with the rules of the medicinal product regulatory department of the State Council.

第七十九条　对药品生产过程中的变更，按照其对药品安全性、有效性和质量可控性的风险和产生影响的程度，实行分类管理。属于重大变更的，应当经国务院药品监督管理部门批准，其他变更应当按照国务院药品监督管理部门的规定备案或者报告。

A marketing authorization holder shall, in accordance with the rules of the medicinal product regulatory department of the State Council, comprehensively assess and verify the impact of any modification on the safety, efficacy, and quality controllability of medicinal products.

药品上市许可持有人应当按照国务院药品监督管理部门的规定，全面评估、验证变更事项对药品安全性、有效性和质量可控性的影响。

Article 80 A marketing authorization holder shall conduct the post-market surveillance of adverse reactions to medicinal products, proactively collect, track, and analyze information on suspected adverse reactions to medicinal products, and take timely risk control measures on medicinal products with identified risks.

第八十条　药品上市许可持有人应当开展药品上市后不良反应监测，主动收集、跟踪分析疑似药品不良反应信息，对已识别风险的药品及时采取风险控制措施。

Article 81 A marketing authorization holder, a manufacturer or distributor of medicinal products, or a medical institution shall frequently inspect the quality, therapeutic effects, and adverse reactions of the medicinal products produced, distributed, or used by it. If any suspected adverse reaction is discovered, it shall report in a timely manner to the medicinal product regulatory department and the health department. The specific measures shall be developed by the medicinal product regulatory department of the State Council in conjunction with the health department of the State Council.

第八十一条　药品上市许可持有人、药品生产企业、药品经营企业和医疗机构应当经常考察本单位所生产、经营、使用的药品质量、疗效和不良反应。发现疑似不良反应的，应当及时向药品监督管理部门和卫生健康主管部门报告。具体办法由国务院药品监督管理部门会同国务院卫生健康主管部门制定。

For medicinal products with confirmed occurrences of severe adverse reactions, the medicinal product regulatory department of the State Council or the medicinal product regulatory department of the people's government of a province, autonomous region, or municipality directly under the Central Government shall adopt emergency control measures such as ceasing manufacture, sale, or use based on the actual circumstances, organize an appraisal within five days, and in accordance with the law, make an administrative disposition decision within 15 days from the date of appraisal conclusion.

对已确认发生严重不良反应的药品，由国务院药品监督管理部门或者省、自治区、直辖市人民政府药品监督管理部门根据实际情况采取停止生产、销售、使用等紧急控制措施，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。

Article 82 Where there is any quality problem or other hidden safety risk with a medicinal product, the marketing authorization holder shall immediately cease the sale of the medicinal product, notify the relevant distributors of medicinal products and medical institutions regarding ceasing the sale and use of the medicinal product, recall the medicinal product already sold, publish in a timely manner the recall information, immediately cease the manufacture of the medicinal product when necessary, and report the recall and disposition of the medicinal product to the medicinal product regulatory department and the health department of the people's government of the province, autonomous region, or municipality directly under the Central Government. The manufacturers and distributors of medicinal product distributors and medical institutions shall provide cooperation.

第八十二条 药品存在质量问题或者其他安全隐患的，药品上市许可持有人应当立即停止销售，告知相关药品经营企业和医疗机构停止销售和使用，召回已销售的药品，及时公开召回信息，必要时应当立即停止生产，并将药品召回和处理情况向省、自治区、直辖市人民政府药品监督管理部门和卫生健康主管部门报告。药品生产企业、药品经营企业和医疗机构应当配合。

Where a marketing authorization holder fails to recall any medicinal product as it shall recall in accordance with the law, the medicinal product regulatory department of the people's government of the province, autonomous region, or municipality directly under the Central Government shall order it to recall the medicinal product.

药品上市许可持有人依法应当召回药品而未召回的，省、自治区、直辖市人民政府药品监督管理部门应当责令其召回。

Article 83 A marketing authorization holder shall, on a regular basis, conduct post-market evaluation on the safety, efficacy, and quality controllability of the marketed medicinal products. When necessary, the medicinal product regulatory department of the State Council may order a marketing authorization holder to conduct post-market evaluation or directly organize post-market evaluation.

第八十三条 药品上市许可持有人应当对已上市药品的安全性、有效性和质量可控性定期开展上市后评价。必要时，国务院药品监督管理部门可以责令药品上市许可持有人开展上市后评价或者直接组织开展上市后评价。

Upon evaluation, the registration certificates for medicinal products with uncertain therapeutic effects, with significant adverse reactions, or harmful to people's health for other causes shall be cancelled.

经评价，对疗效不确切、不良反应大或者因其他原因危害人体健康的药品，应当注销药品注册证书。

Medicinal products for which the registration certificates have been cancelled shall not be manufactured or imported, sold, or used.

已被注销药品注册证书的药品，不得生产或者进口、销售和使用。

The medicinal product regulatory departments shall supervise the destruction of or in accordance with the law, take other measures such as harmless treatment on medicinal products for which the registration certificates have been cancelled or beyond the expiry date, among others.

已被注销药品注册证书、超过有效期等的药品，应当由药品监督管理部门监督销毁或者依法采取其他无害化处理等措施。

Chapter VIII Prices and Advertising of Medicinal Products

第八章 药品价格和广告

Article 84 The state shall improve the medicinal product procurement management system, conduct surveillance of medicinal product prices, conduct cost and price investigation of medicinal products, strengthen the supervisory inspection of medicinal product prices, investigate and punish illegal conduct in connection with medicinal product prices such as price monopoly and price gouging, and maintain the order of medicinal product prices.

第八十四条 国家完善药品采购管理制度，对药品价格进行监测，开展成本价格调查，加强药品价格监督检查，依法查处价格垄断、哄抬价格等药品价格违法行为，维护药品价格秩序。

Article 85 For medicinal products with their prices determined by the market, marketing authorization holders, manufacturers and distributors of medicinal products, and medical institutions shall conduct pricing under the principles of fairness, rationality, good faith, and consistency between quality and prices, to provide users of medicinal products with rationally priced medicinal products.

第八十五条 依法实行市场调节价的药品，药品上市许可持有人、药品生产企业、药品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。

Marketing authorization holders, manufacturers and distributors of medicinal products, and medical institutions shall comply with the price management rules for medicinal products of the medicinal product price department of the State Council, and determine and mark the retail prices of medicinal products, and shall be prohibited from making exorbitant profits, price monopoly, and price fraud, among others.

药品上市许可持有人、药品生产企业、药品经营企业和医疗机构应当遵守国务院药品价格主管部门关于药品价格管理的规定，制定和标明药品零售价格，禁止暴利、价格垄断和价格欺诈等行为。

Article 86 Marketing authorization holders, manufacturers and distributors of medicinal products, and medical institutions shall, in accordance with the law, provide the price departments with the actual purchasing and selling prices and quantities of their medicinal products and other information.

第八十六条 药品上市许可持有人、药品生产企业、药品经营企业和医疗机构应当依法向药品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 87 Medical institutions shall provide patients with the price lists of the medicinal products used, truthfully publish the prices of frequently used medicinal products as required, and enhance the management of rational use of medicinal products. The specific measures shall be developed by the health department of the State Council.

第八十七条 医疗机构应当向患者提供所用药品的价格清单，按照规定如实公布其常用药品的价格，加强合理用药管理。具体办法由国务院卫生健康主管部门制定。

Article 88 Marketing authorization holders, manufacturers and distributors of medicinal products, and medical institutions shall be prohibited from giving or receiving kickbacks or other illicit benefits during the purchase and sale of medicinal products.

第八十八条 禁止药品上市许可持有人、药品生产企业、药品经营企业和医疗机构在药品购销中给予、收受回扣或者其他不正当利益。

Marketing authorization holders, manufacturers or distributors of medicinal products, or their agents shall be prohibited from giving any property or other illicit benefits in any name to the persons in charge, medicinal product procurement staff, doctors, pharmacists, and other relevant persons of medical institutions using their medicinal products. The persons in charge, medicinal product procurement staff, doctors, pharmacists, and other relevant persons of medical institutions shall be prohibited from receiving any property or other illicit benefits in any name from marketing authorization holders, manufacturers or distributors of medicinal products, or their agents.

禁止药品上市许可持有人、药品生产企业、药品经营企业或者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、药师等有关人员财物或者其他不正当利益。禁止医疗机构的负责人、药品采购人员、医师、药师等有关人员以任何名义收受药品上市许可持有人、药品生产企业、药品经营企业或者代理人给予的财物或者其他不正当利益。

Article 89 Medicinal product advertisements shall be subject to the approval of the advertising review authority determined by the people's government of the province, autonomous region, or municipality directly under the Central Government where the advertiser is located; and no medicinal product advertisement may be published without such approval.

第八十九条 药品广告应当经广告主所在地省、自治区、直辖市人民政府确定的广告审查机关批准；未经批准的，不得发布。

Article 90 The contents of medicinal product advertisements shall be true, lawful, based on the package leaflet reviewed and approved by the medicinal product regulatory department of the State Council, and free of falsehood.

第九十条 药品广告的内容应当真实、合法，以国务院药品监督管理部门核准的药品说明书为准，不得含有虚假的内容。

Medicinal product advertisements shall not contain any assertion or guarantee pertaining to efficacy or safety; and shall not use the names or images of state authorities, scientific research entities, academic organizations, industry associations, experts, scholars, doctors, pharmacists, and patients, among others, for recommendation or testimonial purposes.

药品广告不得含有表示功效、安全性的断言或者保证；不得利用国家机关、科研单位、学术机构、行业协会或者专家、学者、医师、药师、患者等的名义或者形象作推荐、证明。

The advertisements of non-medicinal products shall not have any content involving medicinal products.

非药品广告不得有涉及药品的宣传。

Article 91 Where this Law is silent regarding the prices and advertising of medicinal products, the Price Law of the People's Republic of China, the Anti-monopoly Law of the People's Republic of China, the Anti-unfair Competition Law of the People's Republic of China, and the Advertisement Law of the People's Republic of China, among others, shall apply.

第九十一条 药品价格和广告，本法未作规定的，适用《中华人民共和国价格法》、《中华人民共和国反垄断法》、《中华人民共和国反不正当竞争法》、《中华人民共和国广告法》等的规定。

Chapter IX Reserves and Supply of Medicinal Products

第九章 药品储备和供应

Article 92 The state shall implement a medicinal product reserve system, and establish medicinal product reserves at both central and local levels.

第九十二条 国家实行药品储备制度，建立中央和地方两级药品储备。

In the event of a major disaster or epidemic or any other emergency, medicinal products may be urgently dispatched and used in accordance with the provisions of the Emergency Response Law of the People's Republic of China.

发生重大灾情、疫情或者其他突发事件时，依照《中华人民共和国突发事件应对法》的规定，可以紧急调用药品。

Article 93 The state shall implement a system of essential medicines, select varieties of essential medicines in an appropriate quantity, strengthen the organization of manufacture and reserves, improve the capabilities to supply essential medicines, and meet the basic medication demand in disease prevention and treatment.

第九十三条 国家实行基本药物制度，遴选适当数量的基本药物品种，加强组织生产和储备，提高基本药物的供给能力，满足疾病防治基本用药需求。

Article 94 The state shall establish a supply and demand surveillance system of medicinal products, collect, consolidate, and analyze in a timely manner the supply and demand information on medicinal products in shortage, issue early warnings on medicinal products in shortage, and take countermeasures.

第九十四条 国家建立药品供求监测体系，及时收集和汇总分析短缺药品供求信息，对短缺药品实行预警，采取应对措施。

Article 95 The state shall implement a listing management system of medicinal products in shortage. The specific measures shall be developed by the health department of the State Council in conjunction with the medicinal product regulatory and other departments of the State Council.

第九十五条 国家实行短缺药品清单管理制度。具体办法由国务院卫生健康主管部门会同国务院药品监督管理部门等部门制定。

Where a marketing authorization holder ceases manufacturing a medicinal product in shortage, it shall report as required to the medicinal product regulatory department of the State Council or the medicinal product regulatory department of the people's government of the province, autonomous region, or municipality directly under the Central Government.

药品上市许可持有人停止生产短缺药品的，应当按照规定向国务院药品监督管理部门或者省、自治区、直辖市人民政府药品监督管理部门报告。

Article 96 The state shall encourage the research, development, and manufacture of medicinal products in shortage, and prioritize the evaluation and approval of medicinal products in shortage as urgently needed clinically and new medicinal products intended for the prevention and treatment of diseases such as major infectious diseases and rare diseases.

第九十六条 国家鼓励短缺药品的研制和生产，对临床急需的短缺药品、防治重大传染病和罕见病等疾病的新药予以优先审评审批。

Article 97 The State Council may restrict or prohibit the export of medicinal products in shortage. When necessary, the relevant departments of the State Council may adopt measures such as organizing manufacture, price intervention, and expanding import to ensure supply of medicinal products.

第九十七条 对短缺药品，国务院可以限制或者禁止出口。必要时，国务院有关部门可以采取组织生产、价格干预和扩大进口等措施，保障药品供应。

Marketing authorization holders and manufacturers and distributors of medicinal products shall guarantee the manufacture and supply of medicinal products as required.

药品上市许可持有人、药品生产企业、药品经营企业应当按照规定保障药品的生产和供应。

Chapter X Supervision and Administration

第十章 监督管理

Article 98 The manufacture (including compounding), sale, and use of counterfeit medicinal products or medicinal products of inferior quality shall be prohibited.

第九十八条 禁止生产（包括配制，下同）、销售、使用假药、劣药。

The following medicinal products are counterfeit medicinal products:

有下列情形之一的，为假药：

(1) Medicinal products with ingredients different from those specified by the national medicinal product standards.

（一）药品所含成份与国家药品标准规定的成份不符；

(2) Non-medical products passed off as medicinal products or one medicinal product is passed off as another medicinal product.

（二）以非药品冒充药品或者以他种药品冒充此种药品；

(3) Spoiled medicinal products.

（三）变质的药品；

(4) Medicinal products with therapeutic indications or actions and indications on their labels exceeding the scope specified.

（四）药品所标明的适应症或者功能主治超出规定范围。

The following medicinal products are medicinal products of inferior quality:

有下列情形之一的，为劣药：

(1) Medicinal products with the strength of ingredients in nonconformity with the national medicinal product standards.

（一）药品成份的含量不符合国家药品标准；

(2) Contaminated medicinal products.

（二）被污染的药品；

(3) Medicinal products with no expiry date marked or with an altered expiry date.

（三）未标明或者更改有效期的药品；

(4) Medicinal products with no batch number marked or with an altered batch number.

（四）未注明或者更改产品批号的药品；

(5) Medicinal products beyond their expiry date.

（五）超过有效期的药品；

(6) Medicinal products containing preservative or inactive ingredients added without permission.

（六）擅自添加防腐剂、辅料的药品；

(7) Other medicinal products in nonconformity with medicinal product standards.

（七）其他不符合药品标准的药品。

No medicinal products may be manufactured or imported without a medicinal product approval certification document; and no medicinal products may be manufactured by using APIs, packaging materials, and containers not evaluated and approved as required.

禁止未取得药品批准证明文件生产、进口药品；禁止使用未按照规定审评、审批的原料药、包装材料和容器生产药品。

Article 99 Medicinal product regulatory departments shall, in accordance with the provisions of laws and regulations, conduct supervisory inspection on, among others, the research, development, manufacture, and distribution of medicinal products and the use of medicinal products by entities using medicinal products, and when necessary, may conduct extended inspection on the entities and individuals providing products or services for the research, development, manufacture, distribution, or use of medicinal products, and the entities and individuals shall provide cooperation, and may not refuse the inspection or withhold the relevant information.

第九十九条 药品监督管理部门应当依照法律、法规的规定对药品研制、生产、经营和药品使用单位使用药品等活动进行监督检查，必要时可以对为药品研制、生产、经营、使用提供产品或者服务的单位和个人进行延伸检查，有关单位和个人应当予以配合，不得拒绝和隐瞒。

Medicinal product regulatory departments shall prioritize the supervisory inspection on high-risk medicinal products.

药品监督管理部门应当对高风险的药品实施重点监督检查。

Where evidence shows that there may be any hidden safety risk, medicinal product regulatory departments shall, based on their supervisory inspection, adopt measures such as admonition, interview, addressing issues within a specified time limit, and suspension of manufacture, sale, use, or import, and disclose the results of inspection and disposition to the public in a timely manner.

对有证据证明可能存在安全隐患的，药品监督管理部门根据监督检查情况，应当采取告诫、约谈、限期整改以及暂停生产、销售、使用、进口等措施，并及时公布检查处理结果。

Medicinal product regulatory departments shall produce credentials in conducting supervisory inspection, and keep trade secrets known during supervisory inspection confidential.

药品监督管理部门进行监督检查时，应当出示证明文件，对监督检查中知悉的商业秘密应当保密。

Article 100 Medicinal product regulatory departments may, as needed in supervision and administration, conduct the sample testing on medicinal product quality. In the sample testing, samples shall be drawn as required, and no charges of any kind shall be collected; and the samples drawn shall be purchased. The necessary funding shall be listed as expenditure according to the provisions issued by the State Council.

第一百条 药品监督管理部门根据监督管理的需要，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；抽样应当购买样品。所需费用按照国务院规定列支。

Medicinal product regulatory departments may place under seal or impound medicinal products and relevant materials thereof where evidence shows that they may be harmful to people's health, but shall make an administrative disposition decision within seven days; or if the medicinal products need to be tested, shall make the decision within 15 days from the date of issue of the testing report.

对有证据证明可能危害人体健康的药品及其有关材料，药品监督管理部门可以查封、扣押，并在七日内作出行政处理决定；药品需要检验的，应当自检验报告书发出之日起十五日内作出行政处理决定。

Article 101 The medicinal product regulatory departments of the State Council, provinces, autonomous regions, and municipalities directly under the central government shall, on a regular basis, announce the results of sample testing on medicinal product quality; and correct any impropriate announcements within the extent of the original announcements.

第一百零一条 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结果；公告不当的，应当在原公告范围内予以更正。

Article 102 Where a party raises any objection to the results of testing of medicinal products, it may, within seven days of receiving the results of testing of medicinal products, apply for re-testing to the original medicinal product control institution or the medicinal product control institution established or designated by the medicinal product regulatory department at the next higher level , or directly apply for re-testing to the medicinal product control institution established or designated by the medicinal product regulatory department of the State Council. The medicinal product control institution accepting the re-testing application shall reach a conclusion of re-testing within the time limit specified by the medicinal product regulatory department of the State Council.

第一百零二条 当事人对药品检验结果有异议的，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指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指定的药品检验机构申请复验。受理复验的药品检验机构应当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 103 Medicinal product regulatory departments shall conduct inspection on the compliance of marketing authorization holders, manufacturers and distributors of medicinal products, research institutions for non-clinical pharmaceutical safety evaluation, and pharmaceutical clinical trial institutions, among others, with the GMP for medicinal products, the GSP for medicinal products, the GLP for pharmaceuticals, and the GCP for pharmaceuticals, among others, and oversee their continuing compliance with the statutory requirements.

第一百零三条 药品监督管理部门应当对药品上市许可持有人、药品生产企业、药品经营企业和药物非临床安全性评价研究机构、药物临床试验机构等遵守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等情况进行检查，监督其持续符合法定要求。

Article 104 The state shall establish a professional and specialized force of medicinal product inspectors. Inspectors shall be familiar with medicinal product laws and regulations, and have specialized knowledge of medicinal products.

第一百零四条 国家建立职业化、专业化药品检查员队伍。检查员应当熟悉药品法律法规，具备药品专业知识。

Article 105 Medicinal product regulatory departments shall establish credit files on medicinal product safety for marketing authorization holders, manufacturers and distributors of medicinal products, research institutions for non-clinical pharmaceutical safety evaluation, pharmaceutical clinical trial institutions, and medical institutions to record, among others, the grant of permits, results of routine supervisory inspection, and investigation and disposition of illegal conduct, and disclose to the public and update in a timely manner the files in accordance with the law; and shall increase the frequency of supervisory inspection of those with bad credit records, and may impose joint sanctions on them in accordance with the provisions issued by the state.

第一百零五条 药品监督管理部门建立药品上市许可持有人、药品生产企业、药品经营企业、药物非临床安全性评价研究机构、药物临床试验机构和医疗机构药品安全信用档案，记录许可颁发、日常监督检查结果、违法行为查处等情况，依法向社会公布并及时更新；对有不良信用记录的，增加监督检查频次，并可以按照国家规定实施联合惩戒。

Article 106 Medicinal product regulatory departments shall publish their e-mail addresses and telephone numbers, accept requests for consultation, complaints, and reports, and provide replies, conduct verification, and process them in a timely manner in accordance with the law. For a report substantiated upon investigation, the reporting person shall be rewarded according to the relevant provisions.

第一百零六条 药品监督管理部门应当公布本部门的电子邮件地址、电话，接受咨询、投诉、举报，并依法及时答复、核实、处理。对查证属实的举报，按照有关规定给予举报人奖励。

Medicinal product regulatory departments shall keep the reporting person information confidential, and protect the lawful rights and interests of the reporting persons. If a reporting person reports on the entity employing him or her, the entity may not retaliate against the reporting person by rescinding or modifying the labor contract with him or her or otherwise.

药品监督管理部门应当对举报人的信息予以保密，保护举报人的合法权益。举报人举报所在单位的，该单位不得以解除、变更劳动合同或者其他方式对举报人进行打击报复。

Article 107 The state shall implement a unified publication system of medicinal product safety information. The national overall status of medicinal product safety, the medicinal product safety risk alerts, the major medicinal product safety events and investigation and disposition thereof, and the other information requiring unified publication as determined by the State Council shall be published in a unified manner by the medicinal product regulatory department of the State Council. Where the impact of a medicinal product safety risk alert or a major medicinal product safety event and investigation and disposition thereof is limited to a particular region, such information may also be published by the medicinal product regulatory department of the people's government of the relevant province, autonomous region, or municipality directly under the Central Government. The aforesaid information may not be published without authorization.

第一百零七条 国家实行药品安全信息统一公布制度。国家药品安全总体情况、药品安全风险警示信息、重大药品安全事件及其调查处理信息和国务院确定需要统一公布的其他信息由国务院药品监督管理部门统一公布。药品安全风险警示信息和重大药品安全事件及其调查处理信息的影响限于特定区域的，也可以由有关省、自治区、直辖市人民政府药品监督管理部门公布。未经授权不得发布上述信息。

The publication of medicinal product safety information shall be in a timely, accurate, and comprehensive manner, with necessary explanations to avoid misleading the public.

公布药品安全信息，应当及时、准确、全面，并进行必要的说明，避免误导。

No entity or individual may fabricate or disseminate false medicinal product safety information.

任何单位和个人不得编造、散布虚假药品安全信息。

Article 108 A people's government at or above the county level shall develop an emergency preparedness and response plan for medicinal product safety events. Marketing authorization holders, manufacturers and distributors of medicinal products, and medical institutions shall develop their respective disposition plans for medicinal product safety events, and organize training and emergency response drills.

第一百零八条 县级以上人民政府应当制定药品安全事件应急预案。药品上市许可持有人、药品生产企业、药品经营企业和医疗机构等应当制定本单位的药品安全事件处置方案，并组织开展培训和应急演练。

When a medicinal product safety event occurs, the people's government at or above the county level shall immediately organize response work in accordance with the emergency preparedness and response plan; and the relevant entity shall immediately adopt effective disposition measures to prevent any aggravation of harm.

发生药品安全事件，县级以上人民政府应当按照应急预案立即组织开展应对工作；有关单位应当立即采取有效措施进行处置，防止危害扩大。

Article 109 Where a medicinal product regulatory department fails to discover any systemic medicinal product safety risk in a timely manner or fails to eliminate any hidden medicinal product safety risk within its regulatory jurisdiction in a timely manner, the people's government at the same level or the medicinal product regulatory department of the people's government at a higher level shall interview the primary person in charge of the medicinal product regulatory department.

第一百零九条 药品监督管理部门未及时发现药品安全系统性风险，未及时消除监督管理区域内药品安全隐患的，本级人民政府或者上级人民政府药品监督管理部门应当对其主要负责人进行约谈。

Where a local people's government fails to fulfill its medicinal product safety duties or fails to eliminate any regional major hidden medicinal product safety risk in a timely manner, the people's government at a higher level or the medicinal product regulatory department of the people's government at a higher level shall interview the primary person in charge of the local people's government.

地方人民政府未履行药品安全职责，未及时消除区域性重大药品安全隐患的，上级人民政府或者上级人民政府药品监督管理部门应当对其主要负责人进行约谈。

The departments and local people's governments interviewed shall immediately adopt measures to address issues in their supervision and administration of medicinal products.

被约谈的部门和地方人民政府应当立即采取措施，对药品监督管理工作进行整改。

The interview and addressing of issues shall be included in the records of review and evaluation of the medicinal product supervision and administration work of the relevant departments and local people's governments.

约谈情况和整改情况应当纳入有关部门和地方人民政府药品监督管理工作评议、考核记录。

Article 110 The local people's governments and their medicinal product regulatory departments shall not restrict or preclude the entry into their respective jurisdictions of medicinal products manufactured by marketing authorization holders and manufacturers of medicinal products from other parts of the country by means such as a testing or approval requirement for medicinal products.

第一百一十条 地方人民政府及其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上市许可持有人、药品生产企业生产的药品进入本地区。

Article 111 Medicinal product regulatory departments and the specialized technical institutions for medicinal products established or designated by them shall neither participate in the manufacture and distribution of medicinal products nor recommend or supervise in their names the manufacture or sale of medicinal products.

第一百一十一条 药品监督管理部门及其设置或者指定的药品专业技术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。

The personnel of medicinal product regulatory departments and the specialized technical institutions for medicinal products established or designated by them shall not participate in the manufacture and distribution of medicinal products.

药品监督管理部门及其设置或者指定的药品专业技术机构的工作人员不得参与药品生产经营活动。

Article 112 Where the State Council has issued any other special provisions for the administration of narcotic drugs, psychotropic substances, poisonous substances for medical use, radiopharmaceuticals, and pharmaceutical precursor chemicals, among others, such other provisions shall apply.

第一百一十二条 国务院对麻醉药品、精神药品、医疗用毒性药品、放射性药品、药品类易制毒化学品等有其他特殊管理规定的，依照其规定。

Article 113 Where a medicinal product regulatory department discovers that any illegal conduct related to medicinal products is suspected of a crime, the case shall be transferred to the public security authority in a timely manner.

第一百一十三条 药品监督管理部门发现药品违法行为涉嫌犯罪的，应当及时将案件移送公安机关。

Where the actor need not be held criminally liable or is exempted from criminal punishment in accordance with the law but shall be held administratively liable, the public security authority, the people's procuratorate, or the people's court shall transfer the case to the medicinal product regulatory department in a timely manner.

对依法不需要追究刑事责任或者免予刑事处罚，但应当追究行政责任的，公安机关、人民检察院、人民法院应当及时将案件移送药品监督管理部门。

Where the public security authority, the people's procuratorate, or the people's court requests the medicinal product regulatory department, the ecology and environment department, or any other department to provide testing conclusions, determination opinions, or assistance in harmless treatment of alleged medicinal products, among others, the relevant department shall provide them or assist in a timely manner.

公安机关、人民检察院、人民法院商请药品监督管理部门、生态环境主管部门等部门提供检验结论、认定意见以及对涉案药品进行无害化处理等协助的，有关部门应当及时提供，予以协助。

Chapter XI Legal Liability

第十一章 法律责任

Article 114 Where any violation of this Law constitutes a crime, the violator shall be held criminally liable in accordance with the law.

第一百一十四条 违反本法规定，构成犯罪的，依法追究刑事责任。

Article 115 Where any medicinal products are manufactured or sold without a manufacturing or distribution permit for medicinal products or a medical institution compounding permit, the violator shall be ordered to shut down, with the illegally manufactured or sold medicinal products and illegal proceeds confiscated, and fined not less than 15 times nor more than 30 times the value of goods of the medicinal products illegally manufactured or sold (including both sold and unsold medicinal products); and if the value of goods is under 100,000 yuan, the fine shall be calculated on the basis of a value of goods of 100,000 yuan.

第一百一十五条 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、销售药品的，责令关闭，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（包括已售出和未售出的药品，下同）货值金额十五倍以上三十倍以下的罚款；货值金额不足十万元的，按十万元计算。

Article 116 Where any counterfeit medicinal products are manufactured or sold, the violator shall be ordered to cease production or business for an overhaul, with confiscation of the illegally manufactured or sold medicinal products and illegal proceeds and cancellation of the medicinal product approval certification document, and fined not less than 15 nor more than 30 times the value of goods of the medicinal products illegally manufactured or sold; if the value of goods is under 100,000 yuan, the fine shall be calculated on the basis of a value of goods of 100,000 yuan; if the circumstances are serious, the manufacturing or distribution permit for medicinal products or the medical institution compounding permit shall be cancelled, and any corresponding application of the violator shall not be accepted for a period of ten years; and if the marketing authorization holder is an overseas enterprise, the import of its medicinal products shall be prohibited for a period of ten years.

第一百一十六条 生产、销售假药的，没收违法生产、销售的药品和违法所得，责令停产停业整顿，吊销药品批准证明文件，并处违法生产、销售的药品货值金额十五倍以上三十倍以下的罚款；货值金额不足十万元的，按十万元计算；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，十年内不受理其相应申请；药品上市许可持有人为境外企业的，十年内禁止其药品进口。

Article 117 Where any medicinal products of inferior quality are manufactured or sold, in addition to confiscation of the illegally manufactured or sold medicinal products and illegal proceeds, the violator shall be fined not less than ten nor more than 20 times the value of goods of the medicinal products illegally manufactured or sold; if the value of goods of the medicinal products illegally manufactured or wholesaled is under 100,000 yuan, the fine shall be calculated on the basis of a value of goods of 100,000 yuan, or if the value of goods of the medicinal products illegally retailed is under 10,000 yuan, the fine shall be calculated on the basis of a value of goods of 10,000 yuan; and if the circumstances are serious, the violator shall be ordered to cease production or business for an overhaul, even with cancellation of the medicinal product approval certification document, the manufacturing or distribution permit for medicinal products, or the medical institution compounding permit.

第一百一十七条 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、销售的药品货值金额十倍以上二十倍以下的罚款；违法生产、批发的药品货值金额不足十万元的，按十万元计算，违法零售的药品货值金额不足一万元的，按一万元计算；情节严重的，责令停产停业整顿直至吊销药品批准证明文件、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。

Where any traditional Chinese medicinal decoction pieces manufactured or sold fail to meet the medicinal product standards, which, however, has not affected their safety and efficacy, the violator shall be ordered to take corrective action within a specified time limit and warned; and may be fined not less than 100,000 yuan nor more than 500,000 yuan.

生产、销售的中药饮片不符合药品标准，尚不影响安全性、有效性的，责令限期改正，给予警告；可以处十万元以上五十万元以下的罚款。

Article 118 Where any counterfeit medicinal products are manufactured or sold, or where any medicinal products of inferior quality are manufactured or sold with any serious circumstances, the legal representative, the primary person in charge, the directly liable executive in charge, or any other liable person of the violator shall, in addition to confiscation of his or her revenue derived from the violator during the period of occurrence of the illegal conduct, be fined not less than 30% of nor more than three times the revenue, and prohibited for life from engaging in the manufacture and distribution of medicinal products, and may be administratively detained by the public security authority for not less than five days nor more than 15 days.

第一百一十八条 生产、销售假药，或者生产、销售劣药且情节严重的，对法定代表人、主要负责人、直接负责的主管人员和其他责任人员，没收违法行为发生期间自本单位所获收入，并处所获收入百分之三十以上三倍以下的罚款，终身禁止从事药品生产经营活动，并可以由公安机关处五日以上十五日以下的拘留。

The raw materials, inactive ingredients, packaging materials, and manufacturing equipment used by the manufacturer exclusively for the manufacture of counterfeit medicinal products or medicinal products of inferior quality shall be confiscated.

对生产者专门用于生产假药、劣药的原料、辅料、包装材料、生产设备予以没收。

Article 119 Where an entity using medicinal products uses any counterfeit medicinal products or medicinal products of inferior quality, it shall be punished according to the provisions on selling counterfeit medicinal products or retailing medicinal products of inferior quality; and if the circumstances are serious, and the legal representative, the primary person in charge, the directly liable executive in charge, or any other liable person of the violator holds a health care professional's practicing certificate, the practicing certificate shall also be cancelled.

第一百一十九条 药品使用单位使用假药、劣药的，按照销售假药、零售劣药的规定处罚；情节严重的，法定代表人、主要负责人、直接负责的主管人员和其他责任人员有医疗卫生人员执业证书的，还应当吊销执业证书。

Article 120 Where any storage, transportation, or other facilitating condition is provided for counterfeit medicinal products, medicinal products of inferior quality, or medicinal products set out in subparagraph (1) to (5) of paragraph 1 of Article 124 of this Law, and the provider knows or should have known the same, in addition to confiscation of all its revenue derived from the storage or transportation, the provider shall be fined not less than one times nor more than five times the illegal revenue; or if the circumstances are serious, be fined not less than five times nor more than 15 times the illegal revenue; and if the illegal revenue is under 50,000 yuan, the fine shall be calculated on the basis of 50,000 yuan.

第一百二十条 知道或者应当知道属于假药、劣药或者本法第一百二十四条第一款第一项至第五项规定的药品，而为其提供储存、运输等便利条件的，没收全部储存、运输收入，并处违法收入一倍以上五倍以下的罚款；情节严重的，并处违法收入五倍以上十五倍以下的罚款；违法收入不足五万元的，按五万元计算。

Article 121 A decision to impose punishment on counterfeit medicinal products or medicinal products of inferior quality shall state the quality inspection conclusion of a medicinal product control institution.

第一百二十一条 对假药、劣药的处罚决定，应当依法载明药品检验机构的质量检验结论。

Article 122 Where a permit or a medicinal product approval certification document is forged, altered, leased, lent, or illegally purchased or sold, in addition to confiscation of illegal proceeds, the violator shall be fined not less than one times nor more than five times the illegal proceeds; or if the circumstances are serious, the violator shall be fined not less than five times nor more than 15 times the illegal proceeds, the manufacturing or distribution permit for medicinal products, the medical institution compounding permit, or the medicinal product approval certification document shall be cancelled, and the legal representative, the primary person in charge, the directly liable executive in charge, or any other liable person of the violator shall be fined not less than 20,000 yuan nor more than 200,000 yuan, and prohibited from engaging in the manufacture and distribution of medicinal products for a period of ten years, and may be administratively detained by the public security authority for not less than five days nor more than 15 days; and if the illegal proceeds are under 100,000 yuan, the fine shall be calculated on the basis of 100,000 yuan.

第一百二十二条 伪造、变造、出租、出借、非法买卖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五倍以下的罚款；情节严重的，并处违法所得五倍以上十五倍以下的罚款，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药品批准证明文件，对法定代表人、主要负责人、直接负责的主管人员和其他责任人员，处二万元以上二十万元以下的罚款，十年内禁止从事药品生产经营活动，并可以由公安机关处五日以上十五日以下的拘留；违法所得不足十万元的，按十万元计算。

Article 123 Where the licensure of a clinical trial, manufacture or distribution of medicinal products, medical institution compounding, or registration of a medicinal product, among others, is fraudulently obtained by providing any false proof, data, information, samples, or other means, the relevant licensure shall be revoked, any corresponding application of the violator shall not be accepted for a period of ten years, and the violator shall be fined not less than 500,000 yuan nor more than 5 million yuan; and if the circumstances are serious, the legal representative, the primary person in charge, the directly liable executive in charge, or any other liable person of the violator shall be fined not less than 20,000 yuan nor more than 200,000 yuan, and prohibited from engaging in the manufacture and distribution of medicinal products for a period of ten years, and may be administratively detained by the public security authority for not less than five days nor more than 15 days.

第一百二十三条 提供虚假的证明、数据、资料、样品或者采取其他手段骗取临床试验许可、药品生产许可、药品经营许可、医疗机构制剂许可或者药品注册等许可的，撤销相关许可，十年内不受理其相应申请，并处五十万元以上五百万元以下的罚款；情节严重的，对法定代表人、主要负责人、直接负责的主管人员和其他责任人员，处二万元以上二十万元以下的罚款，十年内禁止从事药品生产经营活动，并可以由公安机关处五日以上十五日以下的拘留。

Article 124 For any of the following violations of this Law, the medicinal products illegally manufactured, imported, or sold, illegal proceeds, and the raw materials, inactive ingredients, packaging materials, and manufacturing equipment used exclusively for illegal manufacture shall be confiscated, and the violator shall be ordered to cease production or business for an overhaul, and fined not less than 15 times nor more 30 times the value of goods of the medicinal products illegally manufactured, imported, or sold; if the value of goods is under 100,000 yuan, the fine shall be calculated on the basis of 100,000 yuan; and if the circumstances are serious, the medicinal product approval certification document and even the manufacturing or distribution permit for medicinal products or the medical institution compounding permit shall be cancelled, and the legal representative, the primary person in charge, the directly liable executive in charge, or any other liable person of the violator shall, in addition to confiscation of his or her revenue derived from the violator during the period of occurrence of the illegal conduct, be fined not less than 30% of nor more than three times the revenue, and prohibited from engaging in the manufacture and distribution of medicinal products for a period of ten years or even for life, and may be administratively detained by the public security authority for not less than five days nor more than 15 days:

第一百二十四条 违反本法规定，有下列行为之一的，没收违法生产、进口、销售的药品和违法所得以及专门用于违法生产的原料、辅料、包装材料和生产设备，责令停产停业整顿，并处违法生产、进口、销售的药品货值金额十五倍以上三十倍以下的罚款；货值金额不足十万元的，按十万元计算；情节严重的，吊销药品批准证明文件直至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，对法定代表人、主要负责人、直接负责的主管人员和其他责任人员，没收违法行为发生期间自本单位所获收入，并处所获收入百分之三十以上三倍以下的罚款，十年直至终身禁止从事药品生产经营活动，并可以由公安机关处五日以上十五日以下的拘留：

(1) Manufacture or import of any medicinal product without a medicinal product approval certification document.

（一）未取得药品批准证明文件生产、进口药品；

(2) Manufacture or import of any medicinal product by using a medicinal product approval certification document obtained by fraudulent means.

（二）使用采取欺骗手段取得的药品批准证明文件生产、进口药品；

(3) Manufacture of any medicinal product by using an API which has not been evaluated and approved.

（三）使用未经审评审批的原料药生产药品；

(4) Sale of any untested medicinal product which shall be tested.

（四）应当检验而未经检验即销售药品；

(5) Manufacture or sale of any medicinal product prohibited by the medicinal product regulatory department of the State Council from being used.

（五）生产、销售国务院药品监督管理部门禁止使用的药品；

(6) Fabrication of any record of manufacture or inspection.

（六）编造生产、检验记录；

(7) Making any unapproved material modification in the process of manufacture of a medicinal product.

（七）未经批准在药品生产过程中进行重大变更。

Where any medicinal product set out in subparagraphs (1) to (3) of the preceding paragraph is sold, or an entity using medicinal products uses any medicinal product set out in subparagraphs (1) to (5) of the preceding paragraph, the violator shall be punished in accordance with the provision of the preceding paragraph; and if the circumstances are serious, and the legal representative, the primary person in charge, the directly liable executive in charge, or any other liable person of the entity using medicinal products holds a health care professional's practicing certificate, the practicing certificate shall also be cancelled.

销售前款第一项至第三项规定的药品，或者药品使用单位使用前款第一项至第五项规定的药品的，依照前款规定处罚；情节严重的，药品使用单位的法定代表人、主要负责人、直接负责的主管人员和其他责任人员有医疗卫生人员执业证书的，还应当吊销执业证书。

Where a medicinal product which has been legally marketed overseas is imported in a limited amount without approval, and the circumstances are relatively minor, a mitigated punishment may be imposed on the violator or the violator may be exempted from punishment in accordance with the law.

未经批准进口少量境外已合法上市的药品，情节较轻的，可以依法减轻或者免予处罚。

Article 125 For any of the following violations of this Law, the violator shall, in addition to confiscation of medicinal products illegally manufactured or sold, illegal proceeds, packaging materials, and containers, be ordered to cease production or business for an overhaul, and fined not less than 500,000 yuan nor more 5 million yuan; and if the circumstances are serious, the medicinal product approval certification document or the manufacturing or distribution permit for medicinal products shall be cancelled, and the legal representative, the primary person in charge, the directly liable executive in charge, or any other liable person of the violator shall be fined not less than 20,000 yuan nor more than 200,000 yuan, and prohibited from engaging in the manufacture and distribution of medicinal products for a period of ten years and even for life:

第一百二十五条 违反本法规定，有下列行为之一的，没收违法生产、销售的药品和违法所得以及包装材料、容器，责令停产停业整顿，并处五十万元以上五百万元以下的罚款；情节严重的，吊销药品批准证明文件、药品生产许可证、药品经营许可证，对法定代表人、主要负责人、直接负责的主管人员和其他责任人员处二万元以上二十万元以下的罚款，十年直至终身禁止从事药品生产经营活动：

(1) Conducting any pharmaceutical clinical trial without approval.

（一）未经批准开展药物临床试验；

(2) Using any packaging material or container which has not been evaluated and approved immediately in contact with a medicinal product to manufacture the medicinal product, or selling such medicinal product.

（二）使用未经审评的直接接触药品的包装材料或者容器生产药品，或者销售该类药品；

(3) Using any label or package leaflet which has not been reviewed and approved.

（三）使用未经核准的标签、说明书。

Article 126 Except as otherwise provided by this Law, a marketing authorization holder, a manufacturer or distributor of medicinal products, a research institution for non-clinical pharmaceutical safety evaluation, or a pharmaceutical clinical trial institution, among others, which fails to comply with the GMP for medicinal products, the GSP for medicinal products, the GLP for pharmaceuticals, or the GCP for pharmaceuticals, among others, shall be ordered to take corrective action within a specified time limit and warned, and if no corrective action is taken within the specified time limit, shall be fined not less than 100,000 yuan nor more than 500,000 yuan; or if the circumstances are serious, the violator shall be fined not less than 500,000 yuan nor more than 2 million yuan, and be ordered to cease production or business for an overhaul, even its medicinal product approval certification document or manufacturing or distribution permit for medicinal products, among others, shall be cancelled, the research institution for non-clinical pharmaceutical safety evaluation or the pharmaceutical clinical trial institution, among others, shall not conduct any non-clinical pharmaceutical safety evaluation or pharmaceutical clinical trial for a period of five years, and the legal representative, the primary person in charge, the directly liable executive in charge, or any other liable person of the violator shall, in addition to confiscation of his or her revenue derived from the violator during the period of occurrence of the illegal conduct, be fined not less than 10% nor more than 50% of the revenue, and prohibited from engaging in the manufacture and distribution, among others, of medicinal products for a period of ten years or even for life.

第一百二十六条 除本法另有规定的情形外，药品上市许可持有人、药品生产企业、药品经营企业、药物非临床安全性评价研究机构、药物临床试验机构等未遵守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等的，责令限期改正，给予警告；逾期不改正的，处十万元以上五十万元以下的罚款；情节严重的，处五十万元以上二百万元以下的罚款，责令停产停业整顿直至吊销药品批准证明文件、药品生产许可证、药品经营许可证等，药物非临床安全性评价研究机构、药物临床试验机构等五年内不得开展药物非临床安全性评价研究、药物临床试验，对法定代表人、主要负责人、直接负责的主管人员和其他责任人员，没收违法行为发生期间自本单位所获收入，并处所获收入百分之十以上百分之五十以下的罚款，十年直至终身禁止从事药品生产经营等活动。

Article 127 For any of the following violations of this Law, the violator shall be ordered to take corrective action within a specified time limit and warned; and if no corrective action is taken within the time limit, fined not less than 100,000 yuan nor more than 500,000 yuan:

第一百二十七条 违反本法规定，有下列行为之一的，责令限期改正，给予警告；逾期不改正的，处十万元以上五十万元以下的罚款：

(1) Bioequivalence studies are not reported for recordation.

（一）开展生物等效性试验未备案；

(2) Where any safety issue or other risk is discovered during a pharmaceutical clinical trial, the sponsor of the clinical trial fails to adjust in a timely manner the clinical trial protocol or suspend or terminate the clinical trial, or fails to report to the medicinal product regulatory department of the State Council.

（二）药物临床试验期间，发现存在安全性问题或者其他风险，临床试验申办者未及时调整临床试验方案、暂停或者终止临床试验，或者未向国务院药品监督管理部门报告；

(3) A medicinal product traceability system is not established and implemented as required.

（三）未按照规定建立并实施药品追溯制度；

(4) An annual report is not submitted as required.

（四）未按照规定提交年度报告；

(5) A modification in the process of manufacture of medicinal products fails to undergo recordation or is not reported as required.

（五）未按照规定对药品生产过程中的变更进行备案或者报告；

(6) No post-market risk management plan is developed for medicinal products.

（六）未制定药品上市后风险管理计划；

(7) Post-market studies or post-market evaluation is not conducted as required.

（七）未按照规定开展药品上市后研究或者上市后评价。

Article 128 Unless punishable as counterfeit medicinal products or medicinal products of inferior quality in accordance with the law, where labels are not printed on or glued to the packaging of a medicinal product or it is not accompanied with a package leaflet as required, or the label or package leaflet fails to state the relevant information or a required mark is not printed on it as required, the violator shall be ordered to take corrective action and warned; and if the circumstances are serious, the registration certificate for the medicinal product shall be cancelled.

第一百二十八条 除依法应当按照假药、劣药处罚的外，药品包装未按照规定印有、贴有标签或者附有说明书，标签、说明书未按照规定注明相关信息或者印有规定标志的，责令改正，给予警告；情节严重的，吊销药品注册证书。

Article 129 A marketing authorization holder, a manufacturer or distributor of medicinal products, or a medical institution which, in violation of the provisions of this Law, fails to purchase medicinal products from a marketing authorization holder or an enterprise qualified for the manufacture or distribution of medicinal products shall be ordered to take corrective action, and with confiscation of the illegally purchased medicinal products and illegal proceeds, fined not less than two times nor more than ten times the value of goods of the illegally purchased medicinal products; if the circumstances are serious, the violator shall be fined not less than ten times nor more than 30 times the value of goods of the illegally purchased medicinal products, and the medicinal product approval certification document, manufacturing or distribution permit for medicinal products, or medical institution practicing license shall be cancelled; and if the value of goods is under 50,000 yuan, the fine shall be calculated on the basis of 50,000 yuan.

第一百二十九条 违反本法规定，药品上市许可持有人、药品生产企业、药品经营企业或者医疗机构未从药品上市许可持有人或者具有药品生产、经营资格的企业购进药品的，责令改正，没收违法购进的药品和违法所得，并处违法购进药品货值金额二倍以上十倍以下的罚款；情节严重的，并处货值金额十倍以上三十倍以下的罚款，吊销药品批准证明文件、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；货值金额不足五万元的，按五万元计算。

Article 130 A distributor of medicinal products which, in violation of the provisions of this Law, fails to keep records of purchase and sale of medicinal products as required, fails to correctly explain the usage, dosage, and other matters when retailing medicinal products, or fails to dispense prescriptions as required shall be ordered to take corrective action and warned; and if the circumstances are serious, its distribution permit for medicinal products shall be cancelled.

第一百三十条 违反本法规定，药品经营企业购销药品未按照规定进行记录，零售药品未正确说明用法、用量等事项，或者未按照规定调配处方的，责令改正，给予警告；情节严重的，吊销药品经营许可证。

Article 131 The provider of a third-party platform for online trading in medicinal products which, in violation of the provisions of this Law, fails to perform its obligation to examine qualifications, report, or cease the provision of online trading platform services, among others, shall be ordered to take corrective action, and in addition to confiscation of illegal proceeds, fined not less than 200,000 yuan nor more than 2 million yuan; or if the circumstances are serious, shall be ordered to cease business for an overhaul, and fined not less than 2 million yuan nor more than 5 million yuan.

第一百三十一条 违反本法规定，药品网络交易第三方平台提供者未履行资质审核、报告、停止提供网络交易平台服务等义务的，责令改正，没收违法所得，并处二十万元以上二百万元以下的罚款；情节严重的，责令停业整顿，并处二百万元以上五百万元以下的罚款。

Article 132 Where any medicinal product for which a registration certificate has been obtained is imported but fails to undergo recordation as required with the medicinal product regulatory department of the place where the port allowing the import of medicinal products is located, the violator shall be ordered to take corrective action within a specified time limit and warned; and if no corrective action is taken within the specified time limit, the registration certificate for the medicinal product shall be cancelled.

第一百三十二条 进口已获得药品注册证书的药品，未按照规定向允许药品进口的口岸所在地药品监督管理部门备案的，责令限期改正，给予警告；逾期不改正的，吊销药品注册证书。

Article 133 A medical institution which, in violation of the provisions of this Law, places its preparations created from pharmaceutical compounding on the market shall be ordered to take corrective action, and in addition to confiscation of the preparations illegally sold and illegal proceeds, fined not less than two times nor more than five times the value of goods of the preparations illegally sold; or if the circumstances are serious, fined not less than five times nor more than 15 times the value of goods of the preparations illegally sold; and if the value of goods is under 50,000 yuan, the fine shall be calculated on the basis of 50,000 yuan.

第一百三十三条 违反本法规定，医疗机构将其配制的制剂在市场上销售的，责令改正，没收违法销售的制剂和违法所得，并处违法销售制剂货值金额二倍以上五倍以下的罚款；情节严重的，并处货值金额五倍以上十五倍以下的罚款；货值金额不足五万元的，按五万元计算。

Article 134 A marketing authorization holder which fails to conduct the surveillance of adverse reactions to medicinal products or report suspected adverse reactions to medicinal products as required shall be ordered to take corrective action within a specified time limit and warned; and if no corrective action is taken within the specified time limit, shall be ordered to cease production or business for an overhaul, and fined not less than 100,000 yuan nor more than 1 million yuan.

第一百三十四条 药品上市许可持有人未按照规定开展药品不良反应监测或者报告疑似药品不良反应的，责令限期改正，给予警告；逾期不改正的，责令停产停业整顿，并处十万元以上一百万元以下的罚款。

A distributor of medicinal products which fails to report suspected adverse reactions to medicinal products as required shall be ordered to take corrective action within a specified time limit and warned; and if no corrective action is taken within the specified time limit, shall be ordered to cease production or business for an overhaul, and fined not less than 50,000 yuan nor more than 500,000 yuan.

药品经营企业未按照规定报告疑似药品不良反应的，责令限期改正，给予警告；逾期不改正的，责令停产停业整顿，并处五万元以上五十万元以下的罚款。

A medical institution which fails to report suspected adverse reactions to medicinal products as required shall be ordered to take corrective action within a specified time limit and warned; and if no corrective action is taken within the specified time limit, shall be fined not less than 50,000 yuan nor more than 500,000 yuan.

医疗机构未按照规定报告疑似药品不良反应的，责令限期改正，给予警告；逾期不改正的，处五万元以上五十万元以下的罚款。

Article 135 A marketing authorization holder which refuses to recall a medicinal product after the medicinal product regulatory department of the people's government of a province, autonomous region, or municipality directly under the Central Government has ordered it to recall the medicinal product shall be fined not less than five times nor more than ten times the value of goods of the medicinal product to be recalled; if the value of goods is under 100,000 yuan, the fine shall be calculated on the basis of 100,000 yuan; and if the circumstances are serious, the medicinal product approval certification document and the manufacturing and distribution permits for medicinal products of the violator shall be cancelled, and the legal representative, the primary person in charge, the directly liable executive in charge, or any other liable person of the violator shall be fined not less than 20,000 yuan nor more than 200,000 yuan. A manufacturer or distributor of medicinal products or a medical institution which refuses to cooperate in a recall shall be fined not less than 100,000 yuan nor more than 500,000 yuan.

第一百三十五条 药品上市许可持有人在省、自治区、直辖市人民政府药品监督管理部门责令其召回后，拒不召回的，处应召回药品货值金额五倍以上十倍以下的罚款；货值金额不足十万元的，按十万元计算；情节严重的，吊销药品批准证明文件、药品生产许可证、药品经营许可证，对法定代表人、主要负责人、直接负责的主管人员和其他责任人员，处二万元以上二十万元以下的罚款。药品生产企业、药品经营企业、医疗机构拒不配合召回的，处十万元以上五十万元以下的罚款。

Article 136 Where a corporate enterprise in China designated by a marketing authorization holder which is an overseas enterprise fails to perform the relevant obligations in accordance with the provisions of this Law, the provisions of this Law on the legal liability of marketing authorization holders shall apply.

第一百三十六条 药品上市许可持有人为境外企业的，其指定的在中国境内的企业法人未依照本法规定履行相关义务的，适用本法有关药品上市许可持有人法律责任的规定。

Article 137 For any of the following conduct, a heavier punishment shall be imposed on the violator within the range of punishment specified by this Law:

第一百三十七条 有下列行为之一的，在本法规定的处罚幅度内从重处罚：

(1) Narcotic drugs, psychotropic substances, poisonous substances for medical use, radiopharmaceuticals, and pharmaceutical precursor chemicals are passed off as other medicinal products, or vice versa.

（一）以麻醉药品、精神药品、医疗用毒性药品、放射性药品、药品类易制毒化学品冒充其他药品，或者以其他药品冒充上述药品；

(2) Counterfeit medicinal products or medicinal products of inferior quality with pregnant or parturient women or children as the main users are manufactured or sold.

（二）生产、销售以孕产妇、儿童为主要使用对象的假药、劣药；

(3) The biological products manufactured or sold are counterfeit medicinal products or medicinal products of inferior quality.

（三）生产、销售的生物制品属于假药、劣药；

(4) Counterfeit medicinal products or medicinal products of inferior are manufactured or sold, which has had any personal injury consequences.

（四）生产、销售假药、劣药，造成人身伤害后果；

(5) Counterfeit medicinal products or medicinal products of inferior are manufactured or sold again after disposition of such violation.

（五）生产、销售假药、劣药，经处理后再犯；

(6) Supervisory inspection is refused or evaded, relevant evidentiary materials are forged, destroyed, or concealed, or items placed under seal or impounded are used without permission.

（六）拒绝、逃避监督检查，伪造、销毁、隐匿有关证据材料，或者擅自动用查封、扣押物品。

Article 138 A medicinal product control institution which produces any false testing reports shall be ordered to take corrective action, warned, and fined not less than 200,000 yuan nor more than 1 million yuan; the directly liable executive in charge or any other liable person of the violator shall be disciplined by demotion, removal from office, or expulsion in accordance with the law, and in addition to confiscation of illegal proceeds, fined not more than 50,000 yuan; and if the circumstances are serious, its testing qualification shall be revoked. If the untrue testing results produced by a medicinal product control institution cause any losses, it shall assume corresponding compensatory liability.

第一百三十八条 药品检验机构出具虚假检验报告的，责令改正，给予警告，对单位并处二十万元以上一百万元以下的罚款；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、开除处分，没收违法所得，并处五万元以下的罚款；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 139 The administrative punishment as provided for in Articles 115 to 138 of this Law shall be decided by the medicinal product regulatory departments at and above the county level according to their division of functions; and the revocation of licensure or cancellation of permits shall be decided by the original approval or issuing departments.

第一百三十九条 本法第一百一十五条至第一百三十八条规定的行政处罚，由县级以上人民政府药品监督管理部门按照职责分工决定；撤销许可、吊销许可证件的，由原批准、发证的部门决定。

Article 140 Where a marketing authorization holder, a manufacturer or distributor of medicinal products, or a medical institution employs any person in violation of the provisions of this Law, the medicinal product regulatory department or the health department shall order the termination of employment of the person, and impose a fine of not less than 50,000 yuan nor more than 200,000 yuan on the violator.

第一百四十条 药品上市许可持有人、药品生产企业、药品经营企业或者医疗机构违反本法规定聘用人员的，由药品监督管理部门或者卫生健康主管部门责令解聘，处五万元以上二十万元以下的罚款。

Article 141 Where a marketing authorization holder, a manufacturer or distributor of medicinal products, or a medical institution gives or receives kickbacks or other illicit benefits during the purchase and sale of medicinal products, or a marketing authorization holder, a manufacturer or distributor of medicinal products, or its agent gives any property or other illicit benefits to the person in charge, medicinal product procurement staff, doctors, pharmacists, or other relevant persons of a medical institution using its medicinal products, the market regulatory department shall confiscate illegal proceeds, and impose a fine of not less than 300,000 yuan nor more than 3 million yuan on the violator; and if the circumstances are serious, it shall cancel the business license of the marketing authorization holder or the manufacturer or distributor of medicinal products, and the medicinal product regulatory department shall cancel the medicinal product approval certification document or the manufacturing or distribution permit for medicinal products.

第一百四十一条 药品上市许可持有人、药品生产企业、药品经营企业或者医疗机构在药品购销中给予、收受回扣或者其他不正当利益的，药品上市许可持有人、药品生产企业、药品经营企业或者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、药师等有关人员财物或者其他不正当利益的，由市场监督管理部门没收违法所得，并处三十万元以上三百万元以下的罚款；情节严重的，吊销药品上市许可持有人、药品生产企业、药品经营企业营业执照，并由药品监督管理部门吊销药品批准证明文件、药品生产许可证、药品经营许可证。

Where a marketing authorization holder or a manufacturer or distributor of medicinal products bribes a state employee during the research, development, manufacture, or distribution of a medicinal product, the legal representative, the primary person in charge, the directly liable executive in charge, or any other liable person of the violator shall be prohibited for life from engaging in the manufacture and distribution of medicinal products.

药品上市许可持有人、药品生产企业、药品经营企业在药品研制、生产、经营中向国家工作人员行贿的，对法定代表人、主要负责人、直接负责的主管人员和其他责任人员终身禁止从事药品生产经营活动。

Article 142 Where the person in charge, a procurement staff member, or any other relevant person of a marketing authorization holder or a manufacturer or distributor of medicinal products receives any property or other illicit benefits from another marketing authorization holder or manufacturer or distributor of medicinal products or its agent during the purchase and sale of medicinal products, he or she shall, in addition to confiscation of any illegal proceeds, be punished in accordance with the law; and if the circumstances are serious, shall be prohibited from engaging in the manufacture and distribution of medicinal products for a period of five years.

第一百四十二条 药品上市许可持有人、药品生产企业、药品经营企业的负责人、采购人员等有关人员在药品购销中收受其他药品上市许可持有人、药品生产企业、药品经营企业或者代理人给予的财物或者其他不正当利益的，没收违法所得，依法给予处罚；情节严重的，五年内禁止从事药品生产经营活动。

Where the person in charge, a medicinal product procurement staff member, a doctor, a pharmacist, or any other relevant person of a medical institution receives any property or other illicit benefits from a marketing authorization holder, a manufacturer or distributor of medicinal products, or its agent, he or she shall be disciplined by the health department or the entity employing him or her, in addition to confiscation of any illegal proceeds; and if the circumstances are serious, his or her practicing certificate shall also be cancelled.

医疗机构的负责人、药品采购人员、医师、药师等有关人员收受药品上市许可持有人、药品生产企业、药品经营企业或者代理人给予的财物或者其他不正当利益的，由卫生健康主管部门或者本单位给予处分，没收违法所得；情节严重的，还应当吊销其执业证书。

Article 143 Where the fabrication or dissemination of false medicinal product safety information in violation of the provisions of this Law constitutes a public security administration violation, the public security authority shall impose a public security administration punishment on the violator in accordance with the law.

第一百四十三条 违反本法规定，编造、散布虚假药品安全信息，构成违反治安管理行为的，由公安机关依法给予治安管理处罚。

Article 144 A marketing authorization holder, a manufacturer or distributor of medicinal products, or a medical institution whose violation of the provisions of this Law has caused any damage to the users of a medicinal product shall assume compensatory liability in accordance with the law.

第一百四十四条 药品上市许可持有人、药品生产企业、药品经营企业或者医疗机构违反本法规定，给用药者造成损害的，依法承担赔偿责任。

A victim who sustains damage due to any medicinal product's quality problem may claim damages from the marketing authorization holder or the manufacturer of the medicinal product, or claim damages from the distributor of the medicinal product or the medical institution. Upon receipt of the victim's claim for damages, the first receiver liability system shall be implemented, and damages shall be paid in advance; and upon advance payment, recovery may be made in accordance with the law.

因药品质量问题受到损害的，受害人可以向药品上市许可持有人、药品生产企业请求赔偿损失，也可以向药品经营企业、医疗机构请求赔偿损失。接到受害人赔偿请求的，应当实行首负责任制，先行赔付；先行赔付后，可以依法追偿。

Where any counterfeit medicinal product or medicinal product of inferior quality is manufactured or such medicinal product is sold or used knowingly, the victim or a close relative of the victim may, in addition to damages, claim compensation in the amount of ten times the price or three times the loss; and if the amount so calculated is under 1,000 yuan, the additional compensation shall be 1,000 yuan.

生产假药、劣药或者明知是假药、劣药仍然销售、使用的，受害人或者其近亲属除请求赔偿损失外，还可以请求支付价款十倍或者损失三倍的赔偿金；增加赔偿的金额不足一千元的，为一千元。

Article 145 Where a medicinal product regulatory department or a specialized technical institution for medicinal products established or designated by it participates in the manufacture and distribution of medicinal products, the appropriate authority at a higher level shall order it to take corrective action, and confiscate any illegal revenue; and if the circumstances are serious, the directly liable executive in charge and other directly liable persons shall be disciplined in accordance with the law.

第一百四十五条 药品监督管理部门或者其设置、指定的药品专业技术机构参与药品生产经营活动的，由其上级主管机关责令改正，没收违法收入；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处分。

Where any employee of a medicinal product regulatory department or a specialized technical institution for medicinal products established or designated by it participates in the manufacture and distribution of medicinal products, he or she shall be disciplined in accordance with the law.

药品监督管理部门或者其设置、指定的药品专业技术机构的工作人员参与药品生产经营活动的，依法给予处分。

Article 146 Where a medicinal product regulatory department or a medicinal product control institution established or designated by it illegally collects any testing fees during the supervisory testing of medicinal products, it shall be ordered by the relevant government department to refund the fees, and the directly liable executive in charge and other liable persons shall be disciplined in accordance with the law; and if the circumstances are serious, its testing qualification shall be revoked.

第一百四十六条 药品监督管理部门或者其设置、指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处分；情节严重的，撤销其检验资格。

Article 147 For any of the following violations of this Law by a medicinal product regulatory department, the relevant licensure shall be revoked, and the directly liable executive in charge and other liable persons shall be disciplined in accordance with the law:

第一百四十七条 违反本法规定，药品监督管理部门有下列行为之一的，应当撤销相关许可，对直接负责的主管人员和其他直接责任人员依法给予处分：

(1) Approving a pharmaceutical clinical trial which fails to meet the prescribed conditions.

（一）不符合条件而批准进行药物临床试验；

(2) Issuing a registration certificate for a medicinal product which fails to meet the prescribed conditions.

（二）对不符合条件的药品颁发药品注册证书；

(3) Issuing a manufacturing or distribution permit or a medical institution compounding permit to an entity which fails to meet the prescribed conditions.

（三）对不符合条件的单位颁发药品生产许可证、药品经营许可证或者医疗机构制剂许可证。

Article 148 For any of the following violations of this Law by a local people's government at or above the county level, the directly liable executive in charge and other liable persons shall be disciplined by a demerit or a serious demerit; and if the circumstances are serious, disciplined by demotion, removal from office, or expulsion:

第一百四十八条 违反本法规定，县级以上地方人民政府有下列行为之一的，对直接负责的主管人员和其他直接责任人员给予记过或者记大过处分；情节严重的，给予降级、撤职或者开除处分：

(1) Concealment or falsification of a medicinal product safety event in reporting, delay in the reporting of a medicinal product safety event, or omission of a medicinal product safety event in reporting.

（一）瞒报、谎报、缓报、漏报药品安全事件；

(2) Failure to eliminate any regional major hidden medicinal product safety risk in a timely manner, which has caused the occurrence of an exceptionally major medicinal product safety event within the administrative region or the successive occurrences of major medicinal product safety events.

（二）未及时消除区域性重大药品安全隐患，造成本行政区域内发生特别重大药品安全事件，或者连续发生重大药品安全事件；

(3) Ineffective performance of duties, which has had a serious adverse effect or has caused any major loss.

（三）履行职责不力，造成严重不良影响或者重大损失。

Article 149 For any of the following violations of this Law by a medicinal product regulatory department, among others, the directly liable executive in charge and other liable persons shall be disciplined by a demerit or a serious demerit; if the circumstances are relatively serious, disciplined by demotion or removal from office; or if the circumstances are serious, disciplined by expulsion:

第一百四十九条 违反本法规定，药品监督管理等部门有下列行为之一的，对直接负责的主管人员和其他直接责任人员给予记过或者记大过处分；情节较重的，给予降级或者撤职处分；情节严重的，给予开除处分：

(1) Concealment or falsification of a medicinal product safety event in reporting, delay in the reporting of a medicinal product safety event, or omission of a medicinal product safety event in reporting.

（一）瞒报、谎报、缓报、漏报药品安全事件；

(2) Failure to investigate and dispose of a discovered violation of law related to medicinal product safety in a timely manner.

（二）对发现的药品安全违法行为未及时查处；

(3) Failure to discover a systemic medicinal product safety risk in a timely manner, or failure to eliminate a hidden medicinal product safety risk within its regulatory jurisdiction in a timely manner, which has had a serious effect.

（三）未及时发现药品安全系统性风险，或者未及时消除监督管理区域内药品安全隐患，造成严重影响；

(4) Otherwise failing to perform the duties of supervision and administration of medicinal products, which has had a serious adverse effect or has caused any major loss.

（四）其他不履行药品监督管理职责，造成严重不良影响或者重大损失。

Article 150 Where any medicinal product regulatory staff member abuses his or her powers, makes falsification for personal gain, or neglects his or her duties, he or she shall be disciplined in accordance with the law.

第一百五十条 药品监督管理人员滥用职权、徇私舞弊、玩忽职守的，依法给予处分。

Where dereliction of duty or malfeasance in office is committed during the investigation of illegal conduct related to counterfeit medicinal products or medicinal products of inferior quality, the directly liable executive in charge and other liable persons of the medicinal product regulatory department shall be disciplined in a heavier manner in accordance with the law.

查处假药、劣药违法行为有失职、渎职行为的，对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从重给予处分。

Article 151 The value of goods as mentioned in this Chapter shall be calculated at the marked price of the medicinal products illegally manufactured or sold; and absent the marked price, calculation shall be made at the market price of the medicinal products of the same kind.

第一百五十一条 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。

Chapter XII Supplemental Provisions

第十二章 附 则

Article 152 The administration of the planting, collection, and raising of traditional Chinese medicinal materials shall be governed by the provisions of the relevant laws and regulations.

第一百五十二条 中药材种植、采集和饲养的管理，依照有关法律、法规的规定执行。

Article 153 The measures for the administration of regional customary medicinal materials shall be developed by the medicinal product regulatory department of the State Council in conjunction with the traditional Chinese medicine department of the State Council.

第一百五十三条 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主管部门制定。

Article 154 The specific measures for the implementation of this law by the Chinese People's Army and the Chinese People's Armed Police Force shall be developed by the State Council and the Central Military Commission in accordance with this Law.

第一百五十四条 中国人民解放军和中国人民武装警察部队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 155 This Law shall come into force on December 1, 2019.

第一百五十五条 本法自2019年12月1日起施行。