世界中医药学会联合会国际组织标准

International Standard of WFCMS

《中药采购规范》

Specifications for procurement of Chinese medicines

编制说明

Formulation Explanations

《中药采购规范》标准编制组

Standard Compilation Team of Specifications for procurement of Chinese medicines

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一、标准的起草背景

标准既是学科成熟的重要标志，又是衡量客观事物的行为准则；是国家战略性资源和国际竞争力的核心要素；是经济、社会、文化、科技全面发展的技术支撑；是打造中国质量，构建诚信社会，实施精细化管理战略目标的引擎。要让世界各国人民了解中医药、认知中医药、感受中医药、接纳中医药，广泛地运用中医药防病、治病，为人类的健康谋福祉，中医药标准化是条捷径——康庄大道。编制小组肩负着这一使命，于是编制了《中药采购规范》标准文件。

本文件不仅是中医医疗服务体系的重要组成部分，而且是中药药事服务管理的源头。把好中药质量入口关，鉴别中药的真伪优劣，不仅是保障中药质量和临床用药安全的重中之重，而且是民生用药安全与有效的首要环节。目前，国际上对中药采购及验收尚未形成统一标准和规范。因此，亟需构建一套切实可行的中药采购标准体系，规范中药材、中药饮片采购全过程。本文件对812种常用中药材和1054味常用中药饮片，提出了质量验收要求，以及中药采购人员的资质要求，职业操守和规程，及其入库验收的流程，监管中药采购全过程，切实保障中药质量，确保民众用药安全与有效。

本文件由江西中医药大学牵头，联合江西省中医药管理局、深圳市卫生健康委、深圳市人民医院、深圳市第二人民医院、深圳市中医院、香港位元堂药厂有限公司、江西省中医院、江西江中中药饮片有限公司等主要起草单位负责起草。

本文件规定了中药采购人员的资质要求、采购规程、入库验收的流程及验收标准，确保采购过程的标准化和专业化，切实保障中药质量，确保民众用药安全与有效。

二、标准起草过程简介

（一）预研阶段：2016年至2017年，江西中医药大学组织专家在研究论证的基础上提出项目制定建议。专家组从12项深圳地方标准遴选出亟待于解决的中药采购的难题，为了更好地规范医药采购流程，保障药品质量，保证人民的用药安全。2018年6月，召开中药系列标准的遴选论证会。

（二）立项阶段：世界中医药学会联合会对江西中医药呈报的项目建议进行必要的可行性分析和充分论证，于2021年7月19日世界中医药学会联合会发布的《世界中医药学会联合会国际组织标准立项通知》，确认本文件《中药采购规范》的立项。

（三）起草阶段：本文件2017年1月开始起草工作，通过拟定标准内容的构成和起草依据，标准起草工作组收集有关资料、进行专题调查研究和必要的试验验证，按照标准编写要求，编写标准草案（征求意见稿）、编制说明，提出标准征求意见稿，征求海内外相关专家的意见和建议。根据专家的意见和建议，对文本进行了大量的修改、完善，形成了向世界中医药学会联合会申报的草案。

三、主要技术内容介绍

本文件为中药材、中药饮片采购全过程质量标准体系而定，规定了中药采购人员的资质要求及职业操守、采购规程、入库验收的流程及验收标准。本《规范》分为总则、附录2个部分。通则部分：提纲挈领地介绍了《中药采购规范》的通则，包括范围、规范性引用文件、术语与定义、人员资质要求和职业要求、中药采购操作流程以及入库验收的程序及质量要求。

附录部分：附录A(规范性附录)常用中药材质量性状鉴别验收要求；附录B(规范性附录)

常用中药饮片质量性状鉴别验收要求。附录部分品种目录来源于ISO 18668-2《中医药-编码系统 第二部分：中药饮片的编码》中药饮片828种、ISO 18668-3《中医药-编码系统 第三部分：中药材的编码》592 种，并根据常用用药目录参考中华人民共和国国家标准GB31774-2015《中药编码规则及编码》进行补充，最终确定附录A常用中药材812种，附录B常用中药饮片1054味。附录部分凸显了中医药的传承发展与创新发展；本文件一方面记载了812种常用中药材、1054味常用中药饮片的传统性状的经验鉴别要求，传承了中药传统的经验技术和鉴定中药真伪优劣的方法，系统总结了中药材及饮片的传统鉴别特征，使中药采购人员能快速掌握简、便、验、廉的验收方法。另一方面，它与国际标准中药编码相结合,形成了无缝衔接，确保了中药名称的“一名一物一码”，名、物、码的结合，保证了采购、使用中药名称的一致性、可靠性和准确性，以及中药贸易的公平、公正，信息交换的公开透明和一致性。

本文件与ISO 18668-1 《中医药-编码系统 第一部分：中药编码规则》、ISO 18668-2《中医药-编码系统 第二部分：中药饮片的编码》、ISO 18668-3《中医药-编码系统 第三部分：中药材的编码》和ISO 20333《中药在供应链管理中的编码与表示》、ISO 22217《中医药-中药材、中药饮片贮藏规范》,《中药处方书写要求》（SCM 0052-2020~SCM 0056-2020）等 5 项标准相衔接，其作为以上标准的有益补充，可促进完善中药材、中药饮片流通环节的全过程可追溯体系，形成产品质量追溯机制，提高中药产品质量和核心竞争力，保障消费者权益，确保用药安全、有效，并以此推动“互联网+中医药服务”领域的标准化、信息化和现代化进程。

四、重大分歧意见的处理经过和依据

本标准的制定过程中出现的分歧意见，主要集中在“附录B：常用中药饮片质量性状鉴别验收要求”方面，对如何将药材品名和饮片品名进行一一准确归类和对应方面，在标准制定之初，专家对药材品名和饮片品名两个概念内涵与外延提出了一些意见和建议。本标准起草工作组根据“中药材和中药饮片的区别”要则，即“3同3不同”（3同：来源相同、性状相同、鉴别反应相同；3不同：处方应付不同、加工方法不同、监管方法不同），对药材品名和饮片品名进行了规范细分，明确了一种中药材可以包含多种中药饮片。比如，根据上述原则，将“卷柏”归属药材品名，“卷柏炭”归属饮片品名；再如，药材品名“益智”包含“益智仁、炒益智仁、盐益智仁”等3种饮片品名。所以，一种药材通过加工炮制可以产生不同性味归经的中药饮片，我们使用“味”作为本标准的传统沿用习惯，尤其在中药处方的饮片给付方面体现了这一特点，并以标准的形式固化下去，传承下来。

五、其它应予说明的事项

本标准一旦出版，江西中医药大学将为项目实施提供必要的组织保障和经费保障，加强组织领导和团队建设，配合项目负责人带领项目组成员在现有基础上全面完善编写工作，根据临床遣方用药的流程分别对中药处方、调剂、给付与煎煮进行标准。使标准有助于中医药行业的有序发展，节约医疗的成本，更好的服务百姓，使之为当今的产业结构调整和转型升级提供技术支撑。

I. Background of Standard Drafting

Standards are not only an important symbol of the maturity of a discipline, but the principle for measuring objective things. They are the core elements of a country's strategic resources and international competitiveness, the technical support for the all-round development of economy, society, culture, and science and technology, and the engine for achieving the strategic goals of building Chinese quality, constructing an honest society, and implementing refined management. To enable people from all over the world to understand, recognize, experience and accept traditional Chinese medicine (TCM), and to widely use TCM for disease prevention and treatment to benefit human health, the standardization of TCM is a shortcut–a royal road. Bearing this mission, the compilation team developed the standard document *Specifications for Procurement of Chinese medicines*.

The document is not only an essential component of the medical service system of TCM, but the origin of management of pharmaceutical affairs service of Chinese medicine. Ensuring the quality of TCM at the entry point and differentiating the authenticity and quality of Chinese medicine are not only of the utmost importance for guaranteeing the quality of Chinese medicine and the safety of clinical medication but the primary link for the safety and effectiveness of medications related to people's livelihood. Currently, there is no unified standard or specification for procurement and acceptance of Chinese medicine on the international stage. Therefore, there is an urgent need to establish a set of practical procurement standard systems for Chinese medicine to regulate the entire process of procuring Chinese medicinal materials and Decoction Pieces.

The document has put forward quality acceptance requirements for 812 commonly-used Chinese medicinal materials and 1,054 commonly-used Decoction Pieces, along with the qualification requirements, professional ethics, and operating procedures for procurement personnel of Chinese medicine, as well as the warehousing acceptance process. It oversees the entire procurement process of Chinese medicine to ensure the quality of Chinese medicine and the safety and effectiveness of medications for the public.

This document was led by Jiangxi University of Chinese Medicine and jointly drafted by major drafting units including Jiangxi Provincial Administration of Traditional Chinese Medicine, Shenzhen Municipal Health Commission, Shenzhen People's Hospital, Shenzhen Second People's Hospital, Shenzhen Traditional Chinese Medicine Hospital, Wai Yuen Tong

Medicine Manufactory Limited (Hong Kong), Jiangxi Provincial Hospital of Traditional Chinese Medicine, and Jiangxi Jiangzhong Decoction Pieces Co., Ltd.

This document stipulates the qualifications for procurement personnel of Chinese medicine, procurement procedures, process and acceptance standards for warehouse entry inspection, ensuring the standardization and specialization of procurement process, effectively guaranteeing quality of Chinese medicine, and ensuring safety and effectiveness of medications for the public.

II、Introduction to the Drafting Process for Standard

(1)Preliminary Research Stage: From 2016 to 2017, Jiangxi University of Chinese Medicine organized experts to put forward suggestions for project formulation based on research and demonstration. The expert group selected the urgent problems in Chinese medicine procurement from 12 local standards in Shenzhen, aiming to better regulate the pharmaceutical procurement process, ensure drug quality, and guarantee safety of people's medication. In June 2018, a selection and demonstration meeting for the series of Chinese medicine standards was held.

(2) Project Establishment Stage: The World Federation of Chinese Medicine Societies conducted necessary feasibility analyses and comprehensive demonstrations on the project suggestions submitted by Jiangxi University of Chinese Medicine. On July 19, 2021, the World Federation of Chinese Medicine Societies released the *Notice on the Project Initiation of the International Organization Standards of the World Federation of Chinese Medicine Societies*, confirming the project establishment of this document *Specifications for Procurement of Chinese Medicines..*

(3) Drafting Stage: The drafting work of this document commenced in January 2017. By formulating the composition of the standard content and drafting basis, the working group for standard drafting collected relevant materials, conducted special investigations and necessary experimental verifications. In accordance with the requirements for standard compilation, it compiled the draft standard (for soliciting opinions), compilation instructions, and formulated the draft standard for soliciting opinions to solicit opinions and suggestions from relevant experts at home and abroad. Based on the opinions and suggestions of the experts, a large number of modifications and improvements were made to the text, forming a draft to be submitted to the World Federation of Chinese Medicine Societies.

III. Introduction to the Main Technical Contents

This document is formulated for the quality standard system of the entire process of procuring Chinese medicinal materials and decoction pieces. It stipulates the qualification requirements and professional ethics of procurement personne of Chinese medicine, procurement procedures as well as the process and acceptance standards for warehouse entry inspection. This “Specification” is divided into two parts: General Principles and Appendix. The part of General Principles concisely introduces the general rules of the *Specifications for Procurement of Chinese Medicines*, covering scope, normatively referenced documents, terms and definitions, personnel qualifications and professional requirements, procurement procedures of Chinese medicine, and procedures and quality requirements for warehouse entry inspection.

Appendix Part:

Appendix A (Normative Appendix) *Requirements for Quality Character Identification and Acceptance of Commonly-used Chinese Medicinal Materials*; Appendix B (Normative Appendix) *Requirements for Quality Character Identification and Acceptance of Commonly-used Decoction Pieces*. The variety catalog in the appendix part is sourced from ISO 18668-2 *Traditional Chinese Medicine—Coding Systems PartII: Coding of Decoction Pieces* which contains 828 kinds of decoction pieces, and ISO 18668-3 *Traditional Chinese Medicine - Coding Systems Part III: Coding of Chinese Medicinal Materials,* which contains 592 kinds. Supplementary content is added according to the commonly used drug catalog with reference to the national standard of the People's Republic of China GB 31774-2015 *Coding Rules and Codes for Chinese medicine*. Eventually, 812 kinds of commonly used Chinese medicinal materials are determined for Appendix A, and 1,054 kinds of commonly used decoction pieces are determined for Appendix B. The appendix part highlights the inheritance, development, and innovation of Chinese medicine.On the one hand, this document records the empirical identification requirements for the traditional characters of 812 kinds of commonly-used Chinese medicinal materials and 1,054 kinds of commonly-used decoction pieces, inheriting the traditional empirical techniques of Chinese medicine and the methods for identifying the authenticity and quality of Chinese medicine, and systematically summarizing the traditional identification features of Chinese medicinal materials and decoction pieces, enabling procurement personnel of Chinese medicine to quickly master simple, convenient, effective

and inexpensive acceptance methods. On the other hand, it is combined with the international standard coding of Chinese medicine to form a seamless connection, ensuring "one name, one substance, one code" for names of Chinese medicine. The combination of name, substance and code guarantees the consistency, reliability and accuracy of the names of Chinese medicine used in procurement, as well as the fairness and impartiality of trad of Chinese medicine, and the openness, transparency, and consistency of information exchange.

This document is interconnected with five standards, namely ISO 18668-1 *Traditional Chinese Medicine—Coding Systems Part I: Coding Rules for Chinese Medicine*, ISO 18668-2 *Traditional Chinese Medicine—Coding Systems Part 2: Coding for Decoction Pieces*, ISO 18668-3 *Traditional Chinese Medicine—Coding Systems Part 3: Coding of Chinese Medicinal Materials*, ISO 20333 *Coding and Representation of Chinese Medicine in Supply Chain Management*, and ISO 22217 *Traditional Chinese Medicine—Storage Specifications for Chinese Medicinal Materials and Decoction Pieces*, as well as *Requirements for the Prescription Writing of Chinese Medicine* (SCM 0052-2020~SCM 0056-2020). Serving as a beneficial supplement to the above standards, it can contribute to the improvement of the whole-process traceability system in the circulation of Chinese medicinal materials and decoction pieces, establish a product quality traceability mechanism, enhance the quality and core competitiveness of Chinese medicinal products, safeguard the rights and interests of consumers, ensure the safety and effectiveness of medication, and thereby propel the standardization, informatization and modernization processes in the field of "Internet+TCMServices".

IV. Handling Process and Basis of Major Discrepant Opinions

During the formulation of this standard, the discrepant opinions mainly centered on *Appendix B: Requirements for Quality Character Identification and Acceptance of Commonly-used Decoction Pieces*, specifically regarding how to accurately classify and correspond the names of medicinal materials and the names of decoction pieces one by one. At the beginning of the standard formulation, experts put forward some opinions and suggestions on the connotations and denotations of the two concepts of the names of medicinal materials and the names of decoction pieces.Based on the principle of *Differences between Chinese Medicinal Materials and Decoction Pieces*, namely "Three Similarities and Three Differences" (Three Similarities: the same origin, properties and characters, and

identification reactions; Three Differences: different dispensing in prescriptions, processing methods and supervision methods), the drafting working group of this standard carried out standardized subdivision of the names of medicinal materials and the names of decoction pieces, clarifying that one type of Chinese medicinal material can contain multiple types of decoction pieces. For example, according to the above principles, “Selaginella tamariscina” is classified as the name of a medicinal material, and “Carbonized Selaginella tamariscina” is classified as the name of a decoction piece. Another example is that the name of the medicinal material “Alpinia oxyphylla” encompasses three names of decoction pieces, namely “Fructus Alpiniae Oxyphyllae”, “Stir-fried Fructus Alpiniae Oxyphyllae”, and “Salted Fructus Alpiniae Oxyphyllae”. Therefore, one type of medicinal material can produce decoction pieces with different natures, flavors, and meridian tropisms through processing and concocting. We use “flavor” as a traditionally followed convention in this standard, which is especially reflected in the dispensing of decoction pieces in Chinese medicine prescriptions and has been solidified and passed down in the form of a standard.

V. Other Matters Needing Explanations

Once this standard is published, Jiangxi University of Chinese Medicine will provide necessary organizational and financial guarantees for the implementation of the project. It will strengthen organizational leadership and team building, and cooperate with the project leader to lead the team members to comprehensively improve the compilation work on the existing basis. Standards will be formulated for Chinese medicine prescriptions, dispensing, dispensing of decoction pieces and decoction respectively according to the process of prescribing and using medicine in clinical practice. This will make the standard conducive to the orderly development of the TCM industry, save medical costs, better serve the public, and provide technical support for the current industrial structure adjustment, transformation, and upgrading.