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修订）

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第一章　　总则

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

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

第三条　　国家发展现代药和传统药，充分发挥其在预防、医疗和保健中的作用。

国家保护野生药材资源，鼓励培育中药材。

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

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

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

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

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

第二章　　药品生产企业管理

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

《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。

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

第八条　　开办药品生产企业，必须具备以下条件：

（一）具有依法经过资格认定的药学技术人员、工程技术人员及相应的技术工人；

（二）具有与其药品生产相适应的厂房、设施和卫生环境；

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

（四）具有保证药品质量的规章制度。

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

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

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

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

第十一条　　生产药品所需的原料、辅料，必须符合药用要求。

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

第十三条　　经国务院药品监督管理部门或者国务院药品监督管理部门授权的省、自治区、直辖市人民政府药品监督管理部门批准，药品生产企业可以接受委托生产药品。

第三章　　药品经营企业管理

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

《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。

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

第十五条　开办药品经营企业必须具备以下条件：

（一）具有依法经过资格认定的药学技术人员；

（二）具有与所经营药品相适应的营业场所、设备、仓储设施、卫生环境；

（三）具有与所经营药品相适应的质量管理机构或者人员；

（四）具有保证所经营药品质量的规章制度。

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

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

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

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

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

药品经营企业销售中药材，必须标明产地。

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

药品入库和出库必须执行检查制度。

第二十一条　城乡集市贸易市场可以出售中药材，国务院另有规定的除外。

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

第四章　医疗机构的药剂管理

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

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

《医疗机构制剂许可证》应当标明有效期，到期重新审查发证。

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

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

医疗机构配制的制剂，不得在市场销售。

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

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

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

第五章　药品管理

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

完成临床试验并通过审批的新药，由国务院药品监督管理部门批准，发给新药证书。

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

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

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

药品生产企业在取得药品批准文号后，方可生产该药品。

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

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。

国务院药品监督管理部门组织药典委员会，负责国家药品标准的制定和修订。

国务院药品监督管理部门的药品检验机构负责标定国家药品标准品、对照品。

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

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

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

第三十六条　国家实行中药品种保护制度。具体办法由国务院制定。

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

第三十八条　禁止进口疗效不确、不良反应大或者其他原因危害人体健康的药品。

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

医疗单位临床急需或者个人自用进口的少量药品，按照国家有关规定办理进口手续。

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

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

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。

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

（一）国务院药品监督管理部门规定的生物制品；

（二）首次在中国销售的药品；

（三）国务院规定的其他药品。

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

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

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

第四十三条　国家实行药品储备制度。

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

第四十四条　对国内供应不足的药品，国务院有权限制或者禁止出口。

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

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

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

第四十八条　禁止生产（包括配制，下同）、销售假药。

有下列情形之一的，为假药：

（一）药品所含成份与国家药品标准规定的成份不符的；

（二）以非药品冒充药品或者以他种药品冒充此种药品的。

有下列情形之一的药品，按假药论处：

（一）国务院药品监督管理部门规定禁止使用的；

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

（三）变质的；

（四）被污染的；

（五）使用依照本法必须取得批准文号而未取得批准文号的原料药生产的；

（六）所标明的适应症或者功能主治超出规定范围的。

第四十九条　　禁止生产、销售劣药。

药品成份的含量不符合国家药品标准的，为劣药。

有下列情形之一的药品，按劣药论处：

（一）未标明有效期或者更改有效期的；

（二）不注明或者更改生产批号的；

（三）超过有效期的；

（四）直接接触药品的包装材料和容器未经批准的；

（五）擅自添加着色剂、防腐剂、香料、矫味剂及辅料的；

（六）其他不符合药品标准规定的。

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

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

第六章　　药品包装的管理

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

药品生产企业不得使用未经批准的直接接触药品的包装材料和容器。

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。

第五十三条　　药品包装必须适合药品质量的要求，方便储存、运输和医疗使用。

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

第五十四条　　药品包装必须按照规定印有或者贴有标签并附有说明书。

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

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

第七章　　药品价格和广告的管理

第五十五条　　依法实行政府定价、政府指导价的药品，政府价格主管部门应当依照《中华人民共和国价格法》规定的定价原则，依据社会平均成本、市场供求状况和社会承受能力合理制定和调整价格，做到质价相符，消除虚高价格，保护用药者的正当利益。

药品的生产企业、经营企业和医疗机构必须执行政府定价、政府指导价，不得以任何形式擅自提高价格。

药品生产企业应当依法向政府价格主管部门如实提供药品的生产经营成本，不得拒报、虚报、瞒报。

第五十六条　　依法实行市场调节价的药品，药品的生产企业、经营企业和医疗机构应当按照公平、合理和诚实信用、质价相符的原则制定价格，为用药者提供价格合理的药品。

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

第五十七条 药品的生产企业、经营企业、医疗机构应当依法向政府价格主管部门提供其药品的实际购销价格和购销数量等资料。

第五十八条 医疗机构应当向患者提供所用药品的价格清单；医疗保险定点医疗机构还应当按照规定的办法如实公布其常用药品的价格，加强合理用药的管理。具体办法由国务院卫生行政部门规定。

第五十九条 禁止药品的生产企业、经营企业和医疗机构在药品购销中帐外暗中给予、收受回扣或者其他利益。

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

第六十条 药品广告须经企业所在地省、自治区、直辖市人民政府药品监督管理部门批准，并发给药品广告批准文号；未取得药品广告批准文号的，不得发布。

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

第六十一条 药品广告的内容必须真实、合法，以国务院药品监督管理部门批准的说明书为准，不得含有虚假的内容。

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

非药品广告不得有涉及药品的宣传。

第六十二条 省、自治区、直辖市人民政府药品监督管理部门应当对其批准的药品广告进行检查，对于违反本法和《中华人民共和国广告法》的广告，应当向广告监督管理机关通报并提出处理建议，广告监督管理机关应当依法作出处理。

第六十三条 药品价格和广告，本法未规定的，适用《中华人民共和国价格法》、《中华人民共和国广告法》的规定。

第八章 药品监督

第六十四条 药品监督管理部门有权按照法律、行政法规的规定对报经其审批的药品研制和药品的生产、经营以及医疗机构使用药品的事项进行监督检查，有关单位和个人不得拒绝和隐瞒。

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

第六十五条 药品监督管理部门根据监督检查的需要，可以对药品质量进行抽查检验。抽查检验应当按照规定抽样，并不得收取任何费用。所需费用按照国务院规定列支。

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

第六十六条　　国务院和省、自治区、直辖市人民政府的药品监督管理部门应当定期公告药品质量抽查检验的结果；公告不当的，必须在原公告范围内予以更正。

第六十七条　　当事人对药品检验机构的检验结果有异议的，可以自收到药品检验结果之日起七日内向原药品检验机构或者上一级药品监督管理部门设置或者确定的药品检验机构申请复验，也可以直接向国务院药品监督管理部门设置或者确定的药品检验机构申请复验。受理复验的药品检验机构必须在国务院药品监督管理部门规定的时间内作出复验结论。

第六十八条　　药品监督管理部门应当按照规定，依据《药品生产质量管理规范》、《药品经营质量管理规范》，对经其认证合格的药品生产企业、药品经营企业进行认证后的跟踪检查。

第六十九条　　地方人民政府和药品监督管理部门不得以要求实施药品检验、审批等手段限制或者排斥非本地区药品生产企业依照本法规定生产的药品进入本地区。

第七十条　　药品监督管理部门及其设置的药品检验机构和确定的专业从事药品检验的机构不得参与药品生产经营活动，不得以其名义推荐或者监制、监销药品。

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

第七十一条　　国家实行药品不良反应报告制度。药品生产企业、药品经营企业和医疗机构必须经常考察本单位所生产、经营、使用的药品质量、疗效和反应。发现可能与用药有关的严重不良反应，必须及时向当地省、自治区、直辖市人民政府药品监督管理部门和卫生行政部门报告。具体办法由国务院药品监督管理部门会同国务院卫生行政部门制定。

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

第七十二条 药品生产企业、药品经营企业和医疗机构的药品检验机构或者人员，应当接受当地药品监督管理部门设置的药品检验机构的业务指导。

第九章 法律责任

第七十三条 未取得《药品生产许可证》、《药品经营许可证》或者《医疗机构制剂许可证》生产药品、经营药品的，依法予以取缔，没收违法生产、销售的药品和违法所得，并处违法生产、销售的药品（包括已售出的和未售出的药品，下同）货值金额二倍以上五倍以下的罚款；构成犯罪的，依法追究刑事责任。

第七十四条 生产、销售假药的，没收违法生产、销售的药品和违法所得，并处违法生产、销售药品货值金额二倍以上五倍以下的罚款；有药品批准证明文件的予以撤销，并责令停产、停业整顿；情节严重的，吊销《药品生产许可证》、《药品经营许可证》或者《医疗机构制剂许可证》；构成犯罪的，依法追究刑事责任。

第七十五条 生产、销售劣药的，没收违法生产、销售的药品和违法所得，并处违法生产、销售药品货值金额一倍以上三倍以下的罚款；情节严重的，责令停产、停业整顿或者撤销药品批准证明文件、吊销《药品生产许可证》、《药品经营许可证》或者《医疗机构制剂许可证》；构成犯罪的，依法追究刑事责任。

第七十六条 从事生产、销售假药及生产、销售劣药情节严重的企业或者其他单位，其直接负责的主管人员和其他直接责任人员十年内不得从事药品生产、经营活动。

对生产者专门用于生产假药、劣药的原辅材料、包装材料、生产设备，予以没收。

第七十七条 知道或者应当知道属于假劣药品而为其提供运输、保管、仓储等便利条件的，没收全部运输、保管、仓储的收入，并处违法收入百分之五十以上三倍以下的罚款；构成犯罪的，依法追究刑事责任。

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

第七十九条 药品的生产企业、经营企业、药物非临床安全性评价研究机构、药物临床试验机构未按照规定实施《药品生产质量管理规范》、《药品经营质量管理规范》、药物非临床研究质量管理规范、药物临床试验质量管理规范的，给予警告，责令限期改正；逾期不改正的，责令停产、停业整顿，并处五千元以上二万元以下的罚款；情节严重的，吊销《药品生产许可证》、《药品经营许可证》和药物临床试验机构的资格。

第八十条 药品的生产企业、经营企业或者医疗机构违反本法第三十四条的规定，从无《药品生产许可证》、《药品经营许可证》的企业购进药品的，责令改正，没收违法购进的药品，并处违法购进药品货值金额二倍以上五倍以下的罚款；有违法所得的，没收违法所得；情节严重的，吊销《药品生产许可证、《药品经营许可证》或者医疗机构执业许可证书。

第八十一条 进口已获得药品进口注册证书的药品，未按照本法规定向允许药品进口的口岸所在地的药品监督管理部门登记备案的，给予警告，责令限期改正；逾期不改正的，撤销进口药品注册证书。

第八十二条　伪造、变造、买卖、出租、出借许可证或者药品批准证明文件的，没收违法所得，并处违法所得一倍以上三倍以下的罚款；没有违法所得的，处二万元以上十万元以下的罚款；情节严重的，并吊销卖方、出租方、出借方的《药品生产许可证》、《药品经营许可证》、《医疗机构制剂许可证》或者撤销药品批准证明文件；构成犯罪的，依法追究刑事责任。

第八十三条　违反本法规定，提供虚假的证明、文件资料样品或者采取其他欺骗手段取得《药品生产许可证》、《药品经营许可证》、《医疗机构制剂许可证》或者药品批准证明文件的，吊销《药品生产许可证》、《药品经营许可证》、《医疗机构制剂许可证》或者撤销药品批准证明文件，五年内不受理其申请，并处一万元以上三万元以下的罚款。

第八十四条　医疗机构将其配制的制剂在市场销售的，责令改正，没收违法销售的制剂，并处违法销售制剂货值金额一倍以上三倍以下的罚款；有违法所得的，没收违法所得。

第八十五条　药品经营企业违反本法第十八条、第十九条规定的，责令改正，给予警告；情节严重的，吊销《药品经营许可证》。

第八十六条　药品标识不符合本法第五十四条规定的，除依法应当按照假药、劣药论处的外，责令改正，给予警告；情节严重的，撤销该药品的批准证明文件。

第八十七条　药品检验机构出具虚假检验报告，构成犯罪的，依法追究刑事责任；不构成犯罪的，责令改正，给予警告，对单位并处三万元以上五万元以下的罚款；对直接负责的主管人员和其他直接责任人员依法给予降级、撤职、开除的处分，并处三万元以下的罚款；有违法所得的，没收违法所得；情节严重的，撤销其检验资格。药品检验机构出具的检验结果不实，造成损失的，应当承担相应的赔偿责任。

第八十八条　　本法第七十三条至第八十七条规定的行政处罚，由县级以上药品监督管理部门按照国务院药品监督管理部门规定的职责分工决定；吊销《药品生产许可证》、《药品经营许可证、《医疗机构制剂许可证》、医疗机构执业许可证书或者撤销药品批准证明文件的，由原发证、批准的部门决定。

第八十九条　　违反本法第五十五条、第五十六条、第五十七条关于药品价格管理的规定的，依照《中华人民共和国价格法》的规定处罚。

第九十条　　药品的生产企业、经营企业、医疗机构在药品购销中暗中给予、收受回扣或者其他利益的，药品的生产企业、经营企业或者其代理人给予使用其药品的医疗机构的负责人、药品采购人员、医师等有关人员以财物或者其他利益的，由工商行政管理部门处一万元以上二十万元以下的罚款，有违法所得的，予以没收；情节严重的，由工商行政管理部门吊销药品生产企业、药品经营企业的营业执照，并通知药品监督管理部门，由药品监督管理部门吊销其《药品生产许可证》、《药品经营许可证》；构成犯罪的，依法追究刑事责任。

第九十一条　　药品的生产企业、经营企业的负责人、采购人员等有关人员在药品购销中收受其他生产企业、经营企业或者其代理人给予的财物或者其他利益的，依法给予处分，没收违法所得；构成犯罪的，依法追究刑事责任。

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

第九十二条　　违反本法有关药品广告的管理规定的，依照《中华人民共和国广告法》的规定处罚，并由发给广告批准文号的药品监督管理部门撤销广告批准文号，一年内不受理该品种的广告审批申请；构成犯罪的，依法追究刑事责任。

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

第九十三条　药品的生产企业、经营企业、医疗机构违反本法规定，给药品使用者造成损害的，依法承担赔偿责任。

第九十四条　药品监督管理部门违反本法规定，有下列行为之一的，由其上级主管机关或者监察机关责令收回违法发给的证书、撤销药品批准证明文件，对直接负责的主管人员和其他直接责任人员依法给予行政处分；构成犯罪的，依法追究刑事责任：

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

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

（三）对不符合进口条件的药品发给进口药品注册证书的；

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

第九十五条　药品监督管理部门或者其设置的药品检验机构或者其确定的专业从事药品检验的机构参与药品生产经营活动的，由其上级机关或者监察机关责令改正，有违法收入的予以没收；情节严重的，对直接负责的主管人员和其他直接责任人员依法给予行政处分。

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

第九十六条　药品监督管理部门或者其设置、确定的药品检验机构在药品监督检验中违法收取检验费用的，由政府有关部门责令退还，对直接负责的主管人员和其他直接责任人员依法给予行政处分。对违法收取检验费用情节严重的药品检验机构，撤销其检验资格。

第九十七条　　药品监督管理部门应当依法履行监督检查职责，监督已取得《药品生产许可证》、《药品经营许可证》的企业依照本法规定从事药品生产、经营活动。

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

第九十八条　　药品监督管理部门对下级药品监督管理部门违反本法的行政行为，责令限期改正；逾期不改正的，有权予以改变或者撤销。

第九十九条　　药品监督管理人员滥用职权、徇私舞弊、玩忽职守，构成犯罪的，依法追究刑事责任；尚不构成犯罪的，依法给予行政处分。

第一百条　　依照本法被吊销《药品生产许可证》、《药品经营许可证》的，由药品监督管理部门通知工商行政管理部门办理变更或者注销登记。

第一百零一　　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。

第十章　　附则

第一百零二条　　本法下列用语的含义是：

药品，是指用于预防、治疗、诊断人的疾病，有目的地调节人的生理机能并规定有适应症或者功能主治、用法和用量的物质，包括中药材、中药饮片、中成药、

化学原料药及其制剂、抗生素、生化药品、放射性药品、血清、疫苗、血液制品和诊断药品等。

辅料，是指生产药品和调配处方时所用的赋形剂和附加剂。

药品生产企业，是指生产药品的专营企业或者兼营企业。

药品经营企业，是指经营药品的专营企业或者兼营企业。

第一百零三条 中药材的种植、采集和饲养的管理办法，由国务院另行制定。

第一百零四条 国家对预防性生物制品的流通实行特殊管理。具体办法由国务院制定。

第一百零五条 中国人民解放军执行本法的具体办法，由国务院、中央军事委员会依据本法制定。

第一百零六条 本法自 2001 年 12 月 1 日起施行。

DRUG ADMINISTRATION LAW OF THE PEOPLE'S REPUBLIC OF CHINA

(Adopted at the 7th Meeting of the Standing Committee of the Sixth National Peoples Congress on September 20, 1984, revised at the 20th Meeting of the Standing Committee of the Ninth National Peoples Congress on February 28, 2001)

CONTENTS

Chapter I

General Provisions

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

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

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

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

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

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

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

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

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

Chapter II

Control over Drug Manufacturers

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

The valid term and the scope of manufacturing shall be indicated in the Drug Manufacturing Certificate. For renewal of the certificate on expiration, reexamination is required.
When giving approval to the establishment of a new manufacturer, the drug regulatory department shall see to it that, apart from the requirements specified by the provisions in Article 8 of this Law that should be met, the pharmaceutical development programs and policies formulated by the State for the pharmaceutical industry are conformed to and prevent duplicate construction.

Article 8 A drug manufacturer to be established shall meet the following requirements:
(1) having legally qualified pharmaceutical and engineering professionals, and the necessary technical workers;
(2) having the premises, facilities, and hygienic environment required for drug manufacturing;
(3) having the institutions and personnel capable of quality control and testing for drugs to be produced and the necessary instruments and equipment; and
(4) having rules and regulations to ensure the quality of drugs.

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

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

Article 10 With the exception of the processing of prepared slices of Chinese crude drugs, a drug shall be produced in conformity with the National Drug Standard and with the production processes approved by

the drug regulatory department under the State Council, and the production records shall be complete and accurate. When drug manufacturers make any change in the production process that may affect the drug quality, they shall submit the matter for examination and approval to the original approval authority.

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

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

Article 12 Drug manufacturers shall perform quality test of the drugs produced; no drugs that do not meet the national drug standards or that are not produced according to the processing procedures for the prepared slices of Chinese crude drugs formulated by the drug regulatory department of the people's government of the province, autonomous region, or municipality directly under the Central Government may be released.

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

Chapter III
Control over Drug Distributors

Article 14 The establishment of a drug wholesaler shall be subject to approval of the local drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government and be granted the Drug Supply Certificate; the establishment of a drug retailer shall be subject to approval and be granted the said certificate by the local drug regulatory department at or above the country level. With the certificate, the wholesaler and the retailer shall be

registered with the administrative department for industry and commerce. No one may distribute drugs without the certificate.

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

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

Article 15 A drug distributor to be established shall meet the following requirements:
(1) having legally qualified pharmaceutical professionals;
(2) having the business operation premises, equipment, warehouses and hygienic environment required for drug distribution;
(3) having the units or personnel for quality control over the drugs to be distributed; and
(4) having rules and regulations to ensure the quality of the drugs to be distributed.

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

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

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

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

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

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

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

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

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

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

Chapter IV
Control over Pharmaceuticals in Medical Institutions

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

Article 23 To dispense pharmaceutical preparations, a medical institution shall be subject to examination and permission by the administrative department for health of the people's government of the province, autonomous region or municipality directly under the Central Government, and upon approval by the drug regulatory department of the said people's government, a Pharmaceutical Preparation Certificate for

Medical Institution shall be issued to it by the said drug regulatory department. No one may dispense pharmaceutical preparations without the certificate.

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

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

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

No pharmaceutical preparations dispensed by medical institutions may be marketed.

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

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

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

Chapter V

Control over Drugs

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

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

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

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

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

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

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

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

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

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

Article 34 Drug manufacturers, drug distributors and medical institutions shall purchase drugs from pharmaceutical enterprises, which are qualified for production or distribution, with the exception of the Chinese crude drugs where no control by approval number is exercised.

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

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

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

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

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

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

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

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

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

Article 41 The drug regulatory department under the State Council shall designate drug testing institutions to test the following drugs before they are marketed or at the time they are imported; no drugs that fail to pass the testing may be marketed or imported;
(1) biological products specified by the drug regulatory department under the State Council;
(2) drugs to be marketed in China for the first time; and
(3) other drugs specified by the State Council.

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

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

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

Article 43 The State adopts a system for drug reserve.
When major disasters, epidemic situations or other emergencies occur in the country, the department specified by the State Council may transfer drugs from the enterprises to meet the urgent need.

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

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

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

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

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

A drug is a counterfeit drug in any of the following cases:
(1) the ingredients in the drug are different from those specified by the national drug standards; or
(2) a non-drug substance is simulated as a drug or one drug is simulated as another.
A drug shall be treated as a counterfeit drug in any of the following cases:
(1) its use is prohibited by the regulations of the drug regulatory department under the State Council;
(2) it is produced or imported without approval, or marketed without being tested, as required by this Law;
(3)it is deteriorated;
(4) it is contaminated;

(5) it is produced by using drug substances without approval number as required by this Law; or
(6) the indications or functions indicated are beyond the specified scope.

Article 49 Production and distribution of substandard drugs are prohibited.
A drug with content not up to the national drug standards is a substandard drug.
A drug shall be treated as a substandard drug in any of the following cases;
(1) the date of expiry is not indicated or is altered;
(2) the batch number is not indicated or is altered;
(3) it is beyond the date of expiry;
(4) no approval is obtained for the immediate packaging material or container;
(5) colorants, preservatives, spices, flavorings or other excipients are added without authorization; or
(6) other cases where the drug standard are not conformed.

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

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

Chapter VI
Control over Drug Packaging

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

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

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

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

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

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

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

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

Chapter VII
Control over Drug Pricing and Advertising

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

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

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

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

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

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

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

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

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

Article 60 Drug advertisements shall be subject to approval by the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central

Government where the enterprise is located, an approval number of drug advertisement shall be issued. No one may launch advertisements without the approval number.

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

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

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

No-drug advertisements may not deal with drug promotion.

Article 62 Drug regulatory departments of the people's governments of provinces, autonomous regions or municipalities directly under the Central Government shall inspect the drug advertisements approved by them, and inform the advertisement regulatory authority of those advertisements that violate this Law or the Advertisement Law of the People's Republic of China, and put forward suggestions for their handling, and the said authority shall deal with such cases according to law.

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

Chapter VIII

Inspection of Drugs

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

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

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

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

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

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

accepts the application shall, within the time limit specified by the drug regulatory department under the State Council, draw a conclusion from the re-test.

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

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

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

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

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

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

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

Chapter IX
Legal Liabilities

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

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

Article 75 Where substandard drugs are produced or sold, the drugs illegally produced or sold and the illegal gains shall be confiscated, and a fine not less than, but not more than three times, the value of the said drugs shall also be imposed. If the circumstances are serious, an order shall be given to suspend production or business operation for rectification, or the drug approval documents shall be withdrawn and the Drug Manufacturing Certificate, the Drug supply Certificate, or the Pharmaceutical Preparation Certificate for Medical Institution shall be revoked. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

Article 76 Where enterprises or other institutions are engaged in production or sale of counterfeit or substandard drugs, if the circumstances are serious, the persons directly in charge and the other persons

directly responsible shall be prohibited from engaging in the drug production or distribution within 10 years.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

revoke their Drug Manufacturing Certificate, or Drug Distribution Certificate. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

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

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

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

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

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

Article 94 Any drug regulatory department that violates the provisions of this Law sand commits one of the following acts shall be instructed by the competent authority at the next higher level or the

supervisory body to recall the certificates unlawfully issued or to withdraw the drug approval documents, and administrative sanctions shall be given to the persons directly in charge and the other persons directly responsible in accordance with law. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

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

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

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

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

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

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

testing institution that collects testing fees in violation of law, if the circumstances are serious, shall be disqualified for drug testing.

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

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

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

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

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

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

Chapter X

Supplementary Provisions

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

Drugs refer to articles which are used in the prevention, treatment and diagnosis of human diseases and intended for the regulation of the physiological functions of human beings, for which indications, usage and dosage are established, including Chinese crude drugs, prepared slices of Chinese crude drugs, traditional Chinese medicine preparations, chemical drugs substances and their preparations, antibiotics, biochemical drugs, radioactive pharmaceuticals, serum, vaccines, blood products and diagnostic agents.

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

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

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

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

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

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

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