

Vision to Global Pharmacopeia: Convergence and Upcoming Development of Biological Chapters in Chinese Pharmacopoeia

Chinese Pharmacopoeia Commission

Zhong ping Guo

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About Chinese Pharmacopoeias(ChP)

Structures and Contents of ChP

- ▶ Vol. I : Traditional Chinese Medicines (2598 monographs)
- ▶ Vol. II : Chemicals(2603 monographs)
- ▶ Vol. III: Biological Products (137 monographs)
- ▶ Vol. IV: Excipients and Test Methods (317monographs)

Total of 5608 Monographs included

About Chinese Pharmacopoeias(ChP)

Origin, Role and Position

- ▶ ChP (Vol III) has been developed more than 60 years since its initial establishment. The Chinese Biological Regulations (CBR) was first published in 1951, and the ChP (Vol III:Biological Products) in 2005.
- ▶ ChP is prepared and promulgated according to *the Drug Administration Law of the People's Republic of China*, it is official and compulsory quality standards for all medicinal products marketed in China.
- ▶ ChP includes the basic technical requirements for the quality control and test methods, and legally recognized for the manufacturing, supply, use and supervision of medicinal products in China.

About Chinese Pharmacopoeia (ChP)

Main body and Structure of ChP (Vol III)

- ▶ General Notices
- ▶ General Requirements:10
- ▶ General monographs:4 (Recombinant DNA Technology Products, Monoclonal Antibodies, Vaccines for Human Use, Probiotics)
- ▶ Monographs:137 (All are Drug Products. Vaccine: 48, Human Plasma Preparation:18, Animal Sera preparation:18, Recombinant DNA Products:40, Diagnostic Reagents:11, Others:2)
- ▶ General Chapters:
 - Preparations
 - Test Methods
 - Special Materials used during manufacturing
 - Guidance

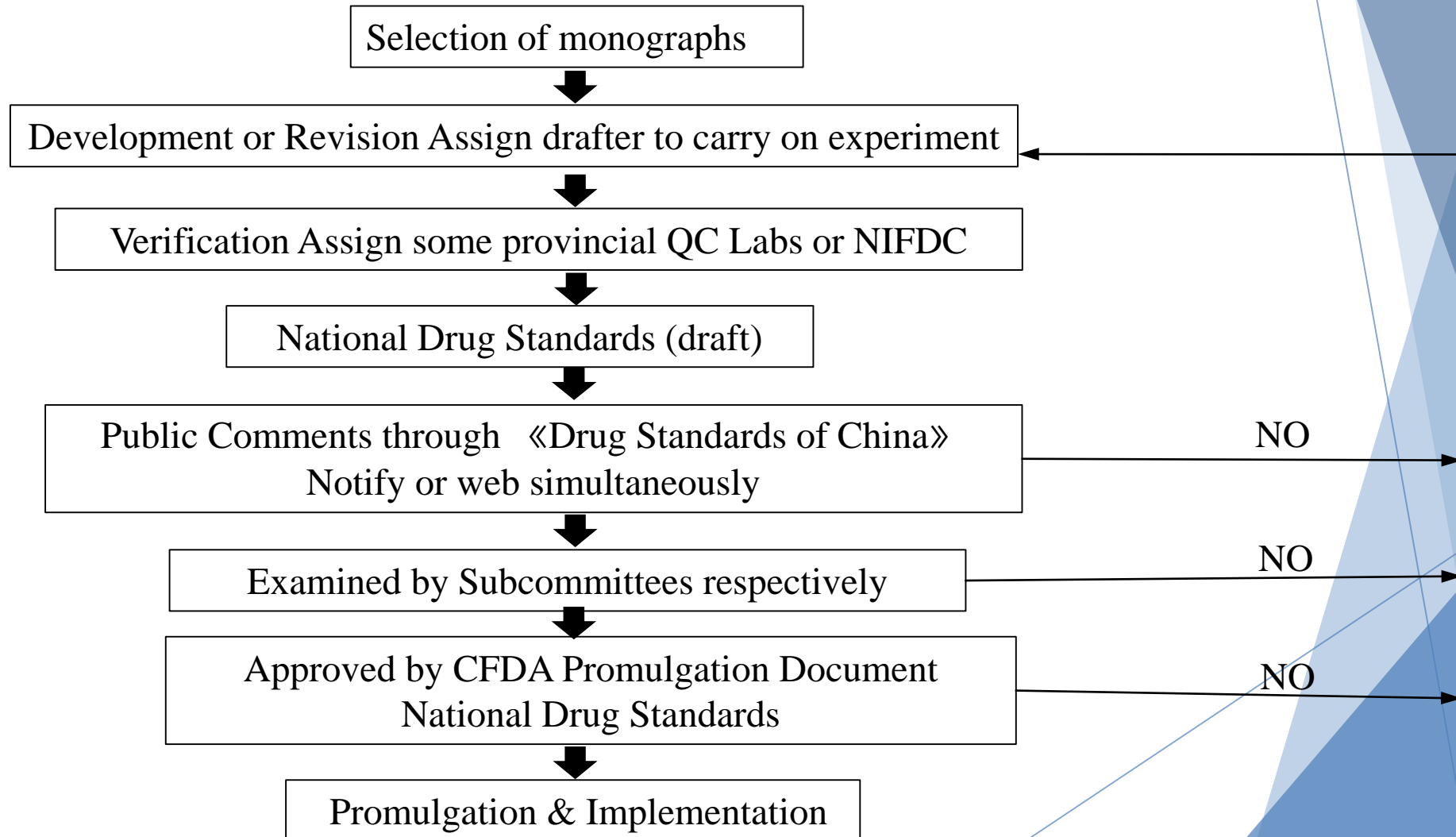
About Chinese Pharmacopoeia (ChP)

Establish of ChP

- ▶ Organization: Chines Pharmacopoeia Commission(ChPC),affiliated with CFDA
- ▶ The 11th Session Chinese Pharmacopoeia Commission (2015--2020):
 - An executive Committee, 26 Professional Committees
 - Total of 406 members
 - 4 Professional Committees for Biological Products (37 members)
- ▶ Quality Policy:
 - Scientificity & advancement
 - Adequacy & Normalization
 - Openness and Fairness
 - High-quality & High-efficient
- ▶ The principles of monograph selecting :
Quality/Efficacy/Safety /Essential

About Chinese Pharmacopoeia (ChP)

Establishment Procedure for National Drug Standards



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Vision to Global Pharmacopeia

- 1、 The 13th Five-Year Plan (2015-2020) for drug safety in China: strengthen drug safety supervision, ensure public safety medication, promote healthy China construction
 - ▶ improve and develop technical standards
 - establish ChP comparing with international advanced level
 - enable the standard of biological products is close to the international advanced level.
 - establish the drug standard elimination mechanism.
 - ▶ Continue to implement Drug standards improvement action plans: develop and revise
 - monographs
 - test methods
 - general chapter
 - guidance

Vision to Global Pharmacopeia

2. Harmonization and Collaboration:

- ▶ With China becoming the member of ICH, further improving to harmonize the quality standards of medicines with advanced international standards have become one of the key priorities of drug administration for Chinese government.
- ▶ The Chinese Pharmacopoeia Commission (ChPC), is committed to improve the Chinese Pharmacopoeia practice and the well-established technical analytical procedure continuously, according to the international general rules, such as WHO GPhP (Good Pharmacopoeia Practices) and ICH guidelines.

Vision to Global Pharmacopeia

- ▶ Collaboration is in progress with:
 - ▶ International Pharmacopoeia
 - ▶ USP
 - ▶ EP
 - ▶ BP
 - ▶ JP
- ▶ Memorandum of Understanding:
 - ▶ Exchange of information on quality standards for medicines
 - ▶ Collaboration on development of test methods and monographs
- ▶ Progress
 - the stage of planning for biological products.

Vision to Global Pharmacopeia

3. The goals expected to achieve :

- ▶ make a pharmaceutical substance or products tested by the harmonized procedure yields the same results and the same accept/reject decision is reached.
- ▶ increase access to and availability affordable quality medicines over in China and worldwide.
- ▶ avoid and eliminate the presence of spurious/ falsified /falsely labeled /counterfeit products.

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An Outline of Up-coming Developments in ChP (Vol. III, 2020 Edition)

General Consideration :

- ▶ to further improve the national standards system of biological products and update the chapters included.
- ▶ to enable ChP more efficient standard development and applicable up-to-date monographs.
- ▶ to maintain the current ChP through a continuous revision process reflective of the technological changes in manufacturing and testing procedures.
- ▶ to sufficiently ensure the accuracy and adequacy of the content of ChP.

An Outling of Up-coming Developments in ChP (Vol. III, 2020 Edition)

Resvision of Up-coming Developments includes:

1. Sysytem/style/structure
2. General Requirements
3. General Monographs
4. Monographs
5. Test Methods
6. Guidances

An Outling of Up-coming Developments in ChP (Vol. III, 2020 Edition)

1. Sysytem/style/strucyure

- ▶ adjusting the table of Contents: for the convenience of information searching
- ▶ restructuring: consistence in the arrangement of the contents among the monographs
- ▶ generic name: harmonization the principles with WHO INN's

An Outling of Up-coming Developments in ChP (Vol. III, 2020 Edition)

2. Inclusion and Revision of General Requirements

- ▶ Viral safety for biological products included in ChP
- ▶ Preparation of national reference materials
- ▶ Requirements for Batch, Filling, Package, and Storage & Transportation
- ▶ Cell Substance, Human Plasma, Animal Plasma

An Outling of Up-coming Developments in ChP (Vol. III, 2020 Edition)

3. Inclusion of New General Monographs

- ▶ mite allergen preparations
- ▶ pegylation(PEG) recombinent protein
- ▶ gene therapeutics

An Outling of Up-coming Developments in ChP (Vol. III, 2020 Edition)

4. Inclusion of New Monographs

- ▶ vaccines: combined vaccines, innovative vaccines
- ▶ recombinant DNA products: hormones, antibodies, cytokines
- ▶ animal plasma products: upgrading and updating of anti-toxins and anti-sera to purified immunoglobulin (equine)
- ▶ In vitro diagnostics: PCR kit for plasma viral screening

An Outling of Up-coming Developments in ChP (Vol. III, 2020 Edition)

Monographs transfer from ChP (Vol. II) to ChP (Vol. III):

- ▶ Hormones: rDNA insulins and somatropin monographs, included the drug material and drug products already included in the section of small moleculars in ChP (Vol. II), and new preparations marketed in China will be elaborated in the section of biological products in ChP (Vol. III)
- ▶ The main body of the monographs will be restructured
 - molecular structure
 - manufacturing process
 - test methods refining

An Outling of Up-coming Developments in ChP (Vol. III, 2020 Edition)

5. Resvision of Monographs

► vaccines:

- Simplify the manufacturing process and parameters.
- reevaluate the fuction of the “direction for use” included in each vaccine monograph
- optimizing the test methods and acceptable criteria for residual HCP and DNA test required in viral vaccines.
- enhancing the quality control of aluminium adjuvant vaccines

► recombinent DNA products :

- supplementary the molecular structure information for each monograph
- upgrading the impurity control, assay and content criteria

An Outling of Up-coming Developments in ChP (Volume III, 2020 Edition)

6. Inclusion of New Test Methods

- ▶ test for the charge isomers analyzing in monoclonal antibodies
- ▶ test for the glycan profiles analyzing in monoclonal antibodies
- ▶ q-PCR for residual DNA
- ▶ general analytical methods: chemoimmunology
- ▶ methods for exogenous viral factors of animal resource products

An Outling of Up-coming Developments in ChP (Vol. III, 2020 Edition)

7.Planning Schedule for ChP (2020 Edition)

- ▶ 2016-2018 : plan (e.g, new monographs collection), project initialization, draft and validation
- ▶ 2019: public comments and consultation, review and examined by subcommittees respectively, approved by CFDA , printing
- ▶ 2020: Publishing & distribution, Promulgation & Implementation

Summary

ChP (Vol. III 2020 Edition) :

- ▶ Focus on the principle of science base and data base;
- ▶ sophisticated methodology: use the state-of-the-art quality control scientific methods
 - life cycle management
 - risk management
 - CQA (Critical Quality Attribute)
 - bioassay validation
 - reference material establish
 - biostatistics
- ▶ harmonization with advanced international standards
- ▶ cooperation and consensus with: regulatory authority and industry
 - industry side: feed-back and contribute, joint communication and discussion

Thank you for
Your Attention!

谢谢！