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Chinese Pharmacopoeia Commission

China Medical Science Press

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(2015)

Volume Ⅳ

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Preface

The Pharmacopoeia of the People's Republic of China 2015 Edition (hereinafter referred to as the "*Chinese Pharmacopoeia*") is the 10th edition of Chinese Pharmacopoeia. All members of the Chinese Pharmacopoeia Commission (ChPC) and the staffs of its permanent institution have worked diligently to complete the compilation of Chinese Pharmacopoeia 2015 edition in accordance with the guiding concepts, basic principles, objectives and requirements set by the Pharmacopoeia Compilation Outline adopted at the Founding Ceremony and Plenary Session of the 10th Chinese Pharmacopoeia Commission under the leadership of the China Food and Drug Administration (CFDA), the vigorous support and assistance of drug control institutions, research institutions and universities at various levels, as well as the proactive participation and coordination of drug manufacturers. On February 4, 2015, the Plenary Session of the Executive Committee of the 10th Chinese Pharmacopoeia Commission adopted this edition of pharmacopoeia, which was approved by the CFDA on June 5, 2015 and came into effect as of December 1, 2015.

The Chinese Pharmacopoeia (ChP) 2015 edition comprises volumes Ⅰ, Ⅱ, Ⅲ and Ⅳ and contains a total of 5,608 monographs, including 1,082 new monographs. Volume Ⅰ contains a total of 2,598 monographs of medicinal materials and the prepared slices of Chinese crude drugs, vegetable, oil fat and extracts, single-item preparations, etc., including 440 new monographs, 517 revisions and seven rejections. Volume Ⅱ contains a total of 2,603 monographs of chemical drugs, antibiotics, biochemical drugs and radioactive drugs, including 492 new monographs, 415 revisions and 28 rejections. Volume Ⅲ contains a total of 137 biologics, including 13 new monographs, 105 revisions and six rejections. In order to address such problems as repetitive inclusion of testing methods and lack of coordination, consistency and standardization among various methods, this edition of pharmacopoeia has integrated the common appendices of various volumes of pharmacopoeia and renamed the original appendices into General Chapters, including general requirements of preparations, testing methods, standard substances, reagents and guidelines. A standard coding system has been established, the general chapters and pharmaceutical excipients have been separately included into volume Ⅳ of the Chinese Pharmacopoeia. Volume Ⅳ contains a total of 317 general chapters, including 38 general requirements for preparations, 240 testing methods, 30 guidelines and nine standard substances and testing solutions and reagents; 270 monographs of pharmaceutical excipients, including 137 new monographs, 97 revisions and two rejections.

This edition of pharmacopoeia is characterized by the following features:

The number of included products has been significantly increased. The scope of products included has been further expanded to initially achieve the full coverage of biologics in the Catalogue of National Essential Medicines and more than 90% of coverage for tradition Chinese medicine (TCM), and chemical drugs. Adjustment has been intensified for certain products with incomplete standards, suspension of manufacturing for many years, excessive clinical adverse reactions and unreasonable dosage forms. This edition of

pharmacopoeia no longer contains a total of 43 products originally included under the ChP 2010 edition.

The pharmacopoeia standard system has been further improved. Various appendices of the previous version of pharmacopoeia have been integrated into the volume Ⅳ of this edition of pharmacopoeia. The revision has improved the pharmacopoeia standard system with general notice, general chapters and monographs as overall, basic and specific requirements respectively. For the first time, it has included "Guidelines for Preparation of Pharmaceutical Standard Substances of China", "Guidelines for General Requirements for Drug Packaging Materials and Containers" and "Guidelines for Pharmaceutical Glass Materials and Containers", and created a more comprehensive pharmacopoeia standard system encompassing drug substances and their preparations, pharmaceutical excipients, drug packaging materials and standard substances.

The application of modern analytical technology has been expanded. On the basis of retaining conventional testing methods, this edition of pharmacopoeia has further expanded the application of new technologies and new testing methods to increase the sensitivity, specificity and stability of testing. The following methods have been employed for the quality control of TCM, including liquid chromatography, tandem mass spectrometry, high-performance liquid chromatography, inductively coupled plasma mass spectroscopy, etc. The following methods of quality control have been employed for chemical drugs, including supercritical fluid chromatography, liquid chromatography at critical condition, powder x-ray diffraction, etc. In addition, the new edition of pharmacopoeia has also adopted capillary electrophoresis for the testing of molecular isomers of monoclonal antibody products, and adopted high-performance liquid chromatography for the testing of molecular size distribution of antitoxin and antiserum product, etc. For the reserves of testing technology, the new version of pharmacopoeia has established method for DNA barcode molecular identification of Chinese herbal medicine, pigment testing method, method for testing of fungal toxin in TCM, near-infrared spectrum method, drug evaluation technology based on gene chip, etc.

Drug safety assurance has been further improved. The new edition of pharmacopoeia has improved "General Principle for Inspection of Crude Drugs and Decoction Pieces", "The Processing of Crude Drugs" and "General Requirements for Pharmaceutical Excipients"; and newly included "General requirements for National Pharmaceutical Reference Standards", "Requirements for Quality Control of the Raw Materials and Excipients Used for the Biologics Production", "General Monograph for Vaccines for Human Use", "General Monograph for Recombinant Monoclonal Antibody Products", etc., and newly included relevant guidelines for microparticle preparations, drug crystal form research and crystal form quality control, establishment of limit for harmful residue of TCM. Volume Ⅰ has set the limits for sulfur dioxide residues in Chinese herbal medicines and prepared slices of Chinese crude drugs, established the limits for harmful elements in marine drugs such as pearls and seaweeds, set inspection standards for 16 pesticide residues including organic chlorine in ginseng and American ginseng products, and newly included the inspection item and limit of "aflatoxin" for 14 Chinese herbal medicines and the prepared slices of Chinese crude drugs including Platycladi Seed. Volume Ⅱ has further strengthened the control of relevant substances, enhanced the system applicability requirements of testing methods, and included the structural information of about 500 impurities; included the control of chiral impurity; included osmolarity testing for intravenous infusion and eye drops and control requirements for antimicrobial agents in injections and eye drops. Volume Ⅲ has enhanced quality control of raw materials and excipients used for the biologics production, standardized the use of antimicrobial agents, and strengthened the control of residual

solutions; included the osmolarity testing, revised the genome sequence testing of virus seed lot used for the vaccine production and stricted the limits for bacterial endotoxin.

Drug efficacy control has been further improved. Testing methods have been revised in a comprehensive manner. Volume Ⅰ has included the specificity microscopic identification and inspection of Chinese herbal medicines and the testing of characteristic amino acid content, etc., established characteristic spectrums for more than 30 standards including the root of red-rooted salvia. Volume Ⅱ has adopted iron chromatography for the testing of acid group content in sulfate or hydrochloride drug substances; adopted methods with greater specificity and accuracy for the testing of preparation content; revised the methods for the inspection of the solution and releasing rates, and strengthened control of oral solid dosage forms and modified-release preparations.

Standards for pharmaceutical excipients have been significantly improved. This edition of pharmacopoeia has included multiple specifications of pharmaceutical excipients in series to meet the needs of pharmaceuticals manufacturing. twenty-one injection-grade excipients have been newly included. Safety control has been enhanced for pharmaceutical excipients such as inclusion of control requirements for residual solutions. Greater attention has been paid to the functional evaluation of excipients. For instance, such inspection items as multi-porosity, powder fineness, powder flow ability, specific surface area and viscosity have been included and the requirements for the research of applicability of standards for pharmaceutical excipients have been enhanced.

Guiding effect of pharmacopoeia has been further strengthened. Guiding effect of this edition of pharmacopoeia for drug quality control has been enhanced through the screening and adjustment of products, adopting the advanced testing methods and formulation of technical guidelines; meanwhile, in light of the tendencies of international drug quality control and standardization as well as the realities of drug manufacturing in China, equal emphasis has been given to the safety and accessibility of medications in the configuration of inspection items and limits in order to guide the sound and science-based development of pharmaceutical industry in China.

This new edition of pharmacopoeia continues to follow the concepts of protecting the wildlife and environment and adhering to the sustainable development and promotion of green standards for TCM. For instance, newly included prescriptions no longer contain the Chinese patent medicines of endangered species or fossils such as leopard bone, antelope's horn, fossil fragments and dens draconis; replacements of toxic solutions in testing reagents are advocated, e. g., the use of reagents containing benzene and mercury is abolished in order to reduce pollution to the environment and laboratory personnel.

The new edition of pharmacopoeia has been drafted in a more public, transparent, standardized and orderly manner. Drafting process of this edition of pharmacopoeia has always adhered to the principles of openness, fairness and justice. The permanent institution of the ChPC has introduced the ISO9001 quality management system (QMS) into the whole-process management of pharmacopoeia standards development, continuously improved administrative system for ChPC and standardized working procedure for pharmacopoeia drafting to ensure the quality of pharmacopoeia developing process. ChPC has vigorously promoted drug standards and scientific research to ensure the progress and quality of pharmacopoeia drafting. Efforts have been made to strictly follow the "working procedure for the developments of ChP", improve the communication and coordination among professional committees, and

enhance the review and publication of standards. All the additions and revisions of standards have been published at the website of ChPC and the results of expert review and feedback comments have been published as well.

On the basis of maintaining scientificity and standardization of pharmacopoeia, this edition of pharmacopoeia emphasizes on enhancing the control requirements of drug safety and efficacy, referencing internationally advanced quality control technologies and experiences, improving the level of this edition of pharmacopoeia, and reflecting current situations on pharmaceutical development and testing technologies in China. It will also play an important role on promoting drug quality improvement, accelerating corporate technology progress and product upgrades, expediting the healthy development of pharmaceutical industry and increasing the authoritativeness and international influence of the Chinese pharmacopoeia in China.

Chinese Pharmacopoeia Commission

June 2015

History of the Pharmacopoeia of the People's Republic of China

***Chinese Pharmacopoeia* 1953 Edition (First Edition)** The Chinese Communist Party and the Chinese Government have attached great importance to medical and health-care for the Chinese people. The People's Republic of China was founded on October 1, 1949 and right in November of that year, the Ministry of Health convened a meeting of medical and pharmaceutical experts in Beijing on the compilation of a pharmacopoeia. In January 1950, the Ministry of Health invited Professor Meng Mudi, a well-known pharmacist from Shanghai, to take up the responsibility for the establishment of the Editorial Commission of Pharmacopoeia of China and its secretariat to deal with daily work concerning the compilation of such a compendium for new China.

In April 1950, a working seminar was held in Shanghai, at which the principles and guidelines on the selection of monographs were discussed and the monographs to be included in the Pharmacopoeia were decided. It was recommended under the direction of the Ministry of Health that the new Pharmacopoeia should be compiled in such a way that it is in conformity with the Chinese situations and that it should be nationalistic, scientific and popular in nature. Thereafter, The Ministry of Health invited 49 experts as members and 35 as correspondent members of the Commission who were appointed to 8 panels (nomenclature, chemicals, pharmaceutical preparations, medicaments of plant origins, biological products, medicaments of animal origins, pharmacology, and dosage) respectively. Health Minister Li Dequan served as the chairperson of the Commission. The first Editorial Commission of Pharmacopoeia of the People's Republic of China was thus formally established.

The first Editorial Commission meeting composed of all members was held in Beijing April 24-28, 1951, where resolutions were made on the title of the Pharmacopoeia, list of selected monographs, the nomenclatures, units of measurement and weights, format, the order of arrangement etc. Based on recommendations from the Commission meeting, the draft of the pharmacopoeia was then revised by the secretariat and submitted to the Ministry of Health for review and the Culture and Education Commission of the State Council for approval at the end of 1952. The Ministry of Health published the first *Chinese Pharmacopoeia* in 1953.

Chinese Pharmacopoeia 1953 edition contained 531 monographs of substances and articles, including 215 chemicals, 65 medicaments from plant origins, oils and fats, 13 medicaments from animal origins, 2 antibiotics, 25 biological products, and 211 pharmaceutical preparations. After the publication of the Pharmacopoeia, the first addendum of the 1953 edition was published in 1957.

***Chinese Pharmacopoeia* 1963 Edition (Second Edition)** The Ministry of Health set up the second Pharmacopoeia Commission in 1955, with 49 members and 68 correspondent members. Due to various

reasons, this Commission failed to fulfill its mission. The third Commission was established in 1957, with 80 members (no correspondent members appointed) and Professor Tang Tenghan, a well-known pharmaceutical chemist, as its chairman. The first meeting of the third Commission was convened from July 28 to August 5 of the same year. Health Minister Li Dequan pointed out at the meeting that it was a big flaw that the first Pharmacopoeia did not cover Chinese traditional medicines that the Chinese people were so used to. At the meeting principles in compiling a Pharmacopoeia were made and nature and purpose of such a compendium were discussed and constitution of the Commission was revised. It was agreed unanimously to admit well-defined Chinese traditional medicines to the Pharmacopoeia. On August 27, six expert committees and a panel under the Commission were approved and set up by the Ministry of Health, namely, the committees of medicines, chemicals, pharmaceutical preparations, biochemicals, pharmacognosy and biological products, and a panel of nomenclature. Under the Commission a Standing Committee was organized, however, routine work in general was dealt with by its Secretariat.

In 1958, it was recommended by the Standing Committee and approved by the Ministry of Health to invite 8 doctors of Chinese traditional medicine and 3 experts of Chinese traditional medicaments as members of an expert committee dealing with the quality specifications of crude drugs used as Chinese traditional medicaments and Chinese patent preparations. Collaborative efforts were made by experts in this field in many parts of this country to incorporate the theory and practical experience of Chinese traditional medicine into the monographs concerned.

The second meeting of this Commission was held in Beijing from June 25 to July 5, 1959. A list of monographs being admitted to the new Pharmacopoeia was proposed and the draft texts reviewed in detail by the expert committee concerned. The work was accomplished in 1962. The State Council approved the publication of *the Pharmacopoeia of the People's Republic of China* 1963 edition. On January 26, 1965, the Ministry of Health issued a document for the *Chinese Pharmacopoeia* 1963 edition and the relevant provisions for its implementation.

The Chinese Pharmacopoeia 1963 edition contained 1310 monographs in its two volumes, each with separated General Notices and relevant appendices. 446 monographs of commonly used Chinese traditional medicaments and 197 monographs of Chinese traditional patent preparations were admitted to Volume Ⅰ, and 667 monographs of chemical drugs were admitted to Volume Ⅱ. Additionally, "therapeutic function and chief indication" were stated in the monographs admitted to Volume Ⅰ and "action and use" of those admitted to Volume Ⅱ.

***Chinese Pharmacopoeia* 1977 Edition (Third Edition)** The Pharmacopoeia Commission stopped functioning in 1966 due to the turmoil caused by the "Cultural Revolution". On April 28, 1972, the State Council agreed to the suggestion in the report of the Ministry of Health that "the Commission should be re-established with the participation of Ministries of Health, Petroleum and Chemical industry, Commerce and the PLA's Ministry of Health, headed by the Ministry of Health". A working meeting of the Pharmacopoeia Commission was convened under the above direction from May 31 to June 10 of the same year in Beijing. 88 Representatives of various competent authorities and organizations, including all Provincial (Autonomous regional or Municipality under the Central Government) Departments of Drug Policy and Management, Institutes for Drug Control and others attended the meeting. The focus of the meeting was on the guiding principle, working process, requirements and objects of the editing of the national Pharmacopoeia. The revision plan was recommended after exchange of past experiences in various aspects. Arrangements were made for the drafting of individual monographs by the