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Editorial

Implementation of Pharmacopoeia Regulations

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Pharmacopoeia, pharmacopeia, or pharmacopoea, is a law book containing directions for the identification of compound medicines, and published by the authority of a government or pharmaceutical society under a government or an organization (such as World Health Organization, WHO). As a national pharmacopoeia, it is engaged in the practice of pharmacy, and therefore competent rather to decide upon the kind of preparations required than upon the method of their manufacture.

There are the national pharmacopoeias, like *the Chinese Pharmacopoeia*, *the EU Pharmacopoeia* and *the U.S. Pharmacopoeia*. The necessity for this element in the construction of a pharmacopoeia that meets periodically that is largely constituted by physicians, pharmacists, and other public health professionals, setting standards published. In most of which pharmaceutical products are represented on applicable quality standard for monograph, drugs and drug ingredients must conform to the compendial requirements (such as for strength, quality or purity) or be deemed adulterated or misbranded under the national drug laws.

The Pharmacopoeia of the People's Republic of China 2015 version (*Chinese Pharmacopoeia 2015*) is recognized by the WHO as the official *Chinese Pharmacopoeia 2015* presided by the China Food and Drug Administration, completed by the 10th Pharmacopoeia Commission, and published by China Medical Science and Technology Publishing House in 2015. It is an official compendium of drugs, covering Chinese materia medica (CMM), chemical medicines, and biological medicines which include the information on the standards of purity, description, test, dosage, precaution, storage, and the strength for each drug. The new pharmacopoeia is engaged in adhering to scientific, practical, standardized, drug safety and quality control, and standards of the advanced nature of principle, and seeking to cover the species and social health insurance reimbursement catalogs kinds in *National Essential Drugs List*.

In the review titled "Revision and Improvement of Criterion on Traditional Chinese Medicines in *Chinese Pharmacopoeia* 2015" (CHM 2016, 7(3): 196-208), the authors introduced the revision and improvement of quality evaluation and control standards of traditional Chinese medicines in Part one of *Chinese Pharmacopoeia 2015*. The *Chinese Pharmacopoeia* showed that biotechniques have been widely used in an overview of chemical characterization of CMM.

Authors suggested that although the achievements have been obtained, the quality evaluation and control system of CMM are still far away from the essence of the theory on traditional Chinese medicine (TCM), and it is a challenge to evaluate the medicinal property and efficiency of CMM in the view of the theory on TCM using current techniques.

It is also a challenge to international pharmacopoeia regulation and *Good Pharmacopoeia Practice* (GPhP). We know that the drug regulation is a multi-faceted activity, in which the pharmacopoeia plays a special role in Drug Administration. Today, the GPhP regulation is being implemented, and also increasingly subject to international attention. Therefore, the establishment of regulational pharmaceutical preparation is very necessary.

On March 4 2016, a document was issued by the China State Council for promoting the healthy development of the pharmaceutical industry. It is said to improve *Pharmacopoeia of People's Republic of China* is the core of the national drug standards and the basic quality standards. The improvement of scientific rationality and operability of the standard, as well as the enhancement of the authority and seriousness of the standard are significant, especially, for the specifications and the importance of quality control standards of traditional herbs and folk medicines and these productions as well. Therefore, the *Chinese Pharmacopoeia* is the fundamental law in pharmacy, to align with which pharmaceutical enterprises should direct and supervise the production process in the field from manufactory to market. To require the State to ensure the strategic security of the national drug products is safe, effective, and controllable quality. It is the mandate and responsibility, especially to improve the sustainable development of Chinese medicinal products. While it is a long way to go for the implementation of the regulations of pharmacopoeia.