NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

Special Regulations on Registration and Management of Traditional Chinese Medicines

Chapter 1 General Provisions

Article 1 In order to promote the inheritance, innovation, and development of traditional Chinese medicine, follow the patterns of TCM research, and strengthen the development and registration management of new TCMs, the regulations are hereby formulated in accordance with "the Drug Administration Law of the People's Republic of China," "the Law of the People's Republic of China on Traditional Chinese Medicine," "Implementation Regulations of the Drug Administration Law of the People's Republic of China," "Measures for the Drug Registration Management," and other laws, regulations, and rules.

Article 2 The research and development of new TCMs should focus on reflecting the original thinking and holistic view of TCM, and it should be encouraged to research and develop TCMs by using TCM theory-oriented research methods and modern science and technology. It is supported to develop the new TCMs with rich clinical practice experience in TCM based on ancient classic formulas, empirical formulas prescribed by prestigious veteran TCM practitioners, and TCM preparations prepared by medical institutions (hereinafter referred to as medical institution TCM preparations); it is supported to develop the new TCMs with systemic regulatory intervention functions on the human body, etc., and it is encouraged to study and explain the mechanism of TCMs' actions by applying emerging science and technology.

Article 3 The development of new TCMs should adhere to being oriented by clinical value, pay attention to clinical benefit and risk assessment, give full play to the unique advantages and functions of TCMs in disease prevention and treatment, and focus on meeting unmet clinical needs.

Article 4 The development of new TCMs should be in line with the theory of TCM. Under the guidance of TCM theory, formulas should be reasonably formulated, and functions, main syndromes to be treated, applicable population, dosage, duration of treatment, efficacy characteristics, and contraindications should be drawn up. It is encouraged to observe patterns of disease progression, syndrome transformation, symptom changes, drug reactions, etc. in TCM clinical practice to provide supportive evidence under TCM theory for the development of new TCMs.

Article 5 The new TCMs derived from TCM clinical practice should be developed on the basis of summarizing individual medication experience; they should gradually clarify the main functions, applicable population, dosage regimens, and clinical benefits and formulate a fixed formula through clinical practice to develop a new TCM suitable for group medication. It is encouraged to carry out research

中药注册管理专门规定

第一章 总 则

第一条 为促进中医药传承创新发展，遵循中医药研究规律，加强中药新药研制与注册管理，根据《中华人民共和国药品管理法》《中华人民共和国中医药法》《中华人民共和国药品管理法实施条例》《药品注册管理办法》等法律、法规和规章，制定本规定。

第二条 中药新药研制应当注重体现中医药原创思维及整体观，鼓励运用传统中药研究方法和现代科学技术研究、开发中药。支持研制基于古代经典名方、名老中医经验方、医疗机构配制的中药制剂（以下简称医疗机构中药制剂）等具有丰富中医临床实践经验的中药新药；支持研制对人体具有系统性调节干预功能等的中药新药，鼓励应用新兴科学和技术研究阐释中药的作用机理。

第三条 中药新药研制应当坚持以临床价值为导向，重视临床获益与风险评估，发挥中医药防病治病的独特优势和作用，注重满足尚未满足的临床需求。

第四条 中药新药研制应当符合中医药理论，在中医药理论指导下合理组方，拟定功能、主治病证、适用人群、剂量、疗程、疗效特点和服药宜忌。鼓励在中医临床实践中观察疾病进展、证候转化、症状变化、药后反应等规律，为中药新药研制提供中医药理论的支持证据。

第五条 来源于中医临床实践的中药新药，应当在总结个体用药经验的基础上，经临床实践逐步明确功能主治、适用人群、给药方案和临床获益，形成固定处方，在此基础上研制成适合群体用药的中药新药。鼓励在中医临床实践过程中开展高质

with high quality based on application experience in human in TCM clinical practice, clarify the clinical positioning and clinical value of TCMs, and continuously analyze and summarize based on scientific methods to obtain sufficient evidence to support registration.

Article 6 The registration review of TCMs should adopt an evidence system for review that combines TCM theory, application experience in human, and clinical trials to comprehensively evaluate the safety, effectiveness, and quality controllability of TCMs.

Article 7 The evaluation of the efficacy of TCMs should be based on the clinical treatment characteristics of TCMs, and the indicators in terms of the efficacy outcome should be determined to be compatible with the clinical positioning of TCMs and reflect their functional characteristics and advantages. The efficacy of TCMs can be evaluated by using indicators including the recovery from disease or delayed progress of disease, the improvement of the condition or symptoms, the improvement of the patient's disease-related body functions or quality of life, increasing efficacy and reducing toxicity of TCMs through use in combination with chemical pharmaceuticals, or reducing the dosage of chemical pharmaceuticals with obvious side effects.

It is encouraged to evaluate the efficacy of TCMs by using real-world research, new biomarkers, surrogate endpoint decision-making, patient-centered drug development, adaptive design, enrichment design, etc.

Article 8 The safety and benefit-risk ratio of TCMs should be comprehensively evaluated, and the full life cycle management of TCMs should be strengthened based on the composition and characteristics of formulas, TCM theory, application experience in human, clinical trials, and results from necessary research on non-clinical safety.

Article 9 The registration applicant (hereinafter referred to as the applicant) who develops TCMs should strengthen the quality control on the source of raw TCM material and prepared TCM pieces, conduct an assessment on the available resources of raw materials, ensure the source traceability of raw materials, and clarify their origins, provenances, collecting periods, etc. It should strengthen quality control throughout the entire production process to maintain stable and controllable quality between batches. TCM ingredients in a formula can be fed after their respective quality uniformities are fulfilled.

Article 10 Applicants should ensure the sustainable availability of resources for raw TCM materials and pay attention to the impact on the ecological environment. Those involving endangered wild animals and plants must comply with relevant national regulations.

Chapter 2 Registration Classification and Marketing Approval for TCMs

Article 11 The registration classification of TCMs includes innovative TCMs, modified new TCMs, complex-formulated TCM preparations derived from ancient classical formulas and from formulas prescribed by prestigious veteran practitioners, TCMs with identical names and identical formulas, etc. The TCMs registration classification with specific conditions and the required corresponding application dossier should be implemented in accordance with the requirements set in the relevant regulations with regard to the registration classification and application dossier for TCMs.

Article 12 The research and development of new TCMs should be based on the registration classification of TCMs, and the path and model should be selected

量的人用经验研究，明确中药临床定位和临床价值，基于科学方法不断分析总结，获得支持注册的充分证据。

第六条 中药注册审评，采用中医药理论、人用经验和临床试验相结合的审评证据体系，综合评价中药的安全性、有效性和质量可控性。

第七条 中药的疗效评价应当结合中医药临床治疗特点，确定与中药临床定位相适应、体现其作用特点和优势的疗效结局指标。对疾病痊愈或者延缓发展、病情或者症状改善、患者与疾病相关的机体功能或者生存质量改善、与化学药品等合用增效减毒或者减少毒副作用明显的化学药品使用剂量等情形的评价，均可用于中药的疗效评价。

鼓励将真实世界研究、新型生物标志物、替代终点决策、以患者为中心的药物研发、适应性设计、富集设计等用于中药疗效评价。

第八条 应当根据处方组成及特点、中医药理论、人用经验、临床试验及必要的非临床安全性研究结果，综合评判中药的安全性和获益风险比，加强中药全生命周期管理。

第九条 注册申请人（以下简称申请人）研制中药应当加强中药材、中药饮片的源头质量控制，开展药材资源评估，保证中药材来源可追溯，明确药材基原、产地、采收期等。加强生产全过程的质量控制，保持批间质量的稳定可控。中药处方药味可经质量均一化处理后投料。

第十条 申请人应当保障中药材资源的可持续利用，并应当关注对生态环境的影响。涉及濒危野生动植物的，应当符合国家有关规定。

第二章 中药注册分类与上市审批

第十一条 中药注册分类包括中药创新药、中药改良型新药、古代经典名方中药复方制剂、同名同方药等。中药注册分类的具体情形和相应的申报资料要求按照中药注册分类及申报资料要求有关规定执行。

第十二条 中药新药的研发应当结合中药注册分类，根据品种情况选择符合其

for research and development in line with the characteristics of TCMs. The TCMs with efficacy characteristics should be discovered and explored based on TCM theory and application experience in human; their efficacy should be confirmed mainly through application experience in human and/or necessary clinical trials; TCMs to be developed based on pharmacological screening studies should undergo necessary Phase I clinical trials; and Phase II and III clinical trials should be carried out in a sequential manner.

Article 13 Simplified registration and approval will be implemented for marketing applications of complex-formulated TCM preparations derived from ancient classical formulas and formulas prescribed by prestigious veteran practitioners, and specific requirements should be implemented in accordance with relevant regulations.

Article 14 Review and approval with priority will be implemented for registration applications of new TCMs with clear clinical positioning and obvious clinical value in the following cases:
(1) medicine for the prevention and treatment of major diseases, emerging and unexpected contagious diseases, and rare diseases;
(2) medication with an urgent clinical need and a shortage in the market;
(3) medication for children;
(4) newly discovered raw TCM materials and their preparations, or new officinal parts in raw TCM materials and their preparations;
(5) TCMs with a clear profile of medicinal substances and a basically clear mechanism of action.

Article 14 Review and approval with priority will be implemented for registration applications for new TCMs.

Article 15 In the case that TCMs are used for the treatment of serious life-threatening diseases for which there is no effective treatment method, and TCMs are urgently needed as determined by the State Council's health department or competent department of TCM, if the existing data from clinical trials and empirical evidence based on application experience in human with high quality can show efficacy and predict clinical value, it can be approved with additional conditions, and the relevant matters should be stated in the drug registration certificate.

Article 16 In the event of a public health emergency, if TCMs are deemed urgently needed by the State Council's health department or competent department of TCM, the TCMs may be directly applied for clinical trials, marketing licenses, or adding functions and indications in accordance with special approval procedures by using empirical evidence based on application experience in human.

Chapter 3 The Rational Application of Empirical Evidence Based on Application experience in human

Article 17 Application experience in human for TCMs is usually accumulated in clinical practice and has certain regularity, repeatability and clinical value, including the understanding and summary of TCM formulas and preparations in terms of clinical positioning, applicable population, dosage, efficacy characteristics and clinical benefits, etc., which are accumulated in the process of clinical use.

Article 18 Applicants may collect and collate application experience in human through multiple channels and should be responsible for the authenticity and traceability of the data. The standardized collection, collation, and evaluation of application experience in human should meet relevant requirements. As the data

特点的研发路径或者模式。基于中医药理论和人用经验发现、探索疗效特点的中药，主要通过人用经验和 / 或者必要的临床试验确认其疗效；基于药理学筛选研究确定拟研发的中药，应当进行必要的 I 期临床试验，并循序开展 II 期临床试验和 III 期临床试验。

第十三条 对古代经典名方中药复方制剂的上市申请实施简化注册审批，具体要求按照相关规定执行。

第十四条 对临床定位清晰且具有明显临床价值的以下情形中药新药等的注册申请实行优先审评审批：

（一）用于重大疾病、新发突发传染病、罕见病防治；

（二）临床急需而市场短缺；

（三）儿童用药；

（四）新发现的药材及其制剂，或者药材新的药用部位及其制剂；

（五）药用物质基础清楚、作用机理基本明确。

第十五条 对治疗严重危及生命且尚无有效治疗手段的疾病以及国务院卫生健康或者中医药主管部门认定急需的中药，药物临床试验已有数据或者高质量中药人用经验证据显示疗效并能预测其临床价值的，可以附条件批准，并在药品注册证书中载明有关事项。

第十六条 在突发公共卫生事件时，国务院卫生健康或者中医药主管部门认定急需的中药，可应用人用经验证据直接按照特别审批程序申请开展临床试验或者上市许可或者增加功能主治。

第三章 人用经验证据的合理应用

第十七条 中药人用经验通常在临床实践中积累，具有一定的规律性、可重复性和临床价值，包含了在临床用药过程中积累的对中药处方或者制剂临床定位、适用人群、用药剂量、疗效特点和临床获益等的认识和总结。

第十八条 申请人可以多途径收集整理人用经验，应当对资料的真实性、可溯源性负责，人用经验的规范收集整理与评估应当符合有关要求。作为支持注册申请关键证据的人用经验数据，由药品监督管

on application experience in human is regarded as the key evidence to support the registration application, the drug regulatory administration should organize and carry out the corresponding drug registration verification in accordance with relevant procedures.

Article 19 Application experience in human for which there is reasonable and sufficient analysis conducted on data and the correct interpretation given to the result can be used as evidence to support the registration application. Applicants can determine follow-up research strategies and provide corresponding application dossiers according to the degree to which the evidence supports based on application experience in human in terms of the safety and effectiveness of TCM.

Article 20 The ingredients in a formula (including origin, officinal parts, preparation, etc.) and dosage of TCMs should be fixed in application experience in human that are regarded as key evidence to support registration applications. The key pharmaceutical information and quality of the applied preparation should be basically consistent with the TCMs in application experience in human. If the preparation process, excipients, etc. are changed, an evaluation should be conducted, and data on research and evaluation that supports the relevant changes should be provided.

Article 21 In the case that the formulas of innovative TCMs are derived from ancient classic formulas and formulas described by prestigious veteran practitioners or from TCM clinically experienced formulas, if their formulas' composition, clinical positioning, usage, dosage, etc. are basically consistent with those in previous clinical applications, their traditional processes are basically consistent with those used in clinics, and their functions and indications, applicable population, dosage regimen, clinical benefits, etc. can be preliminary determined through application experience in human, the research on non-clinical effectiveness may not be conducted.

Article 22 For the complex-formulated TCM preparations composed of prepared TCM pieces, the data should be generally provided in terms of single-dose and repeated-dose toxicity trials on rodent, and other data on toxicological trials should be provided when necessary.

In the case that the prepared TCM pieces in a formula of complex-formulated TCM preparation have national drug standards or drug registration standards, and the formula does not contain toxic ingredients or does not contain prepared TCM pieces that have been proven to be toxic by modern toxicology and likely cause serious adverse reactions, and if the preparation uses traditional techniques, and is not used for special groups such as pregnant women and children, and if no obvious toxicity is found in the preparation by single-dose and the repeated-dose toxicity trials on one animal, generally, there is no need to provide the repeated-dose toxicity trials on another animal, nor trial data on pharmacological safety, genotoxicity, carcinogenicity, reproductive toxicity and other.

The term "toxic ingredients" mentioned in this regulation refers to the toxic TCM species included in the "Measures for the Administration of Toxic Drugs for Medical Use."

Article 23 In the case that the new TCMs are derived from clinical practice, if application experience in human can provide research and supportive evidence in terms of clinical positioning, screening of the applicable population, exploration of treatment courses, dosage exploration, etc., phase II clinical trials may not be

理部门按照相关程序组织开展相应的药品注册核查。

第十九条 对数据进行合理、充分的分析并给予正确结果解释的人用经验，可作为支持注册申请的证据。申请人可根据已有人用经验证据对药物安全性、有效性的支持程度，确定后续研究策略，提供相应的申报资料。

第二十条 作为支持注册申请关键证据的人用经验所用药物的处方药味（包括基原、药用部位、炮制等）及其剂量应当固定。申报制剂的药学关键信息及质量应当与人用经验所用药物基本一致，若制备工艺、辅料等发生改变，应当进行评估，并提供支持相关改变的研究评估资料。

第二十一条 中药创新药处方来源于古代经典名方或者中医临床经验方，如处方组成、临床定位、用法用量等与既往临床应用基本一致，采用与临床使用药物基本一致的传统工艺，且可通过人用经验初步确定功能主治、适用人群、给药方案和临床获益等的，可不开展非临床有效性研究。

第二十二条 由中药饮片组成的中药复方制剂一般提供啮齿类动物单次给药毒性试验和重复给药毒性试验资料，必要时提供其他毒理学试验资料。

如中药复方制剂的处方组成中的中药饮片均具有国家药品标准或者具有药品注册标准，处方不含毒性药味或者不含有经现代毒理学证明有毒性、易导致严重不良反应的中药饮片，采用传统工艺，不用于孕妇、儿童等特殊人群，且单次给药毒性试验和一种动物的重复给药毒性试验未发现明显毒性的，一般不需提供另一种动物的重复给药毒性试验，以及安全药理学、遗传毒性、致癌性、生殖毒性等试验资料。

本规定所称毒性药味，是指《医疗用毒性药品管理办法》中收载的毒性中药品种。

第二十三条 来源于临床实践的中药新药，人用经验能在临床定位、适用人群筛选、疗程探索、剂量探索等方面提供研究、支持证据的，可不开展 II 期临床试验。

第二十四条 已有人用经验中药的临床研发，在处方、生产工艺固定的基础上，

conducted.

Article 24 If there are application experience in human for the clinical research and development of TCMs and the data exists in an applicable real-world setting with high quality on the basis of fixed formulas and production processes, and if the real-world evidence being formed through well-designed clinical studies is scientific and sufficient, the applicant can apply to use real-world evidence as one of the bases to support product marketing after communicating and reaching an agreement with the national agency of drug evaluation on the real-world research proposal.

Article 25 Medical institutions are responsible for the safety, effectiveness, and quality controllability of TCM preparations administered in the institutions. They should continue to collect and collate the data on the application experience in human of TCM preparations used in medical institutions in a standardized manner and report them to the local provincial drug regulatory administrations on an annual basis. Submit a report on the collection, collation, and evaluation of application experience in human in TCM preparations used in medical institutions.

Article 26 For the new TCMs developed by medical institutions, if formula composition, process route, clinical positioning, usage and dosage, etc. are basically consistent with previous clinical applications, if their functions and indications, applicable population, usage and dosage are consistent with those in previous clinical applications, and if applicable populations, dosage regimens, and clinical benefits can be preliminary determined through application experience in human, studies on non-clinical effectiveness may not be carried out. If the formula composition, extraction process, dosage form, immediate packaging, etc. of the TCM preparation to be developed are consistent with that used in medical institutions, research information may not be provided, such as dosage form selection, process route screening, and research on immediate packaging, based on pharmaceutical research information on the preparation provided by the medical institution.

Article 27 According to specific product conditions, applicants may communicate with the national agency of drug evaluation about TCM theory, research proposals, and data on application experience in human during the critical stage of research and development.

Chapter 4 Innovative TCMs

Article 28 Innovative TCMs should have sufficient evidence of effectiveness and safety, and randomized controlled clinical trials should principally be conducted before marketing.

Article 29 It is encouraged, as per TCM clinical practice, to explore the use of sequential combination medication on the basis of clinical treatment plans to carry out clinical trials and efficacy evaluations of innovative TCMs.

Article 30 It is encouraged for clinical trials of innovative TCMs to give priority to the use of placebo controls, or placebo controls loaded with basic treatment, if they meet ethical requirements.

Article 31 Prepared TCM pieces, extracts, etc. can be used as formula components of complex-formulated TCM preparations. If the prepared TCM pieces or extracts contained in a formula do not have national drug standards or drug registration standards, their quality standards should be appended to the standard of the TCM

存在适用的高质量真实世界数据，且通过设计良好的临床研究形成的真实世界证据科学充分的，申请人就真实世界研究方案与国家药品审评机构沟通并达成一致后，可申请将真实世界证据作为支持产品上市的依据之一。

第二十五条 医疗机构对医疗机构中药制剂的安全性、有效性及质量可控性负责，应当持续规范收集整理医疗机构中药制剂人用经验资料，并按年度向所在地省级药品监督管理部门提交医疗机构中药制剂人用经验收集整理与评估的报告。

第二十六条 来源于医疗机构制剂的中药新药，如处方组成、工艺路线、临床定位、用法用量等与既往临床应用基本一致，且可通过人用经验初步确定功能主治、适用人群、给药方案和临床获益等的，可不开展非临床有效性研究。如处方组成、提取工艺、剂型、直接接触药品的包装等与该医疗机构中药制剂一致的，在提供该医疗机构中药制剂的药学研究资料基础上，可不提供剂型选择、工艺路线筛选、直接接触药品的包装材料研究等研究资料。

第二十七条 申请人可根据具体品种情况，在关键研发阶段针对中医药理论、人用经验研究方案和人用经验数据等，与国家药品审评机构进行沟通交流。

第四章 中药创新药

第二十八条 中药创新药应当有充分的有效性、安全性证据，上市前原则上应当开展随机对照的临床试验。

第二十九条 鼓励根据中医临床实践，探索采用基于临床治疗方案进行序贯联合用药的方式开展中药创新药临床试验及疗效评价。

第三十条 鼓励中药创新药临床试验在符合伦理学要求的情况下优先使用安慰剂对照，或者基础治疗加载的安慰剂对照。

第三十一条 中药饮片、提取物等均可作为中药复方制剂的处方组成。如含有无国家药品标准且不具有药品注册标准的中药饮片、提取物，应当在制剂药品标准中附设其药品标准。

第三十二条 提取物及其制剂应当具

preparation.

Article 32 Extracts and their preparations should have sufficient basis for establishing research subjects to conduct research on effectiveness, safety, and quality control. A reasonable preparation process should be studied and fixed. The structural type of a large class of homologous compounds and the structures of major components should be studied and clarified, and the quality of the extracts and preparations should be fully characterized to ensure uniformity and stability in quality between different batches of extracts and preparations by establishing quality control items in quality standards in terms of assays and fingerprints or characteristic chromatography for the main components and large class of homologous compounds.

Article 33 In the case that new extracts and their preparations are applied for registration, if preparations made by a single ingredient or extract from a single ingredient are already on the market and the functions and indications between applying one and marketed one are basically the same, comparative studies of such preparations between non-clinic and clinic preparations should be conducted to illustrate their advantages and characteristics.

Article 34 In the case that new raw TCM materials and their preparations are applied for registration, it should provide research information on the nature and flavor, channel tropism, efficacy, etc. for the raw TCM materials, and relevant research should provide supportive evidence for the proposed nature and flavor, channel tropism, efficacy, etc. for the new raw TCM materials.

Article 35 The complex-formulated TCM preparations can be divided into different cases according to different indications:
(1) The complex-formulated TCM preparations whose indications are described with syndromes refer to the preparations used to treat TCM syndromes under the guidance of TCM theory, including those to treat TCM diseases or TCM symptoms. The functions and indications should be expressed in the professional terminology of TCM;
(2) The complex-formulated TCM preparations whose indications are described with diseases in combination with syndromes. The "diseases" involved refer to the diseases under modern medical science, while the "syndromes" involved refer to the syndromes under TCM theory. The functions should be expressed in professional terms of TCM, and the indications should be expressed with diseases under modern medical science in combination with syndromes under TCM theory;
(3) The complex-formulated TCM preparations whose indications are described with diseases refer to the preparations specially used to treat special diseases for which the formulas are formulated under the guidance of TCM theory. The "diseases" involved refer to diseases under modern medical science; the functions should be expressed in professional terms of TCM, and indications should be expressed in terms of modern medical diseases.

Article 36 In the case that applicants apply for registration of innovative TCMs, phased research may be conducted according to the characteristics of TCMs and the general patterns of new drug research and development, it should focus on the main purpose of each phase, such as applying for clinical trials, pre-phase III clinical trials, and applying for marketing authorization. Phased research on TCMs should reflect the concept of quality coming from design and focus on the integrity and systematicity

有充分的立题依据，开展有效性、安全性和质量可控性研究。应当研究确定合理的制备工艺。应当研究明确所含大类成份的结构类型及主要成份的结构，通过建立主要成份、大类成份的含量测定及指纹或者特征图谱等质控项目，充分表征提取物及制剂质量，保证不同批次提取物及制剂质量均一稳定。

第三十三条 新的提取物及其制剂的注册申请，如已有单味制剂或者单味提取物制剂上市且功能主治（适应症）基本一致，应当与该类制剂进行非临床及临床对比研究，以说明其优势与特点。

第三十四条 新药材及其制剂的注册申请，应当提供该药材性味、归经、功效等的研究资料，相关研究应当为新药材拟定的性味、归经、功效等提供支持证据。

第三十五条 中药复方制剂根据主治的不同，可以分为不同情形：

（一）主治为证候的中药复方制剂，是指在中医药理论指导下，用于治疗中医证候的中药复方制剂，包括治疗中医学的病或者症状的中药复方制剂，功能主治应当以中医专业术语表述；

（二）主治为病证结合的中药复方制剂，所涉及的“病”是指现代医学的疾病，“证”是指中医的证候，其功能用中医专业术语表述、主治以现代医学疾病与中医证候相结合的方式表述；

（三）主治为病的中药复方制剂，属于专病专药，在中医药理论指导下组方。所涉及的“病”是现代医学疾病，其功能用中医专业术语表述，主治以现代医学疾病表述。

第三十六条 中药创新药的注册申请人可根据中药特点、新药研发的一般规律，针对申请临床试验、III 期临床试验前、申请上市许可等不同研究阶段的主要目的进行分阶段研究。中药药学分阶段研究应当体现质量源于设计理念，注重研究的整体性和系统性。

第三十七条 中药创新药应当根据处方药味组成、药味药性，借鉴用药经验，以满足临床需求为宗旨，在对药物生产工艺、理化性质、传统用药方式、生物学特性、剂型特点、临床用药的安全性、患者

of the research.

Article 37 Dosage form and administration route should be reasonably selected for innovative TCMs according to the formula composition, flavor and nature of the ingredient, drawing on medication experience in order to meet clinical needs based on comprehensive analysis such as production process, physical and chemical properties, traditional medication methods, biological characteristics, dosage form characteristics, clinical medication safety, patient medication compliance, etc. Injection administration is not encouraged if oral administration is allowed.

Article 38 It should conduct corresponding non-clinical safety trials for the development of innovative TCMs based on the safety information obtained from the TCM characteristics, clinical application, etc. Corresponding non-clinical safety trials can be carried out according to different registration classifications, risk assessment situations, and development processes.

Article 39 The samples used in non-clinical safety trials should be samples of pilot scale or above. When it is applied for clinical trials, information should be provided to describe the preparation samples used for non-clinical safety trials. TCM preparations for clinical trials should generally use production-scale samples. When it is applied for marketing authorization, information should be provided to describe the preparation of samples for clinical trials, including experimental samples and placebos.

Article 40 Phase I clinical trials should necessarily be carried out under the following circumstances:
(1) The formula contains a toxic ingredient;
(2) The formulas contain prepared TCM pieces and extracts that do not have national drug standards or drug registration standards, in addition to those containing prepared TCM pieces that have a history of customary use and are included in the provincial standards for processing TCM pieces;
(3) Results from non-clinical safety trials show obvious toxic reactions and indicate that there may be certain safety risks to the human body;
(4) TCM registration applications that require data on human pharmacokinetics to guide clinical medication.

Chapter 5 Modified new TCMs

Article 41 It is to support holders of drug marketing authorization (hereinafter referred to as holders) to carry out research on modified new TCMs. The research and development of modified TCMs should follow the principles of necessity, scientificity, and rationality, and the purpose of modification should be clear. Research should be conducted on the existing TCMs on the market and based on an objective, scientific, and comprehensive understanding of the modified TCMs, focusing on the defects of the modified TCMs or the newly discovered therapeutic characteristics and potentialities during clinical application. When modified new TCMs are developed for children, the development should be consistent with the children's growth and development characteristics and medication habits.

Article 42 The modified new TCMs applying for changing the dosage form or administration route of the existing marketed TCMs should have advantages and characteristics in clinical application, such as increased effectiveness, improved safety, enhanced compliance, etc., or should promote environmental protection and upgrade safety levels of production, etc. under the prerequisite that the modified TCMs' effectiveness and safety are not reduced.

用药依从性等方面综合分析的基础上合理选择剂型和给药途径。能选择口服给药的不选择注射给药。

第三十八条 中药创新药的研制，应当根据药物特点、临床应用情况等获取的安全性信息，开展相应的非临床安全性试验。可根据不同注册分类、风险评估情况、开发进程开展相应的非临床安全性试验。

第三十九条 非临床安全性试验所用样品，应当采用中试或者中试以上规模的样品。申报临床试验时，应当提供资料说明非临床安全性试验用样品制备情况。临床试验用药品一般应当采用生产规模的样品。申报上市时，应当提供资料说明临床试验用药品的制备情况，包括试验药物和安慰剂。

第四十条 以下情形，应当开展必要的Ⅰ期临床试验：

（一）处方含毒性药味；

（二）除处方含确有习用历史且被省级中药饮片炮制规范收载的中药饮片外，处方含无国家药品标准且不具有药品注册标准的中药饮片、提取物；

（三）非临床安全性试验结果出现明显毒性反应且提示对人体可能具有一定的安全风险；

（四）需获得人体药代数据以指导临床用药等的中药注册申请。

第五章 中药改良型新药

第四十一条 支持药品上市许可持有人（以下简称持有人）开展改良型新药的研究。改良型新药的研发应当遵循必要性、科学性、合理性的原则，明确改良目的。应当在已上市药品的基础上，基于对被改良药品的客观、科学、全面的认识，针对被改良中药存在的缺陷或者在临床应用过程中新发现的治疗特点和潜力进行研究。研制开发儿童用改良型新药时，应当符合儿童生长发育特征及用药习惯。

第四十二条 改变已上市中药剂型或者给药途径的改良型新药，应当具有临床应用优势和特点，如提高有效性、改善安全性、提高依从性等，或者在有效性、安全性不降低的前提下，促进环境保护、提升生产安全水平等。

Article 43 The rationality and necessity for changing the administration route should be explained when a marketed TCM is applied for registration to change the administration route, corresponding non-clinical research should be conducted, and clinical trials should be carried out by focusing on the purpose of modification to prove the advantages and characteristics in clinical application for changing the administration route.

Article 44 In the case that a marketed TCM is applied for registration to change the dosage form, sufficient evidence should be provided to demonstrate its scientific rationality based on the clinical treatment needs, the medicine's physical and chemical properties, and its biological properties. Applicants should carry out corresponding pharmaceutical research based on the specific situations of the new dosage form and conduct non-clinical research on effectiveness and safety, as well as clinical trials when necessary.

In the case that medication is for children and special groups (such as those with dysphagia, etc.), or some marketed TCMs aim to be improved in terms of clinical use compliance through changing dosage forms due to inconvenient use caused by special usage, clinical trials may not be conducted if comparative studies show that there is no significant change in the substance profile and absorption and the utilization of medicinal components exiting in the TCM with the changed dosage form, and if the TCM with the original dosage form has sufficient evidence on the clinical value.

Article 45 In the case that a TCM is applied for registration to add functions and indications, in addition to the cases specified in Articles 23 and 46, the data on non-clinical effectiveness research should be provided, and phase II and phase III clinical trials should be carried out sequentially.

In the case that a TCM is applied for registration to extend the medication cycle or increase the dose, data on non-clinical safety research should be provided. New tests on non-clinical safety do not need to be conducted if relevant studies on non-clinical safety have been conducted before marketing that can support extending the cycle or increasing the dose.

If the applicant who is not a holder of a marketed TCM applies for registration to add functions and indications to the marketed TCM, a registration application for the new TCM with the identical name and identical formula should be submitted.

Article 46 In the case that a marketed TCM is applied for registration to add functions and indications, the data on the non-clinical effectiveness test does not need to be provided if empirical evidence in human application supports the corresponding clinical positioning. The data on non-clinical safety tests does not need to be provided if the dosage and treatment duration do not increase and the applicable population remains unchanged.

Article 47 It is encouraged to apply new technologies and new processes suitable for products' characteristics to improve marketed TCMs. If modified production processes or modified excipients of a marketed TCM cause significant changes in the component profile or the absorption and utilization of the medicinal components existing in the modified TCM, relevant trials on non-clinical effectiveness and safety should be carried out by taking an objective at a study on improving effectiveness or safety, and phase II and phase III clinical trials should be submitted according to the registration application for the modified new drug.

第四十三条　改变已上市药品给药途径的注册申请，应当说明改变给药途径的合理性和必要性，开展相应的非临床研究，并围绕改良目的开展临床试验，证明改变给药途径的临床应用优势和特点。

第四十四条　改变已上市中药剂型的注册申请，应当结合临床治疗需求、药物理化性质及生物学性质等提供充分依据说明其科学合理性。申请人应当根据新剂型的具体情形开展相应的药学研究，必要时开展非临床有效性、安全性研究和临床试验。

对儿童用药、特殊人群（如吞咽困难者等）用药、某些因用法特殊而使用不便的已上市中药，通过改变剂型提高药物临床使用依从性，若对比研究显示改剂型后药用物质基础和药物吸收、利用无明显改变，且原剂型临床价值依据充分的，可不开展临床试验。

第四十五条　中药增加功能主治，除第二十三条和第四十六条规定的情形外，应当提供非临床有效性研究资料，循序开展 II 期临床试验及 III 期临床试验。

延长用药周期或者增加剂量者，应当提供非临床安全性研究资料。上市前已进行相关的非临床安全性研究且可支持其延长周期或者增加剂量的，可不进行新的非临床安全性试验。

申请人不持有已上市中药申请增加功能主治的，应当同时提出同名同方药的注册申请。

第四十六条　已上市中药申请增加功能主治，其人用经验证据支持相应临床定位的，可不提供非临床有效性试验资料。使用剂量和疗程不增加，且适用人群不变的，可不提供非临床安全性试验资料。

第四十七条　鼓励运用适合产品特点的新技术、新工艺改进已上市中药。已上市中药生产工艺或者辅料等的改变引起药用物质基础或者药物的吸收、利用明显改变的，应当以提高有效性或者改善安全性等为研究目的，开展相关的非临床有效性、安全性试验及 II 期临床试验、III 期临床试验，按照改良型新药注册申报。

第六章 古代经典名方中药复方制剂

Chapter 6 The TCM complex-formulated preparations derived from ancient classic formulas or formulas prescribed by prestigious veteran practitioners

Article 48 In the case that the TCM complex-formulated preparations derived from ancient classic formulas or the formulas prescribed by prestigious veteran practitioners do not contain incompatible ingredients, virulent toxic and highly toxic ingredients labeled in TCM standards, or toxic ingredients proven by modern toxicology, traditional process techniques and traditional administration routes should be applied, and functions and indications should be expressed in TCM terms. The development of this category of TCM complex-formulated preparations does not require research on non-clinical effectiveness or clinical trials. A special format should be given to the TCM approval number.

Article 49 The TCM complex-formulated preparations derived from ancient classic formulas or the formulas prescribed by prestigious veteran practitioners are reviewed by a model based on expert opinions. The Expert Review Committee for the TCM complex-formulated preparations derived from ancient classic formulas or the formulas prescribed by prestigious veteran practitioners, which primarily consists of TCM masters, academicians, and nationally renowned TCM practitioners, conducts technical reviews on this category of preparations and issues technical review opinions on whether to agree with marketing the preparation.

Article 50 In the case that TCM complex-formulated preparations are applied for marketing in light of the catalog of ancient classic formulas or the formulas prescribed by prestigious veteran practitioners, the applicant should conduct corresponding pharmaceutical research and research on non-clinical safety. In principle, preparations' formula composition, origins and officinal parts of raw TCM materials as ingredients, processing specifications, converted dosage, usage and dosage, functions, and indications should be consistent with the key information of ancient classic formulas or formulas prescribed by prestigious veteran practitioners issued by the country.

Article 51 In the case that other TCM complex-formulated preparations derived from ancient classic formulas or the formulas prescribed by prestigious veteran practitioners are applied for registration, corresponding pharmaceutical research and data on non-clinical safety trials should be provided; additionally, the key information and basis of ancient classic formulas should be provided; and a systematic summary of the TCM clinical practice should be provided as well to illustrate its clinical value. The addition, subtraction, and modification of ancient classic formulas or the formulas prescribed by prestigious veteran practitioners should be carried out under the guidance of TCM theory.

Article 52 Applicants are encouraged to communicate with the national drug evaluation agency on major issues such as research on benchmark samples and non-clinical safety, standardized collection and collation of application experience in human , and a summary of TCM clinical practice at the critical stage of research and development based on the characteristics of ancient classic formulas and the formulas prescribed by prestigious veteran practitioners.

Article 53 After marketing a TCM complex-formulated preparation derived from ancient classic formulas or the

第四十八条 古代经典名方中药复方制剂处方中不含配伍禁忌或者药品标准中标有剧毒、大毒及经现代毒理学证明有毒性的药味，均应当采用传统工艺制备，采用传统给药途径，功能主治以中医术语表述。该类中药复方制剂的研制不需要开展非临床有效性研究和临床试验。药品批准文号给予专门格式。

第四十九条 古代经典名方中药复方制剂采用以专家意见为主的审评模式。由国医大师、院士、全国名中医为主的古代经典名方中药复方制剂专家审评委员会对该类制剂进行技术审评，并出具是否同意上市的技术审评意见。

第五十条 按古代经典名方目录管理的中药复方制剂申请上市，申请人应当开展相应的药学研究和非临床安全性研究。其处方组成、药材基原、药用部位、炮制规格、折算剂量、用法用量、功能主治等内容原则上应当与国家发布的古代经典名方关键信息一致。

第五十一条 其他来源于古代经典名方的中药复方制剂的注册申请，除提供相应的药学研究和非临床安全性试验资料外，还应当提供古代经典名方关键信息及其依据，并应当提供对中医临床实践进行的系统总结，说明其临床价值。对古代经典名方的加减化裁应当在中医药理论指导下进行。

第五十二条 鼓励申请人基于古代经典名方中药复方制剂的特点，在研发的关键阶段，就基准样品研究、非临床安全性研究、人用经验的规范收集整理及中医临床实践总结等重大问题与国家药品审评机构进行沟通交流。

第五十三条 古代经典名方中药复方制剂上市后，持有人应当开展药品上市后临床研究，不断充实完善临床有效性、安全性证据。持有人应当持续收集不良反应信息，及时修改完善说明书，对临床使用过程中发现的非预期不良反应及时开展非临床安全性研究。

第七章 同名同方药

第五十四条 同名同方药的研制应当避免低水平重复。申请人应当对用于对照

formulas prescribed by prestigious veteran practitioners, the holder should carry out post-market clinical research on the preparation and continuously enrich and improve the evidence of clinical effectiveness and safety. The holder should continue to collect information on adverse reactions, timely revise and improve the package insert, and timely conduct studies on non-clinical safety when unexpected adverse reactions are discovered during clinical use.

Chapter 7 TCMs with the identical name and identical formula

Article 54 Low-level duplication should be avoided in the development of TCMs with identical names and identical formulas. Applicants should evaluate the clinical value of marketed TCMs with identical names and identical formulas that are used as controls (hereinafter referred to as the control TCM with the identical name and identical formula). Regarding the registration of applications for the TCMs to be developed with the identical name and formula of the marketed TCM, the safety, effectiveness, and quality controllability should be no less than those of the marketed TCM.

Article 55 The TCMs to be developed with the identical name and identical formula should be compared with the control TCM with the identical name and identical formula in terms of quality control of the entire process of TCM, including prepared TCM pieces, intermediates, preparations, etc. The applicant should evaluate whether to conduct research on non-clinical safety and clinical trials based on the evidence of the effectiveness and safety of the control TCM with identical name and identical formula, as well as the comparison results of the process techniques, excipients, etc. between the TCM to be developed and the control TCM with identical name and identical formula.

Article 56 Applicants should select a control TCM with an identical name and identical formula as per the results of the clinical value evaluation. Control TCM with an identical name and identical formula should have sufficient evidence of effectiveness and safety. The evidence of effectiveness and safety can generally be regarded as sufficient, such as TCMs that have been approved for marketing after clinical trials that have been carried out in accordance with the requirements with reference to drug registration and management, the marketed TCMs listed in the current version of the Pharmacopoeia of the People's Republic of China, and marketed TCMs that have ever obtained TCM protection certificates.

The term "marketed TCM that have ever obtained TCM protection certificates," as mentioned in the preceding paragraph, refers to protected TCMs that are over the validity period and other protected TCMs that comply with the relevant provisions in the TCM protection system.

Article 57 In the case that TCMs with identical names and identical formulas are applied for registration and need to be compared through clinical trials with control TCMs with identical names and identical formulas, at least Phase III clinical trials must be conducted. The TCM made from an extracted single component can be proven to be consistent with the control TCM with an identical name and identical formula through bioequivalence testing.

Article 58 For TCMs with national drug standards but without a drug approval number, registration applications should be submitted in line with the TCMs with identical names and identical formulas. Applicants should conduct necessary clinical trials based on the TCM theory and application experience in human .

且与研制药物同名同方的已上市中药（以下简称对照同名同方药）的临床价值进行评估。申请注册的同名同方药的安全性、有效性及质量可控性应当不低于对照同名同方药。

第五十五条 同名同方药的研制，应当与对照同名同方药在中药材、中药饮片、中间体、制剂等全过程质量控制方面进行比较研究。申请人根据对照同名同方药的有效性、安全性证据，以及同名同方药与对照同名同方药的工艺、辅料等比较结果，评估是否开展非临床安全性研究及临床试验。

第五十六条 申请人应当基于临床价值评估结果选择对照同名同方药。对照同名同方药应当具有有效性、安全性方面充分的证据，按照药品注册管理要求开展临床试验后批准上市的中药、现行版《中华人民共和国药典》收载的已上市中药以及获得过中药保护品种证书的已上市中药，一般可视作具有充分的有效性、安全性证据。

前款所称获得过中药保护证书的已上市中药，是指结束保护期的中药保护品种以及符合中药品种保护制度有关规定的其他中药保护品种。

第五十七条 申请注册的同名同方药与对照同名同方药需要通过临床试验进行比较的，至少需进行 III 期临床试验。提取的单一成份中药可通过生物等效性试验证明其与对照同名同方药的一致性。

第五十八条 有国家药品标准而无药品批准文号的品种，应当按照同名同方药提出注册申请。申请人应当根据其中医药理论和人用经验情况，开展必要的临床试验。

第五十九条 对照同名同方药有充分的有效性和安全性证据，同名同方药的工艺、辅料与对照同名同方药相同的，或者同名同方药的工艺、辅料变化经研究评估不引起药用物质基础或者药物吸收、利用明显改变的，一般无需开展非临床安全性研究和临床试验。

第八章 上市后变更

第六十条 已上市中药的变更应当遵

Article 59 In the case that the control TCM with identical name and identical formula has sufficient evidence of effectiveness and safety and the TCM to be developed has the same process techniques and excipients as the control TCM with identical name and identical formula, or if the changes in the process techniques and excipients of the TCM to be developed with identical name and identical formula do not cause obvious changes in the medicinal substance profile or the absorption and utilization of medicinal components after research and evaluation, there is generally no need to conduct research on non-clinical safety and clinical trials.

Chapter 8 Post-Marketing Changes

Article 60 Changes to the marketed TCM should follow the characteristics and patterns of TCMs and meet the relevant requirements on necessity, scientificity, and rationality. The holder should perform the main responsibilities of research, evaluation, and management on changes and comprehensively evaluate and verify the impact of changes on TCM's safety, effectiveness, and quality controllability. The categories of change management for marketed TCMs should be determined based on the results of research, evaluation, and related verification. The implementation of changes should be carried out or reported after approval and filing in accordance with regulations. The holder can timely communicate with the corresponding drug regulatory administrations during the research process of post-marketing changes.

Article 61 Changes in pharmaceutical strength should follow the principle of being consistent with the corresponding ingredients in formula and the principle of being compatible with the applicable population, usage and dosage, and filling specifications.

If a product has the same TCM on the market, the applied pharmaceutical strength should generally be consistent with the one with the same TCM on the market.

Article 62 Changes in production processes and excipients should not cause obvious changes in the absorption and utilization of medicinal substances or the medicine. The selection of production equipment should meet the requirements of production processes and quality assurance.

Article 63 In the case that a TCM applies for changes in usage and dosage or expending the scope of the applicable population without changing the administration route, research data on non-clinical safety that can support the changes should be provided, and clinical trials should be conducted when necessary. In addition to the cases stipulated in Article 64, If clinical trials are required when the usage and dosage is changed, or scope of the applicable population is expended, phase II and phase III clinical trials should be conducted in sequence.

If the medication [usage and dosage] of marketed TCMs for children is unclear, necessary clinical trials should be carried out based on the characteristics of children's medication and application experience in human to clarify the dosage and treatment course for children of different ages.

Article 64 In the case that a marketed TCM applies for changes in the usage and dosage or expending the scope of the applicable population, if the functions and indications, and the administration route remain unchanged, and the empirical evidence in application experience in human supports the new usage and dosage or the usage and dosage of

循中药自身特点和规律，符合必要性、科学性、合理性的有关要求。持有人应当履行变更研究及其评估、变更管理的主体责任，全面评估、验证变更事项对药品安全性、有效性和质量可控性的影响。根据研究、评估和相关验证结果，确定已上市中药的变更管理类别，变更的实施应当按照规定经批准、备案后进行或者报告。持有人在上市后变更研究过程中可与相应药品监督管理部门及时开展沟通交流。

第六十一条 变更药品规格应当遵循与处方药味相对应的原则以及与适用人群、用法用量、装量规格相协调的原则。

对于已有同品种上市的，所申请的规格一般应当与同品种上市规格一致。

第六十二条 生产工艺及辅料等的变更不应当引起药用物质或者药物吸收、利用的明显改变。生产设备的选择应当符合生产工艺及品质保障的要求。

第六十三条 变更用法用量或者增加适用人群范围但不改变给药途径的，应当提供支持该项改变的非临床安全性研究资料，必要时应当进行临床试验。除符合第六十四条规定之情形外，变更用法用量或者增加适用人群范围需开展临床试验的，应当循序开展 II 期临床试验和 III 期临床试验。

已上市儿童用药【用法用量】中剂量不明确的，可根据儿童用药特点和人用经验情况，开展必要的临床试验，明确不同年龄段儿童用药的剂量和疗程。

第六十四条 已上市中药申请变更用法用量或者增加适用人群范围，功能主治不变且不改变给药途径，人用经验证据支持变更后的新用法用量或者新适用人群的用法用量的，可不开展 II 期临床试验，仅开展 III 期临床试验。

第六十五条 替代或者减去国家药品标准处方中的毒性药味或者处于濒危状态的药味，应当基于处方中药味组成及其功效，按照相关技术要求开展与原药品进行药学、非临床有效性和 / 或者非临床安全性的对比研究。替代或者减去处方中已明确毒性药味的，可与安慰剂对照开展 III 期临床试验。替代或者减去处方中处于濒危状态药味的，至少开展 III 期临床试验

the new applicable population after the changes, only phase III clinical trials are needed while phase II clinical trials are allowed to be exempted.

Article 65 In the case that a TCM is applied for substituting or subtracting toxic ingredients or endangered ingredients in the formulas listed in a national TCM standard, studies on pharmacy and non-clinical effectiveness and/or non-clinical safety should be carried out in contrast with the original TCM based on the formula composition and efficacy in accordance with relevant technical requirements. If toxic ingredients are clarified in the formula as substituted or subtracted ones, phase III clinical trials should be carried out in contrast with placebo. If ingredients are clarified in the formula as endangered species, at least the studies on the phase III clinical trials should be carried out in contrast with the original TCM. The generic name of the TCM should be changed simultaneously when needed.

Article 66 In the case that the extracts approved as new TCMs and contained in a formula of TCM complex-formulated preparation are applied for changes from outsource to self-extracted source, the applicant should provide accordingly the research data, including but not limited to the pharmacy research on the extract obtained through self-development and on its TCM preparation, as well as the data on studies on the phase III clinical in contrast with the original TCM preparation. The quality standard of the extract should be appended to the preparation standard.

Article 67 In the case that the TCM is applied for deletion of functions and indications or deletion of the scope of the applicable population, the rationale for deletion should be explained. Generally, clinical trials are exempted.

Chapter 9 Registration Standards for TCMs

Article 68 The research and formulation of registration standards for TCMs should aim at achieving a stable and controllable quality of TCMs and establish control indicators that reflect the overall quality of TCMs based on products' characteristics. Reflect on the quality status of products as much as possible, and pay attention to the relationship between the effectiveness and safety of TCMs.

Article 69 It is to support the use of new technologies and new methods to explore and establish fingerprints or characteristic chromatographs, biological effect detection, etc. for quality control of intermediates and preparations of new complex-formulated TCM. The testing items in the registration standards for TCMs, including assays, should have a reasonable limit range.

Article 70 The holder should formulate internal control standards in enterprise that are no lower than the registration standards of the TCM based on products' characteristics and the real case, and improve the quality of TCM preparations by continuously revising and improving its testing items, methods, limits, etc.

Article 71 After a TCM is put on the market, data on production should be accumulated, and a holistic quality standard system including raw TCM materials, prepared TCM pieces, intermediates, and preparations should be continuously revised and improved to ensure the stability and controllability of the TCM quality based on the development of science and technology.

Chapter 10 TCM Name and Package Insert

Article 72 The naming of Chinese proprietary medicines should comply with the requirements with regard to the "Technical Guidelines for Naming Generic Names of Chinese Proprietary Medicines"

的比较研究。必要时，需同时变更药品通用名称。

第六十六条 中药复方制剂处方中所含按照新药批准的提取物由外购变更为自行提取的，申请人应当提供相应研究资料，包括但不限于自行研究获得的该提取物及该中药复方制剂的药学研究资料，提取物的非临床有效性和安全性对比研究资料，以及该中药复方制剂 III 期临床试验的对比研究资料。该提取物的质量标准应当附设于制剂标准后。

第六十七条 对主治或者适用人群范围进行删除的，应当说明删除该主治或者适用人群范围的合理性，一般不需开展临床试验。

第九章 中药注册标准

第六十八条 中药注册标准的研究、制定应当以实现中药质量的稳定可控为目标，根据产品特点建立反映中药整体质量的控制指标。尽可能反映产品的质量状况，并关注与中药有效性、安全性的关联。

第六十九条 支持运用新技术、新方法探索建立用于中药复方新药的中间体、制剂质量控制的指纹图谱或者特征图谱、生物效应检测等。中药注册标准中的含量测定等检测项目应当有合理的范围。

第七十条 根据产品特点及实际情况，持有人应当制定不低于中药注册标准的企业内控标准，并通过不断修订和完善其检验项目、方法、限度范围等，提高中药制剂质量。

第七十一条 药品上市后，应当积累生产数据，结合科学技术的发展，持续修订完善包括中药材、中药饮片、中间体和制剂等在内的完整的质量标准体系，以保证中药制剂质量稳定可控。

第十章 药品名称和说明书

第七十二条 中成药命名应当符合《中成药通用名称命名技术指导原则》的要求及国家有关规定。

第七十三条 中药处方中含毒性药味，或者含有其他已经现代毒理学证明具有毒性、易导致严重不良反应的中药饮片的，应当在该中药说明书【成份】项下标明处

and relevant national regulations.

Article 73 If a TCM formula contains toxic ingredients or contains other prepared TCM pieces that have been proven to be toxic by modern toxicology and can easily cause serious adverse reactions, the name of the toxic ingredient contained in the formula should be indicated under the [ingredients] item in the package insert of the TCM and should be indicated in warning that the preparation contains the toxic TCM pieces.

Article 74 [Precautions] in the package inserts for new TCMs involving use under syndrome differentiation should include, but are not limited to, the following:
(1) Situations that require use with caution due to factors such as TCM syndrome, pathogenesis, physical constitution, etc., as well as drug-related precautions in terms of diet, compatibility, etc.
(2) If there is post-medication care, it should be clarified.

Article 75 The holder should strengthen the management of the entire life cycle of TCMs, strengthen the monitoring, evaluation, and analysis of safety risks, and refer to relevant technical guidelines to timely improve [contraindications], [adverse reactions], and [precautions] in the package insert of TCMs.

When a TCM is applied for re-registration, re-registration will not be granted in accordance with the law if any of the [Contraindications], [Adverse Reactions], and [Precautions] in the package insert of the TCM are still "unclear" after three years from the date of implementation of these regulations.
Article 76 The package insert for TCMs derived from ancient classic formulas or formulas prescribed by prestigious veteran practitioners should list the [source of formula], [theoretical basis for functions and indications], etc.

For new TCMs that use application experience in humans as evidence for approval for marketing or for adding functions and indications, [TCM Clinical Practice] should be included as an item in the package insert.

Chapter 11 Supplementary Provisions
Article 77 Pharmaceutical quality control of natural medicines may be implemented by consulting these regulations. In order to confirm the therapeutic effect of innovative natural medicines, data on at least one Phase III clinical trial should be used to demonstrate their effectiveness. The rest should comply with the relevant requirements with regard to research on new natural medicines.

Article 78 In the case that TCMs and natural medicines are applied for import, the application should comply with the requirements on drug management in the exported countries or regions and should also meet the requirements on safety, effectiveness, and quality controllability of domestic TCMs and natural medicines. Registration application dossiers should be provided in accordance with the requirements for innovative TCMs. It should prevail if the country has other regulations.
Article 79 The development of injections derived from TCMs and natural medicines should comply with the general technical requirements for injection research. The necessity and rationality for choosing an administration route should be demonstrated through sufficient non-clinical studies based on the availability of existing treatment methods. The active components and mechanisms of TCMs' functions should be clarified, comprehensive studies on non-clinical effectiveness and safety should be carried out, and phase I, phase II, and phase

方中所含的毒性中药饮片名称，并在警示语中标明制剂中含有该中药饮片。

第七十四条 涉及辨证使用的中药新药说明书的【注意事项】应当包含，但不限于以下内容：

（一）因中医的证、病机、体质等因素需要慎用的情形，以及饮食、配伍等方面与药物有关的注意事项；

（二）如有药后调护，应当予以明确。

第七十五条 持有人应当加强对药品全生命周期的管理，加强对安全性风险的监测、评价和分析，应当参照相关技术指导原则及时对中药说明书【禁忌】、【不良反应】、【注意事项】进行完善。

中药说明书【禁忌】、【不良反应】、【注意事项】中任何一项在本规定施行之日起满 3 年后申请药品再注册时仍为“尚不明确”的，依法不予再注册。

第七十六条 古代经典名方中药复方制剂说明书中应当列明【处方来源】、【功能主治的理论依据】等项。

人用经验作为批准上市或者增加功能主治证据的中药新药，说明书中应当列入【中医临床实践】项。

第十一章 附 则

第七十七条 天然药物的药学质量控制可参照本规定执行。天然药物创新药在治疗作用确证阶段，应当至少采用一个 III 期临床试验的数据说明其有效性。其余均应当符合天然药物新药研究的有关要求。

第七十八条 申请进口的中药、天然药物，应当符合所在国或者地区按照药品管理的要求，同时应当符合境内中药、天然药物的安全性、有效性和质量可控性要求。注册申报资料按照创新药的要求提供。国家另有规定的，从其规定。

第七十九条 中药、天然药物注射剂的研制应当符合注射剂研究的通用技术要求。应当根据现有治疗手段的可及性，通过充分的非临床研究说明给药途径选择的必要性和合理性。药物活性成份及作用机理应当明确，并应当开展全面的非临床有效性、安全性研究，循序开展 I 期临床试验、II 期临床试验和 III 期临床试验。

中药、天然药物注射剂上市后，持有

III clinical trials should be carried out sequentially.

After the injections of TCMs and natural medicine are launched on the market, holders should carry out post-marketing clinical studies on the medicines, continuously enrich and improve the evidence of clinical effectiveness and safety, continue to collect information on adverse reactions, and timely revise and improve the package inserts. Studies on non-clinical safety should be carried out in a timely manner if any unexpected adverse reactions are discovered during clinical use. Holders should strengthen quality control on injections.

Article 80 The provincial drug regulatory administrations should submit annual reports to the national drug regulatory administration about the approval and filing status of TCM preparations used in medical institutions. The national drug regulatory administration will include information about the approval and filing status of TCM preparations used in medical institutions in the annual national drug review report based on the reports from provincial drug regulatory administrations.

Article 81 The general requirements for drug registration management that are not covered by these regulations should be implemented in accordance with the "Measures for Drug Registration Management." Regulations on the registration and management of raw TCM materials and prepared TCM pieces that need to be implemented upon approval will be formulated separately.

Article 82 These regulations came into effect on July 1, 2023. The "Notice on Issuing Supplementary Regulations on Registration and Management of Traditional Chinese Medicines" issued by the former National Food and Drug Administration's (National Food and Drug Administration Note [2008] No. 3) was abolished simultaneously.

人应当开展药品上市后临床研究，不断充实完善临床有效性、安全性证据，应当持续收集不良反应信息，及时修改完善说明书，对临床使用过程中发现的非预期不良反应及时开展非临床安全性研究。持有人应当加强质量控制。

第八十条 省级药品监督管理部门应当按年度向国家药品监督管理部门提交医疗机构中药制剂审批、备案情况的报告。国家药品监督管理部门根据省级药品监督管理部门提交的报告，将医疗机构中药制剂的审批、备案情况纳入药品审评年度报告。

第八十一条 本规定未涉及的药品注册管理的一般性要求按照《药品注册管理办法》执行。实施审批管理的中药材、中药饮片注册管理规定另行制定。

第八十二条 本规定自 2023 年 7 月 1 日起施行。原国家食品药品监督管理局《关于印发中药注册管理补充规定的通知》（国食药监注〔2008〕3 号）同时废止。

Notes:
- All the Chinese information in the Newsletter is from newspapers and the Internet. All English articles are translated from the Chinese version. In case of any discrepancy, the Chinese version shall prevail.
- For e-paper of the Newsletter, please visit http://www.ccfdie.org

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