中华人民共和国药品管理法实施条例

第一章　总 则

第一条 根据《中华人民共和国药品管理法》（以下简称《药品管理法》），制定本条例。

第二条 国务院药品监督管理部门设置国家药品检验机构。

省、自治区、直辖市人民政府药品监督管理部门可以在本行政区域内设置药品检验机构。地方药品检验机构的设置规划由省、自治区、直辖市人民政府药品监督管理部门提出，报省、自治区、直辖市人民政府批准。

国务院和省、自治区、直辖市人民政府的药品监督管理部门可以根据需要，确定符合药品检验条件的检验机构承担药品检验工作。

第二章　药品生产企业管理

第三条 开办药品生产企业，应当按照下列规定办理《药品生产许可证》：

（一）申办人应当向拟办企业所在地省、自治区、直辖市人民政府药品监督管理部门提出申请。省、自治区、直辖市人民政府药品监督管理部门应当自收到申请之日起30个工作日内，按照国家发布的药品行业发展规划和产业政策进行审查，并作出是否同意筹建的决定。

（二）申办人完成拟办企业筹建后，应当向原审批部门申请验收。原审批部门应当自收到申请之日起30个工作日内，依据《药品管理法》第八条规定的开办条件组织验收；验收合格的，发给《药品生产许可证》。申办人凭《药品生产许可证》到工商行政管理部门依法办理登记注册。

第四条 药品生产企业变更《药品生产许可证》许可事项的，应当在许可事项发生变更30日前，向原发证机关申请《药品生产许可证》变更登记；未经批准，不得变更许可事项。原发证机关应当自收到申请之日起15个工作日内作出决定。申请人凭变更后的《药品生产许可证》到工商行政管理部门依法办理变更登记手续。

第五条 省级以上人民政府药品监督管理部门应当按照《药品生产质量管理规范》和国务院药品监督管理部门规定的实施办法和实施步骤，组织对药品生产企业的认证工作；符合《药品生产质量管理规范》的，发给认证证书。其中，生产注射剂、放射性药品和国务院药品监督管理部门规定的生物制品的药品生产企业的认证工作，由国务院药品监督管理部门负责。

《药品生产质量管理规范》认证证书的格式由国务院药品监督管理部门统一规定。

第六条 新开办药品生产企业、药品生产企业新建药品生产车间或者新增生产剂型的，应当自取得药品生产证明文件或者经批准正式生产之日起30日内，按照规定向药品监督管理部门申请《药品生产质量管理规范》认证。受理申请的药品监督管理部门应当自收到企业申请之日起6个月内，组织对申请企业是否符合《药品生产质量管理规范》进行认证；认证合格的，发给认证证书。

第七条 国务院药品监督管理部门应当设立《药品生产质量管理规范》认证检查员库。《药品生产质量管理规范》认证检查员必须符合国务院药品监督管理部门规定的条件。进行《药品生产质量管理规范》认证，必须按照国务院药品监督管理部门的规定，从《药品生产质量管理规范》认证检查员库中随机抽取认证检查员组成认证检查组进行认证检查。

第八条 《药品生产许可证》有效期为5年。有效期届满，需要继续生产药品的，持证企业应当在许可证有效期届满前6个月，按照国务院药品监督管理部门的规定申请换发《药品生产许可证》。

药品生产企业终止生产药品或者关闭的，《药品生产许可证》由原发证部门缴销。

第九条 药品生产企业生产药品所使用的原料药，必须具有国务院药品监督管理部门核发的药品批准文号或者进口药品注册证书、医药产品注册证书；但是，未实施批准文号管理的中药材、中药饮片除外。

第十条 依据《药品管理法》第十三条规定，接受委托生产药品的，受托方必须是持有与其受托生产的药品相适应的《药品生产质量管理规范》认证证书的药品生产企业。

疫苗、血液制品和国务院药品监督管理部门规定的其他药品，不得委托生产。

第三章　药品经营企业管理

第十一条 开办药品批发企业，申办人应当向拟办企业所在地省、自治区、直辖市人民政府药品监督管理部门提出申请。省、自治区、直辖市人民政府药品监督管理部门应当自收到申请之日起30个工作日内，依据国务院药品监督管理部门规定的设置标准作出是否同意筹建的决定。申办人完成拟办企业筹建后，应当向原审批部门申请验收。原审批部门应当自收到申请之日起30个工作日内，依据《药品管理法》第十五条规定的开办条件组织验收；符合条件的，发给《药品经营许可证》。申办人凭《药品经营许可证》到工商行政管理部门依法办理登记注册。

第十二条 开办药品零售企业，申办人应当向拟办企业所在地设区的市级药品监督管理机构或者省、自治区、直辖市人民政府药品监督管理部门直接设置的县级

药品监督管理机构提出申请。受理申请的药品监督管理机构应当自收到申请之日起30个工作日内，依据国务院药品监督管理部门的规定，结合当地常住人口数量、地域、交通状况和实际需要进行审查，作出是否同意筹建的决定。申办人完成拟办企业筹建后，应当向原审批机构申请验收。原审批机构应当自收到申请之日起15个工作日内，依据《药品管理法》第十五条规定的开办条件组织验收；符合条件的，发给《药品经营许可证》。申办人凭《药品经营许可证》到工商行政管理部门依法办理登记注册。

第十三条 省、自治区、直辖市人民政府药品监督管理部门负责组织药品经营企业的认证工作。药品经营企业应当按照国务院药品监督管理部门规定的实施办法和实施步骤，通过省、自治区、直辖市人民政府药品监督管理部门组织的《药品经营质量管理规范》的认证，取得认证证书。《药品经营质量管理规范》认证证书的格式由国务院药品监督管理部门统一规定。

新开办药品批发企业和药品零售企业，应当自取得《药品经营许可证》之日起30日内，向发给其《药品经营许可证》的药品监督管理部门或者药品监督管理机构申请《药品经营质量管理规范》认证。受理药品零售企业认证申请的药品监督管理机构应当自收到申请之日起7个工作日内，将申请移送负责组织药品经营企业认证工作的省、自治区、直辖市人民政府药品监督管理部门。省、自治区、直辖市人民政府药品监督管理部门应当自收到认证申请之日起3个月内，按照国务院药品监督管理部门的规定，组织对申请认证的药品批发企业或者药品零售企业是否符合《药品经营质量管理规范》进行认证；认证合格的，发给认证证书。

第十四条 省、自治区、直辖市人民政府药品监督管理部门应当设立《药品经营质量管理规范》认证检查员库。《药品经营质量管理规范》认证检查员必须符合国务院药品监督管理部门规定的条件。进行《药品经营质量管理规范》认证，必须

按照国务院药品监督管理部门的规定，从《药品经营质量管理规范》认证检查员库中随机抽取认证检查员组成认证检查组进行认证检查。

第十五条 国家实行处方药和非处方药分类管理制度。国家根据非处方药品的安全性，将非处方药分为甲类非处方药和乙类非处方药。

经营处方药、甲类非处方药的药品零售企业，应当配备执业药师或者其他依法经资格认定的药学技术人员。经营乙类非处方药的药品零售企业，应当配备经设区的市级药品监督管理机构或者省、自治区、直辖市人民政府药品监督管理部门直接设置的县级药品监督管理机构组织考核合格的业务人员。

第十六条 药品经营企业变更《药品经营许可证》许可事项的，应当在许可事项发生变更30日前，向原发证机关申请《药品经营许可证》变更登记；未经批准，不得变更许可事项。原发证机关应当自收到企业申请之日起15个工作日内作出决定。申请人凭变更后的《药品经营许可证》到工商行政管理部门依法办理变更登记手续。

第十七条 《药品经营许可证》有效期为5年。有效期届满，需要继续经营药品的，持证企业应当在许可证有效期届满前6个月，按照国务院药品监督管理部门的规定申请换发《药品经营许可证》。

药品经营企业终止经营药品或者关闭的，《药品经营许可证》由原发证机关缴销。

第十八条 交通不便的边远地区城乡集市贸易市场没有药品零售企业的，当地药品零售企业经所在地县（市）药品监督管理机构批准并到工商行政管理部门办理登记注册后，可以在该城乡集市贸易市场内设点并在批准经营的药品范围内销售非处方药品。

第十九条 通过互联网进行药品交易的药品生产企业、药品经营企业、医疗机构及其交易的药品，必须符合《药品管理法》和本条例的规定。互联网药品交易服务的管理办法，由国务院药品监督管理部门会同国务院有关部门制定。

第四章　医疗机构的药剂管理

第二十条 医疗机构设立制剂室，应当向所在地省、自治区、直辖市人民政府卫生行政部门提出申请，经审核同意后，报同级人民政府药品监督管理部门审批；省、自治区、直辖市人民政府药品监督管理部门验收合格的，予以批准，发给《医疗机构制剂许可证》。

省、自治区、直辖市人民政府卫生行政部门和药品监督管理部门应当在各自收到申请之日起30个工作日内，作出是否同意或者批准的决定。

第二十一条 医疗机构变更《医疗机构制剂许可证》许可事项的，应当在许可事项发生变更30日前，依照本条例第二十条的规定向原审核、批准机关申请《医疗机构制剂许可证》变更登记；未经批准，不得变更许可事项。原审核、批准机关应当在各自收到申请之日起15个工作日内作出决定。

医疗机构新增配制剂型或者改变配制场所的，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验收合格后，依照前款规定办理《医疗机构制剂许可证》变更登记。

第二十二条 《医疗机构制剂许可证》有效期为5年。有效期届满，需要继续配制制剂的，医疗机构应当在许可证有效期届满前6个月，按照国务院药品监督管理部门的规定申请换发《医疗机构制剂许可证》。

医疗机构终止配制制剂或者关闭的，《医疗机构制剂许可证》由原发证机关缴销。

第二十三条 医疗机构配制制剂，必须按照国务院药品监督管理部门的规定报送有关资料和样品，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，并发给制剂批准文号后，方可配制。

第二十四条 医疗机构配制的制剂不得在市场上销售或者变相销售，不得发布医疗机构制剂广告。

发生灾情、疫情、突发事件或者临床急需而市场没有供应时，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，在规定期限内，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。

国务院药品监督管理部门规定的特殊制剂的调剂使用以及省、自治区、直辖市之间医疗机构制剂的调剂使用，必须经国务院药品监督管理部门批准。

第二十五条 医疗机构审核和调配处方的药剂人员必须是依法经资格认定的药学技术人员。

第二十六条 医疗机构购进药品，必须有真实、完整的药品购进记录。药品购进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、供货单位、购货数量、购进价格、购货日期以及国务院药品监督管理部门规定的其他内容。

第二十七条 医疗机构向患者提供的药品应当与诊疗范围相适应，并凭执业医师或者执业助理医师的处方调配。

计划生育技术服务机构采购和向患者提供药品，其范围应当与经批准的服务范围相一致，并凭执业医师或者执业助理医师的处方调配。

个人设置的门诊部、诊所等医疗机构不得配备常用药品和急救药品以外的其他药品。常用药品和急救药品的范围和品种，由所在地的省、自治区、直辖市人民政府卫生行政部门会同同级人民政府药品监督管理部门规定。

第五章　药品管理

第二十八条 药物非临床安全性评价研究机构必须执行《药物非临床研究质量管理规范》，药物临床试验机构必须执行《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》由国务院药品监督管理部门分别商国务院科学技术行政部门和国务院卫生行政部门制定。

第二十九条 药物临床试验、生产药品和进口药品，应当符合《药品管理法》及本条例的规定，经国务院药品监督管理部门审查批准；国务院药品监督管理部门可以委托省、自治区、直辖市人民政府药品监督管理部门对申报药物的研制情况及条件进行审查，对申报资料进行形式审查，并对试制的样品进行检验。具体办法由国务院药品监督管理部门制定。

第三十条 研制新药，需要进行临床试验的，应当依照《药品管理法》第二十九条的规定，经国务院药品监督管理部门批准。

药物临床试验申请经国务院药品监督管理部门批准后，申报人应当在经依法认定的具有药物临床试验资格的机构中选择承担药物临床试验的机构，并将该临床试验机构报国务院药品监督管理部门和国务院卫生行政部门备案。

药物临床试验机构进行药物临床试验，应当事先告知受试者或者其监护人真实情况，并取得其书面同意。

第三十一条 生产已有国家标准的药品，应当按照国务院药品监督管理部门的规定，向省、自治区、直辖市人民政府药品监督管理部门或者国务院药品监督管理部门提出申请，报送有关技术资料并提供相关证明文件。省、自治区、直辖市人民政府药品监督管理部门应当自受理申请之日起 30 个工作日内进行审查，提出意见后报送国务院药品监督管理部门审核，并同时将审查意见通知申报方。国务院药品监督管理部门经审核符合规定的，发给药品批准文号。

第三十二条 生产有试行期标准的药品，应当按照国务院药品监督管理部门的规定，在试行期满前 3 个月，提出转正申请；国务院药品监督管理部门应当自试行期满之日起 12 个月内对该试行期标准进行审查，对符合国务院药品监督管理部门规定的转正要求的，转为正式标准；对试行标准期满未按照规定提出转正申请或者原试行标准不符合转正要求的，国务院药品监督管理部门应当撤销该试行标准和依据该试行标准生产药品的批准文号。

第三十三条 变更研制新药、生产药品和进口药品已获批准证明文件及其附件中载明事项的，应当向国务院药品监督管理部门提出补充申请；国务院药品监督管理部门经审核符合规定的，应当予以批准。

第三十四条 国务院药品监督管理部门根据保护公众健康的要求，可以对药品生产企业生产的新药品种设立不超过 5 年的监测期；在监测期内，不得批准其他企业生产和进口。

第三十五条 国家对获得生产或者销售含有新型化学成份药品许可的生产者或者销售者提交的自行取得且未披露的试验数据和其他数据实施保护，任何人不得对该未披露的试验数据和其他数据进行不正当的商业利用。

自药品生产者或者销售者获得生产、销售新型化学成份药品的许可证明文件之日起 6 年内，对其他申请人未经已获得许可的申请人同意，使用前款数据申请生产、销售新型化学成份药品许可的，药品监督管理部门不予许可；但是，其他申请人提交自行取得数据的除外。

除下列情形外，药品监督管理部门不得披露本条第一款规定的数据：

（一）公共利益需要；

（二）已采取措施确保该类数据不会被不正当地进行商业利用。

第三十六条 申请进口的药品，应当是在生产国家或者地区获得上市许可的药品；未在生产国家或者地区获得上市许可的，经国务院药品监督管理部门确认该药品品种安全、有效而且临床需要的，可以依照《药品管理法》及本条例的规定批准进口。

进口药品，应当按照国务院药品监督管理部门的规定申请注册。国外企业生产的药品取得《进口药品注册证》，中国香港、澳门和台湾地区企业生产的药品取得《医药产品注册证》后，方可进口。

第三十七条 医疗机构因临床急需进口少量药品的，应当持《医疗机构执业许可证》向国务院药品监督管理部门提出申请；经批准后，方可进口。进口的药品应当在指定医疗机构内用于特定医疗目的。

第三十八条 进口药品到岸后，进口单位应当持《进口药品注册证》或者《医药产品注册证》以及产地证明原件、购货合同副本、装箱单、运单、货运发票、出厂检验报告书、说明书等材料，向口岸所在地药品监督管理部门备案。口岸所在地药品监督管理部门经审查，提交的材料符合要求的，发给《进口药品通关单》。进口单位凭《进口药品通关单》向海关办理报关验放手续。

口岸所在地药品监督管理部门应当通知药品检验机构对进口药品逐批进行抽查检验；但是，有《药品管理法》第四十一条规定情形的除外。

第三十九条 疫苗类制品、血液制品、用于血源筛查的体外诊断试剂以及国务院药品监督管理部门规定的其他生物制品在销售前或者进口时，应当按照国务院药品监督管理部门的规定进行检验或者审核批准；检验不合格或者未获批准的，不得销售或者进口。

第四十条 国家鼓励培育中药材。对集中规模化栽培养殖、质量可以控制并符合国务院药品监督管理部门规定条件的中药材品种，实行批准文号管理。

第四十一条 国务院药品监督管理部门对已批准生产、销售的药品进行再评价，根据药品再评价结果，可以采取责令修改药品说明书，暂停生产、销售和使用的措施；对不良反应大或者其他原因危害人体健康的药品，应当撤销该药品批准证明文件。

第四十二条 国务院药品监督管理部门核发的药品批准文号、《进口药品注册证》、《医药产品注册证》的有效期为5年。有效期届满，需要继续生产或者进口的，应当在有效期届满前6个月申请再注册。药品再注册时，应当按照国务院药品监督管理部门的规定报送相关资料。有效期届满，未申请再注册或者经审查不符合国务院药品监督管理部门关于再注册的规定的，注销其药品批准文号、《进口药品注册证》或者《医药产品注册证》。

第四十三条 非药品不得在其包装、标签、说明书及有关宣传资料上进行含有预防、治疗、诊断人体疾病等有关内容的宣传；但是，法律、行政法规另有规定的除外。

第六章　药品包装的管理

第四十四条 药品生产企业使用的直接接触药品的包装材料和容器，必须符合药用要求和保障人体健康、安全的标准，并经国务院药品监督管理部门批准注册。

直接接触药品的包装材料和容器的管理办法、产品目录和药用要求与标准，由国务院药品监督管理部门组织制定并公布。

第四十五条 生产中药饮片，应当选用与药品性质相适应的包装材料和容器；包装不符合规定的中药饮片，不得销售。中药饮片包装必须印有或者贴有标签。

中药饮片的标签必须注明品名、规格、产地、生产企业、产品批号、生产日期，实施批准文号管理的中药饮片还必须注明药品批准文号。

第四十六条 药品包装、标签、说明书必须依照《药品管理法》第五十四条和国务院药品监督管理部门的规定印制。

药品商品名称应当符合国务院药品监督管理部门的规定。

第四十七条 医疗机构配制制剂所使用的直接接触药品的包装材料和容器、制剂的标签和说明书应当符合《药品管理法》第六章和本条例的有关规定，并经省、自治区、直辖市人民政府药品监督管理部门批准。

第七章　药品价格和广告的管理

第四十八条 国家对药品价格实行政府定价、政府指导价或者市场调节价。

列入国家基本医疗保险药品目录的药品以及国家基本医疗保险药品目录以外具有垄断性生产、经营的药品，实行政府定价或者政府指导价；对其他药品，实行市场调节价。

第四十九条 依法实行政府定价、政府指导价的药品，由政府价格主管部门依照《药品管理法》第五十五条规定的原则，制定和调整价格；其中，制定和调整药品销售价格时，应当体现对药品社会平均销售费用率、销售利润率和流通差率的控制。具体定价办法由国务院价格主管部门依照《中华人民共和国价格法》（以下简称《价格法》）的有关规定制定。

第五十条 依法实行政府定价和政府指导价的药品价格制定后，由政府价格主管部门依照《价格法》第二十四条的规定，在指定的刊物上公布并明确该价格施行的日期。

第五十一条 实行政府定价和政府指导价的药品价格，政府价格主管部门制定和调整药品价格时，应当组织药学、医学、经济学等方面专家进行评审和论证；必要时，应当听取药品生产企业、药品经营企业、医疗机构、公民以及其他有关单位及人员的意见。

第五十二条 政府价格主管部门依照《价格法》第二十八条的规定实行药品价格监测时，为掌握、分析药品价格变动和趋势，可以指定部分药品生产企业、药品经营企业和医疗机构作为价格监测定点单位；定点单位应当给予配合、支持，如实提供有关信息资料。

第五十三条 发布药品广告，应当向药品生产企业所在地省、自治区、直辖市人民政府药品监督管理部门报送有关材料。省、自治区、直辖市人民政府药品监督管理部门应当自收到有关材料之日起10个工作日内作出是否核发药品广告批准文号的决定；核发药品广告批准文号的，应当同时报国务院药品监督管理部门备案。具体办法由国务院药品监督管理部门制定。

发布进口药品广告，应当依照前款规定向进口药品代理机构所在地省、自治区、直辖市人民政府药品监督管理部门申请药品广告批准文号。

在药品生产企业所在地和进口药品代理机构所在地以外的省、自治区、直辖市发布药品广告的，发布广告的企业应当在发布前向发布地省、自治区、直辖市人民政府药品监督管理部门备案。接受备案的省、自治区、直辖市人民政府药品监督管理部门发现药品广告批准内容不符合药品广告管理规定的，应当交由原核发部门处理。

第五十四条 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决定，责令暂停生产、销售和使用的药品，在暂停期间不得发布该品种药品广告；已经发布广告的，必须立即停止。

第五十五条 未经省、自治区、直辖市人民政府药品监督管理部门批准的药品广告，使用伪造、冒用、失效的药品广告批准文号的广告，或者因其他广告违法活动被撤销药品广告批准文号的广告，发布广告的企业、广告经营者、广告发布者必须立即停止该药品广告的发布。

对违法发布药品广告，情节严重的，省、自治区、直辖市人民政府药品监督管理部门可以予以公告。

第八章　药品监督

第五十六条 药品监督管理部门（含省级人民政府药品监督管理部门依法设立的药品监督管理机构，下同）依法对药品的研制、生产、经营、使用实施监督检查。

第五十七条 药品抽样必须由两名以上药品监督检查人员实施，并按照国务院药品监督管理部门的规定进行抽样；被抽检方应当提供抽检样品，不得拒绝。

药品被抽检单位没有正当理由，拒绝抽查检验的，国务院药品监督管理部门和被抽检单位所在地省、自治区、直辖市人民政府药品监督管理部门可以宣布停止该单位拒绝抽检的药品上市销售和使用。

第五十八条 对有掺杂、掺假嫌疑的药品，在国家药品标准规定的检验方法和检验项目不能检验时，药品检验机构可以补充检验方法和检验项目进行药品检验；经国务院药品监督管理部门批准后，使用补充检验方法和检验项目所得出的检验结果，可以作为药品监督管理部门认定药品质量的依据。

第五十九条 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根据药品质量抽查检验结果，定期发布药品质量公告。药品质量公告应当包括抽验

药品的品名、检品来源、生产企业、生产批号、药品规格、检验机构、检验依据、检验结果、不合格项目等内容。药品质量公告不当的，发布部门应当自确认公告不当之日起5日内，在原公告范围内予以更正。

当事人对药品检验机构的检验结果有异议，申请复验的，应当向负责复验的药品检验机构提交书面申请、原药品检验报告书。复验的样品从原药品检验机构留样中抽取。

第六十条 药品监督管理部门依法对有证据证明可能危害人体健康的药品及其有关证据材料采取查封、扣押的行政强制措施的，应当自采取行政强制措施之日起7日内作出是否立案的决定；需要检验的，应当自检验报告书发出之日起15日内作出是否立案的决定；不符合立案条件的，应当解除行政强制措施；需要暂停销售和使用的，应当由国务院或者省、自治区、直辖市人民政府的药品监督管理部门作出决定。

第六十一条 药品抽查检验，不得收取任何费用。

当事人对药品检验结果有异议，申请复验的，应当按照国务院有关部门或者省、自治区、直辖市人民政府有关部门的规定，向复验机构预先支付药品检验费用。复验结论与原检验结论不一致的，复验检验费用由原药品检验机构承担。

第六十二条 依据《药品管理法》和本条例的规定核发证书、进行药品注册、药品认证和实施药品审批检验及其强制性检验，可以收取费用。具体收费标准由国务院财政部门、国务院价格主管部门制定。

第九章　法律责任

第六十三条 药品生产企业、药品经营企业有下列情形之一的，由药品监督管理部门依照《药品管理法》第七十九条的规定给予处罚：

（一）开办药品生产企业、药品生产企业新建药品生产车间、新增生产剂型，在国务院药品监督管理部门规定的时间内未通过《药品生产质量管理规范》认证，仍进行药品生产的；

（二）开办药品经营企业，在国务院药品监督管理部门规定的时间内未通过《药品经营质量管理规范》认证，仍进行药品经营的。

第六十四条 违反《药品管理法》第十三条的规定，擅自委托或者接受委托生产药品的，对委托方和受托方均依照《药品管理法》第七十四条的规定给予处罚。

第六十五条 未经批准，擅自在城乡集市贸易市场设点销售药品或者在城乡集市贸易市场设点销售的药品超出批准经营的药品范围的，依照《药品管理法》第七十三条的规定给予处罚。

第六十六条 未经批准，医疗机构擅自使用其他医疗机构配制的制剂的，依照《药品管理法》第八十条的规定给予处罚。

第六十七条 个人设置的门诊部、诊所等医疗机构向患者提供的药品超出规定的范围和品种的，依照《药品管理法》第七十三条的规定给予处罚。

第六十八条 医疗机构使用假药、劣药的，依照《药品管理法》第七十四条、第七十五条的规定给予处罚。

第六十九条 违反《药品管理法》第二十九条的规定，擅自进行临床试验的，对承担药物临床试验的机构，依照《药品管理法》第七十九条的规定给予处罚。

第七十条 药品申报者在申报临床试验时，报送虚假研制方法、质量标准、药理及毒理试验结果等有关资料和样品的，国务院药品监督管理部门对该申报药品的临床试验不予批准，对药品申报者给予警告；情节严重的，3 年内不受理该药品申报者申报该品种的临床试验申请。

第七十一条 生产没有国家药品标准的中药饮片，不符合省、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的；医疗机构不按照省、自治区、直辖市人民政府药品监督管理部门批准的标准配制制剂的，依照《药品管理法》第七十五条的规定给予处罚。

第七十二条 药品监督管理部门及其工作人员违反规定，泄露生产者、销售者为获得生产、销售含有新型化学成份药品许可而提交的未披露试验数据或者其他数据，造成申请人损失的，由药品监督管理部门依法承担赔偿责任；药品监督管理部门赔偿损失后，应当责令故意或者有重大过失的工作人员承担部分或者全部赔偿费用，并对直接责任人员依法给予行政处分。

第七十三条 药品生产企业、药品经营企业生产、经营的药品及医疗机构配制的制剂，其包装、标签、说明书违反《药品管理法》及本条例规定的，依照《药品管理法》第八十六条的规定给予处罚。

第七十四条 药品生产企业、药品经营企业和医疗机构变更药品生产经营许可事项，应当办理变更登记手续而未办理的，由原发证部门给予警告，责令限期补办变更登记手续；逾期不补办的，宣布其《药品生产许可证》、《药品经营许可证》和《医疗机构制剂许可证》无效；仍从事药品生产经营活动的，依照《药品管理法》第七十三条的规定给予处罚。

第七十五条 违反本条例第四十八条、第四十九条、第五十条、第五十一条、第五十二条关于药品价格管理的规定的，依照《价格法》的有关规定给予处罚。

第七十六条 篡改经批准的药品广告内容的，由药品监督管理部门责令广告主立即停止该药品广告的发布，并由原审批的药品监督管理部门依照《药品管理法》第九十二条的规定给予处罚。

药品监督管理部门撤销药品广告批准文号后，应当自作出行政处理决定之日起5个工作日内通知广告监督管理机关。广告监督管理机关应当自收到药品监督管理部门通知之日起15个工作日内，依照《中华人民共和国广告法》的有关规定作出行政处理决定。

第七十七条 发布药品广告的企业在药品生产企业所在地或者进口药品代理机构所在地以外的省、自治区、直辖市发布药品广告，未按照规定向发布地省、自治区、直辖市人民政府药品监督管理部门备案的，由发布地的药品监督管理部门责令限期改正；逾期不改正的，停止该药品品种在发布地的广告发布活动。

第七十八条 未经省、自治区、直辖市人民政府药品监督管理部门批准，擅自发布药品广告的，药品监督管理部门发现后，应当通知广告监督管理部门依法查处。

第七十九条 违反《药品管理法》和本条例的规定，有下列行为之一的，由药品监督管理部门在《药品管理法》和本条例规定的处罚幅度内从重处罚：

（一）以麻醉药品、精神药品、医疗用毒性药品、放射性药品冒充其他药品，或者以其他药品冒充上述药品的；

（二）生产、销售以孕产妇、婴幼儿及儿童为主要使用对象的假药、劣药的；

（三）生产、销售的生物制品、血液制品属于假药、劣药的；

（四）生产、销售、使用假药、劣药，造成人员伤害后果的；

（五）生产、销售、使用假药、劣药，经处理后重犯的；

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

第八十条 药品监督管理部门设置的派出机构，有权作出《药品管理法》和本条例规定的警告、罚款、没收违法生产、销售的药品和违法所得的行政处罚。

第八十一条 药品经营企业、医疗机构未违反《药品管理法》和本条例的有关规定，并有充分证据证明其不知道所销售或者使用的药品是假药、劣药的，应当没收其销售或者使用的假药、劣药和违法所得；但是，可以免除其他行政处罚。

第八十二条 依照《药品管理法》和本条例的规定没收的物品，由药品监督管理部门按照规定监督处理。

第十章　附 则

第八十三条 本条例下列用语的含义：

药品合格证明和其他标识，是指药品生产批准证明文件、药品检验报告书、药品的包装、标签和说明书。

新药，是指未曾在中国境内上市销售的药品。

处方药，是指凭执业医师和执业助理医师处方方可购买、调配和使用的药品。

非处方药，是指由国务院药品监督管理部门公布的，不需要凭执业医师和执业助理医师处方，消费者可以自行判断、购买和使用的药品。

医疗机构制剂，是指医疗机构根据本单位临床需要经批准而配制、自用的固定处方制剂。

药品认证，是指药品监督管理部门对药品研制、生产、经营、使用单位实施相应质量管理规范进行检查、评价并决定是否发给相应认证证书的过程。

药品经营方式，是指药品批发和药品零售。

药品经营范围，是指经药品监督管理部门核准经营药品的品种类别。

药品批发企业，是指将购进的药品销售给药品生产企业、药品经营企业、医疗机构的药品经营企业。

药品零售企业，是指将购进的药品直接销售给消费者的药品经营企业。

第八十四条 《药品管理法》第四十一条中“首次在中国销售的药品”，是指国内或者国外药品生产企业第一次在中国销售的药品，包括不同药品生产企业生产的相同品种。

第八十五条 《药品管理法》第五十九条第二款“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”中的“财物或者其他利益”，是指药品的生产企业、经营企业或者其代理人向医疗机构的负责人、药品采购人员、医师等有关人员提供的目的在于影响其药品采购或者药品处方行为的不正当利益。

第八十六条 本条例自 2002 年 9 月 15 日起施行。

Regulations for Implementation of the Drug Administration Law of the People's Republic of China

Chapter I
General Provisions

Article 1 The Regulations are formulated in accordance with the Drug Administration Law of the People's Republic of China (hereinafter referred to as the Drug Administration law).

Article 2 The drug regulatory department under the State Council shall establish a national drug testing institute.

The drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government may establish drug testing institutes within its respective administrative area. The plan for the establishment of local drug testing institutes shall be proposed by the drug regulatory department of the people's government of the province, autonomous region and municipality directly under the Central Government and submitted to the people's government of the province, autonomous region and municipality directly under the Central Government for approval.

The drug regulatory department under the State Council and the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government may, when necessary, designate any testing institute fulfilling the requirements for drug testing to undertake drug testing.

Chapter II
Control over Drug Manufacturers

Article 3 A Drug Manufacturing Certificate shall be acquired for establishment of a drug manufacturer according to the following procedures:

(1) The applicant shall submit an application to the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government, where the manufacturing site is to be located. The drug regulatory department of the people's government

of the province, autonomous region or municipality directly under the Central Government shall, within 30 working days from the date it receives the application, make a review according to the pharmaceutical industry development programs and policies issued by the State and make a decision on approval or disapproval.

(2) After completion of establishment of the planned manufacturer, the applicant shall apply to the original approving department for acceptance inspection. The original approving department shall, within 30 working days from the date it receives the application, arrange an acceptance inspection according to the requirements for the establishment of such manufacturers set forth in Article 8 of the Drug Administration Law; a Drug Manufacturing Certificate shall be issued to the applicant if the inspection is passed. The applicant shall, by holding the Drug Manufacturing Certificate, register with the administrative department for industry and commerce in accordance with law.

Article 4 Any drug manufacturer that intends to alter the approved items in the Drug Manufacturing Certificate shall, 30 days prior to alteration of any approved items, apply to the original certificate-issuing authority for registration of alteration; no approved items may be altered without approval. The original certificate-issuing authority shall make a decision within 15 working days from the date it receives the application. The application shall, by holding the Drug Manufacturing Certificate with altered items, register the alteration with the administrative department for industry and commerce in accordance with law.

Article 5 The drug regulatory department of the people's government at or above the provincial level shall organize inspections of drug manufacturers in accordance with the Good Manufacturing Practice for Pharmaceutical Products (GMP) and the measures and schedule for implementing the GMP formulated by the drug regulatory department under the State Council, and issue a certificate to the manufacturer that complies with the GMP. For the manufacturer producing injections or radioactive pharmaceuticals and for that producing biological products specified by the drug regulatory department under the State Council, the inspection of which shall be conducted by the drug regulatory department under the State Council. The format of GMP certificate shall be uniformly provided for by the drug regulatory department under the State Council.

Article 6 Any newly-established drug manufacturer or manufacturer with newly –built drug manufacturing workshops or newly-added dosage forms for production shall, within 30 days from the

date it obtains the approval documents for manufacturing drug or from the date its formal production is approved, apply to the drug regulatory department for GMP certification as required. The drug regulatory department accepting the application shall, within six months from the date it receives the application, organize inspections as to the compliance with the GMP requirements by the applying manufacturer. A certificate shall be issued to the manufacturer if the inspection is passed.

Article 7 The drug regulatory department under the State Council shall set up a database of GMP inspectors. A GMP inspector shall be qualified as required by the drug regulatory department under the State Council. A GMP inspection shall be conducted by a team of inspectors randomly selected from the database of GMP inspectors according to the provisions of the drug regulatory department under the State Council.

Article 8 The valid term of a Drug Manufacturing Certificate is five years. To continue its drug production, the Certificate holder shall, six months prior to the expiry date of the Certificate, apply for the renewal of the Drug Manufacturing Certificate according to the provisions of the drug regulatory department under the State Council.

Where a drug manufacturer terminates its drug production or is closed down, its Drug Manufacturing Certificate shall be withdrawn by the original certificate-issuing authority.

Article 9 Any drug substance used by a drug manufacturer to produce drug products shall have a drug approval number or an import drug license or a pharmaceutical product license issued by the drug regulatory department under the State Council upon examination, with the exception of Chinese crude drugs and the prepared slices of Chinese crude drugs over which no control by approval number is exercised.

Article 10 In accordance with the provisions in Article 13 of the Drug Administration Law, any drug manufacturer being entrusted with contract production of the drug shall have a GMP certificate corresponding to the contracted drug.

No vaccines, blood products or other drugs specified by the drug regulatory department under the State Council may be contracted for production.

Chapter III

Control over Drug Distributors

Article 11 For establishment of a drug wholesaler, the applicant shall submit an application to the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government, where the planned drug wholesaler is to be located. The drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government shall, within 30 working days from the date it receives the application, make a decision on approval or disapproval according to the standards for establishment set forth by the drug regulatory department under the State Council. After completion of establishment of the planned wholesaler, the applicant shall apply to the original approving department for acceptance inspection. The original approving department shall, within 30 working days from the date it receives the application, organize an acceptance inspection according to the requirements for establishment of drug distributors set forth in Article 15 or the Drug Administration Law and issue the Drug Supply Certificate to the applicant if the inspection is passed. The applicant shall, with the Certificate, register with the administrative department for industry and commerce in accordance with law.

Article 12 For establishment of a drug retailer, the applicant shall submit an application to the drug regulatory institution of the municipality divided into districts, or to the drug regulatory institution at the county level which is directly set up by the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government, where the planned retailer is to be located. The drug regulatory institution accepting the application shall, within 30 working days from the date it receives the application, make a decision on approval or disapproval after the review according to the provisions of the drug regulatory department under the State Council, taking into consideration the number of permanent residents, territory, transportation and practical needs in the place. After completion of establishment of the planned retailer, the applicant shall apply to the original approving department for acceptance inspections. The original approving department shall, within 15 working days from the date it receives the application, organize acceptance inspections according to the requirements for establishment of drug distributors set forth in Article 15 of the Drug Administration Law and issue a Drug Supply Certificate if inspections are passed. The applicant shall, with the Certificate, register with the administrative department for industry and commerce in accordance with law.

Article 13 The drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government shall be responsible for the certification of drug distributors. A drug distributor shall, according to the implementing measures and schedule formulated by the drug regulatory department under the State Council, undergo the Good Supply Practice for Pharmaceutical Products (GSP) inspections organized by the local drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government and obtain a GSP certificate. The format of GSP certificate shall be uniformly provided for by the drug regulatory department under the State Council.

Any newly-established drug wholesaler or retailer shall, within 30 days from the date it obtains the Drug Supply Certificate, apply for the GSP certification to the drug regulatory department or institution which has issued it the Drug Supply Certificate. The drug regulatory institution accepting the drug retailer's application for certification shall, within seven working days from the date it receives the application, transfer the application to the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government, which is responsible for organizing inspections of drug distributors. The drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central government shall, within three months from the date it receives the application, organize inspections of the drug wholesaler or retailer as to its compliance with the GSP according to the provisions of the drug regulatory department under the State Council and issue a GSP certificate to the drug wholesaler or retailer passing the inspections.

Article 14 A database of GSP inspectors shall be set up by the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government. A GSP inspector shall be qualified as required by the drug regulatory department under the State Council. A GSP inspection shall be conducted by a team of inspectors randomly selected from the said database according to the provisions of the drug regulatory department under the State Council.

Article 15 The State adopts a classification system for prescription drugs and non-prescription drugs. The State subdivides non-prescription drugs into Class A drugs and Class B drugs according to the level of safety.

Any drug retailer distributing prescription drugs or Class A non-prescription drugs shall have licensed pharmacists or other pharmaceutical technicians whose qualifications are legally recognized. Any retailer

distributing Class B non-prescription drugs shall have pharmacy staff members who have passed the examination organized by the local drug regulatory institution of the municipality divided into districts or by the local drug regulatory institution at the county level which is directly set up by the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government.

Article 16 Any drug distributor that intends to alter the approved items in the Drug Supply Certificate shall, 30 days prior to the alteration of any approved items, apply to the original certificate-issuing authority for registration of alteration; no approved items may be altered without approval. The original certificate-issuing authority shall make a decision within 15 working days from the date it receives the application. The application shall, by holding the Drug Supply Certificate with the altered items, register the alteration with the administrative department for industry and commerce in accordance with law.

Article 17 The valid term of a Drug Supply Certificate is five years. To continue its drug distribution, the Certificate holder shall, six months prior to the expiry date of the Certificate, apply for the renewal of the Drug Supply Certificate according to the provisions of the drug regulatory department under the State Council.

Where a drug distributor terminates its drug distribution or is closed down, its Drug Supply Certificate shall be withdrawn by the original certificate-issuing authority.

Article 18 Where there is no drug retailers at town or country fairs in remote areas with poor communications, the local drug retailers may, after obtaining approval from the local drug regulatory institution of the county (municipality) and being registered with the administrative department for industry and commerce, set up stores at the fairs to sell non-prescription drugs within the approved scope for drug distribution.

Article 19 Drug manufacturers, drug distributors and medical institutions engaged in on-line drug transactions through Internet and the drugs so transacted shall be in conformity with the provisions in the Drug Administration Law and in the Regulations. The measures for administration of on-line drug distribution services shall be formulated by the drug regulatory department under the State Council jointly with the other relevant departments under the State Council.

Chapter IV

Control over Pharmaceuticals in Medical Institutions

Article 20 To establish a pharmaceutical preparation unit in a medical institution, an application shall be submitted to the local health administrative department of the people's government of the province, autonomous region or municipality directly under the Central Government, and, after being consented upon examination, be presented to the drug regulatory department of the people's government at the same level for review and approval. Approval shall be given to the medical institution if it passes the review by the said drug regulatory department and a Pharmaceutical Preparation Certificate for Medical Institution shall be issued to it.

The health administrative department and the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government shall, within 30 working days from the dates they receive the application respectively, make their own decisions whether or not to consent or approve the application accordingly.

Article 21 Any medical institution that intends to alter the approved items in the Pharmaceutical Preparation Certificate for Medical Institution shall, 30 days prior to the alteration of any approved items, apply to the original examining and approving departments for registration of alteration according to the provisions in Article 20 of the Regulations; no approved items may be altered without approval. The original examining and approving departments shall make their own decisions within 15 working days from the dates they receive the application respectively.

Any medical institution which intends to add new dosage forms or change dispensing sites shall, after passing the acceptance inspection by the local drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government, go through the registration of alteration of the Pharmaceutical Preparation Certificate for Medical Institution according to the provisions in the preceding paragraph.

Article 22 The valid term of a Pharmaceutical Preparation Certificate for Medical institution is five years. To continue dispensing a pharmaceutical preparation, the medical institution shall, six month prior to the expiry date of the Certificate, apply for the renewal of the Pharmaceutical Preparation Certificate for Medical Institution according to the provisions of the drug regulatory department under the State Council.

Where a medical institution terminates dispensing Pharmaceutical Preparations or is closed down, its Pharmaceutical Preparation Certificate for Medical Institution shall be withdrawn by the original certificate-issuing authority.

Article 23 To dispense a pharmaceutical preparation, the medical institution shall submit the dossier and samples according to the provisions of the drug regulatory department under the State Council, and the pharmaceutical preparation may only be dispensed after being approved by the local drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government and being issued a pharmaceutical preparation approval number.

Article 24 No pharmaceutical preparations dispensed by medical institutions may be marketed or marketed in disguised forms, nor may any advertisement of such pharmaceutical preparations be released.

When a major disaster, epidemic situation or any other emergency occurs, or there is an urgent need clinically but no supply of the needed drug in market, the pharmaceutical preparations dispensed by a medical institution may be subject to transfer allocation and use by other designated medical institutions within a specified time limit, 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.

Transfer allocation and use of special pharmaceutical preparations regulated by the drug regulatory department under the State Council, and the transfer allocation and use of pharmaceutical preparations dispensed by medical institutions among provinces, autonomous regions, or municipalities directly under the Central Government shall be subject to the approval by the drug regulatory department under the State Council.

Article 25 Pharmacy personnel of medical institutions who check and dispense prescriptions shall be the pharmaceutical technicians whose qualifications are legally recognized.

Article 26 When purchasing drugs, medical institutions shall keep the authentic and complete records. In purchase records shall be indicted the adopted name of the drug in China, dosage form, strength, batch number, date of expiry, manufacturer, supplier, purchase volume, purchase price, date of purchase and other items specified by the drug regulatory department under the State Council.

Article 27 Drugs provided to patients by medical institutions shall be within the scope of diagnoses and treatments and dispensed according to the prescriptions of licensed doctors or licensed assistant doctors.

The scope of drugs purchased and provided to patients by family planning technical service institutions shall be in conformity with the scope of services approved and the drugs shall be dispensed according to the prescriptions of licensed doctors or licensed assistant doctors.

Out-patient departments, clinics and any other medical institutions, which are set up by individuals, may not purchase or provide drugs other than those commonly used and those for emergency treatment. The range and category of the drugs commonly used and those for emergency treatment shall be determined by the local health administrative department of the people's government of the province, autonomous region, or municipality directly under the Central Government jointly with the drug regulatory department at the same level.

Chapter V
Control over Drugs

Article 28 Institutions for non-clinical safety evaluation and study of drugs shall implement the Good Laboratory Practice for Non-Clinical Laboratory Studies (GLP) and institutions for drug clinical trial shall implement the Good Clinical Practice (GCP). The GLP and GCP shall be formulated by the drug regulatory department under the State Council through respective consultation with the science and technology administrative department under the State Council and the health administrative department under the State Council.

Article 29 Clinical trials, manufacturing or importation of drugs shall be in conformity with the provisions in the Drug Administration Law and in the Regulations, and shall be reviewed and approved by the drug regulatory department under the State Council. The drug regulatory department under the State Council may authorize the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government to conduct site inspection of research and development conditions of the drugs being applied, to conduct preliminary review of the submitted dossier, and to test the pilot samples. The specific measures therefore shall be formulated by the drug regulatory department under the State Council.

Article 30 Any clinical trial to be conducted for research and development of a new drug shall be subject to the approval by the drug regulatory department under the State Council in accordance with the provisions in Article 29 of the Drug Administration Law.

When an application for conducting clinical trials is approved by the drug regulatory department under the State Council, the applicant shall select institutions for clinical trials from the lawfully certified ones to conduct the trials, and make a report thereof to the drug regulatory department and health administrative department under the State Council for the record.

Prior to the drug clinical trial, the institution for drug clinical trial shall provide the subjects or their guardians with the truthful information on the trial, and obtain a written informed consent

Article 31 For production of a drug admitted by national drug standards, an application shall, in accordance with the provisions of the drug regulatory department under the State Council, be submitted to the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government or to the drug regulatory department under the State Council, and the relevant technical data and supporting documents shall be provided. The drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government shall, within 30 working days from the date it receives the application, review and make comments, and report the matter to the drug regulatory department under the State Council for review while notifying the applicant of its comments. If all the requirements are fulfilled upon review, a drug approval number shall be issued by the drug regulatory department under the State Council.

Article 32 Where a drug is produced according to an interim standard, an application shall be submitted for formalization of the standard three months prior to the expiry date of the interim standard according to the provisions of the drug regulatory department under the State Council; the drug regulatory department under the State Council shall, within 12 months from the expiry date of the interim standard, review and approve the interim standard as formal one if it fulfills the requirements for the formalization set forth by the drug regulatory department under the State Council. Where an applicant does not make such an application or the original interim standard fails to fulfill the requirements for the formalization, the drug regulatory department under the State Council shall withdraw the interim standard and the approval number for drug production issued on the basis of the said interim standard.

Article 33 For alteration of any items indicated in the approval documents and their attachments for new drug research and development, production or importation of a drug, a supplementary application shall be submitted to the drug regulatory department under the State Council; if all the requirements are fulfilled upon review, an approval shall be given by the drug regulatory department under the State Council.

Article 34 The drug regulatory department under the State Council may, based on the needs for protection of public health, set an observation period of not more than five years for a new drug produced by a drug manufacturer; and no approval shall be given to any other manufacturer to produce or import the said drug during the observations period.

Article 35 The State protects undisclosed data of drug study and others which are independently acquired and submitted by drug manufacturers or sellers to obtain production or marketing approval of the drugs in question which contain new chemical entities. No one may make unfair commercial use of the said data.

Within six years from the date a drug manufacturer or seller obtains the approval documents for producing or marketing a drug containing new chemical entities, if any other applicant uses the data mentioned in the preceding paragraph to apply for approval for production or marketing of the drug in question without permission of the original applicant who has obtained the approval, no approval may be given to any other applicant by the drug regulatory department except that the data submitted are acquired independently.

No drug regulatory department may disclose the data set forth in the first paragraph of this Article except
(1) for the need of public interests; or
(2) where steps are taken to ensure that the data are protected against unfair commercial use.

Article 36 Any drug applied to be imported shall be the one obtained marketing authorization in the country or region of manufacturing. A drug without such an authorization may be approved of its importation in accordance with the provisions in the Drug Administration Law and in the Regulations, provided that its safety, efficacy and clinical needs have been confirmed by the drug regulatory department under the State Council.

For importation of a drug, an application for registration shall be made according to provisions of the drug regulatory department under the State Council. A drug may only be imported after an Import Drug

License is given if it is produced by a foreign manufacturer, or a Pharmaceutical Product License is given if it is produced by a manufacturer in Hong Kong, Macao or Taiwan of China.

Article 37 Any medical institution that urgently needs to import a small amount of drugs shall, with a Practicing License of Medical Institution, submit an application to the drug regulatory department under the State Council, and the drugs in question may only be imported upon approval. Such import drugs shall only be used in the designated medical institution for specified purpose.

Article 38 After import drugs arrive at the port, the drug importer shall file a record with the local drug regulatory department in the place where the port is located with the Import Drug License or Pharmaceutical Product License, the original copy of the certificate or origin, duplicate copy of the purchase contract, packing list, bill of freight, shipping invoice, certificate of analysis for the release of drugs by the manufacturer, inset sheet and other documents. The said drug regulatory department shall review the documents submitted and issued a Drug Import Note if they comply with the requirements. The drug importer shall, with the Drug Import Note, complete the formalities for customs declaration and clearance with the Customs.

The drug regulatory department in the place where the port is located shall notify the drug testing institution to conduct sampling and testing of the import drugs on each batch basis with the exception of the circumstances set forth in Article 41 of the Drug Administration Law.

Article 39 Vaccines, blood products, diagnostic reagents in vitro for blood donor screening and other biological products regulated by the drug regulatory department under the State Council shall be subject to testing or review for approval according to the provisions of the drug regulatory department under the State Council before being marketed or imported; any product that fails in testing or has not been approved shall not be marketed or imported.

Article 40 The State encourages cultivation of Chinese crude drugs. Control through approval number shall be exercised over the Chinese crude drugs that can be cultivated or raised on a large scale and in an intensified way and whose quality can be controlled and fulfills the requirements laid down by the drug regulatory department under the State Council.

Article 41 The drug regulatory department under the State Council shall re-evaluate the drugs approved for production and marketing and, on the basis of the re-evaluation results, may take measures to order

the revision of insert sheet or suspension of production, marketing or use of a drug, or withdraw the approval documents of drugs with serious adverse reaction or harmful to human health due to other reasons.

Article 42 The valid term of a drug approval number, Import Drug License and Pharmaceutical Product License issued by the drug regulatory department under the State Council is five years. To continue its drug production or importation, the applicant shall submit a re-registration application six months prior to the expiry date. When making re-registration of a drug, the applicant shall submit the relevant data according to the provisions of the drug regulatory department under the State Council. If no application for the re-registration of a drug is made upon expiration of the valid term, or the application fails to comply with the provisions on re-registration of the drug regulatory department under the State Council upon review, the drug approval number, Import Drug License or Pharmaceutical Product License shall be withdrawn.

Article 43 No contents involving prevention, treatment or diagnosis of human diseases shall be included in the package, label or insert sheet and the related promotional materials for promoting a non-drug product, except as otherwise provided by laws or administrative regulations.

Chapter VI
Control over Drug Packaging

Article 44 Immediate packaging materials and containers used by drug manufacturers shall fulfill the requirements for medicinal use and the standards for ensuring human health and safety, and be subject to registration upon approval by the drug regulatory department under the State Council.

The drug regulatory department under the State Council shall be responsible for working out and issuing the measures for control over immediate packaging materials and containers, the product directories and the requirements and standards for medicinal use.

Article 45 Packaging materials and containers selected for production of prepared slices of a Chinese crude drug shall accommodate to drug properties. No prepared slices of a Chinese crude drug may be marketed whose package fails to conform to regulations. A label shall be printed on or attached to the package of prepared slices of a Chinese crude drug.

On the label of prepared slices of a Chinese crude drug shall be indicated the name of the drug, specifications, origin or production, manufacturer, product batch number and production date; if the said drug is controlled by approval number, the drug approval number shall also be indicated.

Article 46 The package, label and insert sheet of a drug shall be printed in accordance with the provisions in Article 54 of the Drug Administration Law and those formulated by the drug regulatory department under the State Council.

The trade name of a drug shall conform to the provisions of the drug regulatory department under the State Council.

Article 47 The immediate packaging materials and containers, used by medical institutions for dispensing pharmaceutical preparations, as well as the labels and insert sheets thereof, shall conform to the provisions in Chapter VI of the Drug Administration Law and the relevant provisions in the Regulations, and 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.

Chapter VII
Control over Drug Pricing and Advertising

Article 48 For drug pricing, the State exercises a system under which the prices are fixed or guided by the government or regulated by the market.

For drugs listed in the directory of drugs for national basic medical insurance and drugs not listed in the directory but monopolistically manufactured and distributed, their prices shall be fixed or guided by the government; the prices of other drugs shall be regulated by the market.

Article 49 For a drug whose price is fixed or guided by the government according to law, the competent pricing department of the government shall fix and adjust its sale prices in accordance with the principle set forth in Article 55 of the Drug Administration Law; and, in fixing and adjusting its sale price, control over the average social rate of drug sales cost, drug sales profit margin, and the differential rate in drug circulation shall be manifested. The specific pricing measures shall be formulated by the competent

pricing department under the State Council in accordance with the relevant provisions in the Pricing Law of the People's Republic of China (hereinafter referred to as the Pricing Law).

Article 50 For a drug whose price shall be fixed or guided by the government and is so established, the competent pricing department shall publish the said price and specify the date for going into effect in designated publications in accordance with the provisions in article 24 of the Pricing Law.

Article 51 For a drug whose price is fixed or guided by the government, the competent pricing department shall, in fixing or adjusting the price, organize experts in pharmaceutical, medical, economic and other fields to conduct assessment; and, if necessary, it shall solicit comments from drug manufacturers, drug distributors, medical institutions, citizens and other relevant units and persons.

Article 52 The competent pricing department of the government may, in practicing drug price monitoring according to the provisions in Article 28 of the Pricing Law, appoint certain drug manufactures, drug distributors and medical institutions as drug price monitoring units for the purpose of understanding and analyzing the changes and trends of drug prices; the appointed units shall provide cooperation, support and truthful information.

Article 53 For publishing a drug advertisement, the relevant materials shall be submitted to the local drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government where the drug manufacturer is located. The drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government shall, within ten working days after it receives the relevant materials, make a decision upon review on whether to issue the approval number for drug advertisement. Where the approval number for drug advertisement is issued upon review, a record shall be filed with the drug regulatory department under the State Council concurrently. The specific measures for drug advertisement shall be formulated by the drug regulatory department under the State Council.

For publishing an advertisement for an import drug, an application for approval number for drug advertisement shall be submitted to the local drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government where the drug import agency is located, in accordance with the provisions in the preceding paragraph of this Article.

For publishing an advertisement in a province, autonomous region or municipality directly under the Central Government other than the place where the drug manufacturer or drug import agency is located, any enterprise publishing advertisement shall file a record in advance with the drug regulatory department of the province, autonomous region or municipality directly under the Central Government where the advertisement is to be published. If the drug regulatory department of the province, autonomous region or municipality directly under the Central Government accepting the record finds that the approved contents of the drug advertisement does not conform to the provisions on the control of drug advertisement, it shall turn over the matter to the original verifying and issuing department for handling.

Article 54 For a drug whose production, marketing or use is ordered to be suspended upon decision of the drug regulatory department under the State Council or of the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government, no advertisement for the drug may be published during the period of suspension; where such an advertisement is already published, the publication shall be discontinued immediately.

Article 55 Any enterprise publishing advertisement, advertising agent or advertisement publisher shall immediately discontinue the publication of any drug advertisement without approval by the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government, or whose approval number for drug advertisement is forged, or belongs to others, or is expired, or, whose approval number for drug advertisement is canceled because of other illegal advertising activities.

Where a drug advertisement is published in violation of law and the circumstances are serious, the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government may announce the matter to the public.

Chapter VIII
Inspection of Drugs

Article 56 The Drug regulatory department (including the drug regulatory institution legally established by the drug regulatory department of the people's government of the province, autonomous region or

municipality directly under the Central Government, the same below) shall supervise and inspect the research and development, production, distribution and use of drugs in accordance with law.

Article 57 Sampling of a drug shall be conducted by two or more persons who are responsible for drug supervision and inspection in accordance with the provisions of the drug regulatory department under the State Council.

The party whose drug is to be sampled shall provide samples of the drug for testing and may not refuse. Where the party whose drug is to be sampled refuses the sampling and testing of the drug without justifiable reasons, the drug regulatory department under the State Council and the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government where it is located may announce a stop to marketing and use of the drug, of which the sampling and testing are refused.

Article 58 Where a drug is suspected of being impure or adulterated but unable to be tested by testing method and through the testing items prescribed in the national drug standards, the drug testing institution may conduct tests by adding testing methods and items upon approval by the drug regulatory department under the State Council, the testing results obtained by using the additional testing methods and items may be taken as the basis for certifying the quality of the drugs.

Article 59 The drug regulatory department under the State Council and the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government shall regularly make announcements on drug quality according to the results of sampling and testing. In a drug quality announcement shall be included the names of sampled drugs, sources of the samples, their manufacturers, batch numbers, drug strength, testing institutions, drug specifications, results of testing, and items failing to pass the test, etc. If a drug quality announcement is improperly made, the department making the announcement shall, within five days from the date of recognition of the improper announcement, make a correction within the scope in which the original one is made.

Where the party has any objection to the results of testing conducted by the drug testing institution and applies for re-testing, it shall submit a written application and the original testing report to the drug testing institution responsible for re-testing. The sample for re-testing shall be taken form the retaining sample kept by the original testing institution.

Article 60 Where the drug regulatory department takes administrative enforcement measures to seal or seize drugs that have been proved potentially harmful to human health and the related evidentiary materials, it shall, within seven days from the date it takes such measures, make a decision on whether or not to file a case; where it is necessary to test such drugs, it shall, within 15 days from the date the testing report is issued, make a decision whether or not to file a case; where the conditions for filing a case are not met, the administrative enforcement measures shall be withdrawn; where the marketing and use of such drugs need to be suspended, a decision shall be made by the drug regulatory department under the State Council or the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government.

Article 61 No fees may be charged for selective drug sampling and testing.

Where the party has any objection to the results of testing conducted by the drug testing institution and applies for re-testing, it shall pay in advance the fees for drug testing to the drug testing institution responsible for the re-testing according to the provisions of the drug regulatory department under the State Council or of the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government. If the results of re-testing are inconsistent with the original testing results, the fees for the re-testing shall be paid by the original testing institution.

Article 62 Fees may be collected for certificate issuance, drug registration, drug certification, drug testing for approval and mandatory drug testing according to the provisions in the Drug Administration Law and in the Regulations. The specific standards for collecting fees shall be formulated by the finance department under the State Council and the competent pricing department under the State Council.

Chapter IV
Legal Liabilities

Article 63 A drug manufacturer or distributor shall be punished by the drug regulatory department according to the provisions in Article 79 of the Drug Administration Law under any of the following circumstances:

(1) where any newly-established drug manufacturer or any manufacturer with a newly-built workshop or with newly-added dosage forms fails in the GMP certification within the time limit prescribed by the drug regulatory department under the State Council but is still engaged in drug production.
(2) where any newly-established drug distributor fails in GSP certification within the time limit prescribed by the drug regulatory department under the State Council but is still engaged in drug distribution.

Article 64 Any contract giver or acceptor, in violation of the provisions in Article 13 of the Drug Administration Law, giving or accepting the contract for drug production without authorization shall be punished in accordance with the provisions in Article 74 of the Drug Administration Law.

Article 65 Where, without approval, anyone who sets up a store to sell drugs at the town or country fairs, or sells drugs in a store at the fairs beyond the approved scope of drug distribution, shall be punished according to the provisions in Article 73 of the Drug Administration Law.

Article 66 Any medical institution that uses pharmaceutical preparations dispensed by other medical institutions without approval shall be punished according to the provisions in Article 80 of the Drug Administration Law.

Article 67 Any out-patient department, clinic or any other medical institution, which is set up by individuals, if providing patients with drugs beyond the defined scope or kinds of drugs, shall be punished according to the provisions in Article 73 of the Drug Administration Law.

Article 68 Any medical institution that uses counterfeit and substandard drugs shall be punished according to the provisions in Article 74 and 75 of the Drug Administration Law.

Article 69 Any institution, in violation of the provisions in Article 29 of the Drug Administration Law, conducting a drug clinical trial without approval shall be punished according to the provisions in Article 79 of the Drug Administration Law.

Article 70 Where an applicant, in applying for conducting a drug clinical trail, submits false data on drug production procedures, quality specifications, or results of pharmacological and toxicological studies, etc., or submits fraud samples, the drug regulatory department under the State Council shall disapprove the application and give a warning to the applicant; where the circumstances are serious, no application for clinical trial of the said drug submitted by the said applicant may be accepted within three years.

Article 71 Where anyone producing prepared slices of Chinese crude drugs without the national drug standard fails to comply with the processing procedures formulated by the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government, or any medical institution dispensing pharmaceutical preparations fails to comply with the standards approved by the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government, punishment shall be imposed thereupon according to the provisions in Article 75 of the Drug Administration Law.

Article 72 Where the drug regulatory department and its staff members, in violation of regulations, release undisclosed experimental data or other materials submitted by a manufacturer or seller for obtaining approval of production or marketing of a drug containing new chemical entities, thus resulting in losses to the applicant, the drug regulatory department shall be liable for compensation in accordance with law. After compensating the losses, the drug regulatory department shall order the staff members who disclose the said data in purpose or have serious negligence to partially or fully bear the compensation and shall also impose administrative sanctions on those who are directly liable therefor.

Article 73 Any drug manufacturer or distributor producing or distributing drugs or any medical institution dispensing pharmaceutical preparations, whose package, labels or inset sheets are in violation of the provisions in the Drug Administration Law and in the Regulations, shall be punished according to the provisions in Article 86 of the Drug Administration Law.

Article 74 Any drug manufacturer, distributor or medical institution altering any items licensed for manufacturing, distributing, or dispensing drugs without completing the formalities for registration of alteration as required shall be given a warning by the original certificate-issuing department and be ordered to complete the said formalities within a time limit. Its Drug Manufacturing Certificate, Drug Distribution Certificate or Pharmaceutical Preparation Certificate for Medical Institution shall be announced as nullified if it fails to do so within the time limit, and punishment shall be given according to the provisions in Article 73 of the Drug Administration Law if it continues its production and distribution activities.

Article 75 Anyone violating the provisions in Article 48, 49, 50, 51 or 52 of the Regulations concerning the control over drug pricing shall be punished according to the relevant provisions in the Pricing Law.

Article 76 Where the approved content of a drug advertisement is altered without authorization, the advertiser shall be ordered by the drug regulatory department to discontinue publishing the said advertisement without delay, and punishment shall be given by the original approving drug regulatory department according to the provisions in Article 92 of the Drug Administration Law.

After the drug regulatory department withdraws the drug advertisement approval number, it shall notify the organ in charge of advertising supervision and control of the matter within five working days from the date the administrative decision is made. The organ in charge of advertising supervision and control shall, within 15 working days from the date it receives the notification from the drug regulatory department, make an administrative decision for handling the matting according to the relevant provisions in the Advertisement Law of the People's Republic of China.

Article 77 Where any enterprise published a drug advertisement outside the province, autonomous region or municipality directly under the Central Government where the drug manufacturer or drug import agency is located without filing a record with the drug regulatory department of the province, autonomous region or municipality directly under the Central Government where the drug advertisement is published, the drug regulatory department of the province, autonomous region or municipality directly under the Central Government shall order the enterprise to make a rectification within the time limit. If the enterprise fails to make any rectification within the time limit, advertising activities carried out in the place for the said drug shall be discontinued.

Article 78 Where the drug regulatory department finds that a drug advertisement is published without approval by the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government, the drug regulatory department shall notify the organ in charge of advertising supervision and control to investigate and handle the matter in accordance with law.

Article 79 Where anyone that, in violation of the provisions in the Drug Administration Law and in the Regulations, commits any of the following acts shall be given heavier punishment by the drug regulatory department based on the extent of punishment in the Drug Administration Law and in the Regulations:

(1) passing narcotics, psychotropic substances, medicinal toxic drugs and radioactive pharmaceuticals off as other drugs or vice versa;

(2) producing or selling counterfeit or substandard drugs of which the main users are pregnant and parturient women, infants and children;
(3) producing or selling biological and blood products which are defined as counterfeit or substandard drugs;
(4) producing, selling or using counterfeit or substandard drugs, thus inducing harmful results to people;
(5) producing, selling or using counterfeit or substandard drugs again after being punished; or
(6) refusing or evading supervision and inspection, or forging, destroying or concealing relevant evidentiary materials, or using sealed and seized articles without authorization.

Article 80 Branches of drug regulatory departments shall have the authority to, according to the provisions in the Drug Administration Law and in the Regulations, give administrative punishments such as warning, fine and confiscation of drugs illegally produced or marketed and illegal gains therefrom.

Article 81 Where a drug distributor or medical institution dose not violate the relevant provisions in the Drug Administration Law and in the Regulations and has sufficient evidence to prove its unawareness that the drugs being sold or used are counterfeit or substandard drugs, the said drugs and illegal gains therefrom shall be confiscated; however, it may be exempted from other administrative punishments.

Article 82 Articles confiscated according to the provisions in the Drug Administration Law and in the Regulations shall be dealt with under supervision by drug regulatory departments in accordance with provisions.

Chapter X
Supplementary Provisions

Article 83 The terms used in the Regulations are defined as follows:

Drug quality attachment and other marks refer to approval documents for drug production, drug testing reports, drug packages, labels and insert sheets.

New drugs refer to the drugs which have not been marketed within the territory of the People’s Republic of China.

Prescription drugs refer to the drugs that may only be purchased, dispensed or used with prescriptions by licensed doctors or licensed assistant doctors.

Non-prescription drugs refer to the drugs announced by the drug regulatory department under the State Council which can be purchased or used by consumers upon their own judgment without prescriptions by licensed doctors or licensed assistance doctors.

Pharmaceutical preparations in medical institutions refer to pharmaceutical preparations based on fixed prescriptions which have been dispensed upon approval by medical institutions according to their own clinical needs for their own use.

Drug certification refers to the process through which the drug regulatory department inspects and evaluates the units engaging in research and development, production, distribution or use of drugs as to their compliance with corresponding requirements, and decides on whether to issue the corresponding certificates.

Drug distribution refers to drug wholesale and/or retail.

Scope for drug distribution refers to the category of drugs reviewed and approved for distribution by the drug regulatory department.

Drug wholesalers refer to the drug distributors who sell the purchased drugs to drug manufacturers, drug distributors or medical institutions.

Drug retailers refer to the drug distributors who sell the purchased drugs to consumers directly.

Article 84 The term “drugs to be marketed in China for the first time” used in Article 41 of the Drug Administration Law refers to the drugs that are marketed for the firs time in China by domestic or foreign drug manufacturers, including the same product manufactured by different drug manufacturers.

Article 85 In the second paragraph of Article 59 of the Drug Administration Law, “drug manufacturers, drug distributors or their agents are prohibited from offering, under any pretence, 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”, the term “money or things of value or other benefits”

refer to the illegitimate benefits provided by drug manufacturers, drug distributors or their agents to leading members, drug purchasers , physicians, or other related persons of the medical institutions for the purpose of influencing their acts in purchasing or prescribing drugs.

Article 86 The Regulations shall go into effect as of September 15, 2002.