Recognized Pharmacopoeia in Registration system

Mrs. Prapassorn THANAPHOLLERT

Acting Director, Bureau of Drug Control
Food and Drug Administration, THAILAND
Outline

• What is pharmacopoeia?

• Legal basis

• Recognized Official Pharmacopoeia

• Thai Pharmacopoeia, Thai Herbal Pharmacopoeia

• Benefit of the recognized official pharmacopoeia

• Process for updating recognized Official Pharmacopoeia

• Criteria in recognition of pharmacopoeia
What is pharmacopoeia?

-a book containing an official list of medicinal drugs together with articles on their preparation and use.

-an authoritative book containing a list of medicinal drugs with their uses, preparation, dosages, formulas, etc.

-a book described drugs; one issued by an officially recognized authority and serving as standard
What is pharmacopoeia?

-a work containing monographs of therapeutic agents, standards for their strength and purity, and their formulations.

-The various national pharmacopeias are referred to by abbreviations, of which the following are the most frequently encountered: USP, BP, JP, TP, IP, Ph.Eur.
Legal basis

• **Article 4 (1)** of Drug Act B.E.2510 (1967) defines Drug as any substance listed in the official pharmacopoeia as announced by the Minister

• **Chapter 9** of Drug Acts B.E. 2510 (1967) “**Notice concerning Drugs**”

• **Article 76 (1)**: empowers Minister of Public Health to publish Official Pharmacopoeia in Royal Thai Gazette
Legal basis

- **Article 78**: The Ministerial Notification could be done based on recommendation from Drug Committee

- **Chapter 10** of Drug Act B.E.2510(1967) “Drug Registration”

- **Article 80(4)**: Application for modern drug registration shall be accompanied with analytical control method if the non-official compendia method will be used
Recognized Official Pharmacopoeia

Ministerial Notification : Official Pharmacopoeia B.E. 2519
Ministerial Notification : Official Pharmacopoeia B.E. 2531
Ministerial Notification : Official Pharmacopoeia B.E. 2539
Ministerial Notification : Official Pharmacopoeia B.E. 2541
Ministerial Notification : Official Pharmacopoeia B.E. 2543
Ministerial Notification : Official Pharmacopoeia B.E. 2544
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Ministerial Notification : Official Pharmacopoeia B.E. 2547
Ministerial Notification : Official Pharmacopoeia B.E. 2549
Ministerial Notification : Official Pharmacopoeia B.E. 2553
Ministerial Notification : Official Pharmacopoeia B.E. 2554
Ministerial Notification : **Official Pharmacopoeia B.E. 2556**
Recognized Official Pharmacopoeia

Current Ministerial notification: Official Pharmacopoeia B.E. 2556

For Modern Drug
-Thai Pharmacopoeia II, Volume I, Part I and Supplements
-Thai Herbal Pharmacopoeia Volume I and Supplements
-The Fourth Edition of the International Pharmacopoeia and Supplements
-The United States Pharmacopoeia, Thirty-Fourth Revision, and the National Formulary, Twenty-Ninth Edition and Supplements
Recognized Official Pharmacopoeia

- British Pharmacopoeia 2011 Volume 1-5 and Addenda
- British Pharmacopoeia (Veterinary) 2011 and Supplements
- The Seventh Edition of the European Pharmacopoeia and Supplements
Supervision of the drug product quality in Thailand is a shared authority among various Government agencies.

The Thai Pharmacopoeia Committee is responsible for establishing the Thai Pharmacopoeia (TP) which defines national standards to assure the quality of pharmaceutical products whereas the Food and Drug Administration, in co-operation with the Department of Medical Sciences, enforces them.

The TP specifications are thus national standards applicable to all pharmaceutical ingredients and preparations having their official names included in this Pharmacopoeia.
Thai Pharmacopoeia


-TP Volume II will be devoted mainly to the monographs of the selected pharmaceutical preparations.
Thai Herbal Pharmacopoeia

- Recognizing the importance of good quality crude drugs on the quality of finished herbal medicinal products, the “Thai Herbal Pharmacopoeia” was published by the Subcommittee on the Establishment of Thai Herbal Pharmacopoeia under the supervision of the Thai Pharmacopoeia Committee, of which the Department of Medical Sciences (DMSc), Ministry of Public Health serves as the secretariat office.

- The Subcommittee is composed of DMSc officers from the Bureau of Drugs and Narcotics, Medicinal Plant Research Institute, professors specialized in phytochemistry, botany and pharmacognosy from various universities.
Benefit of the recognized official pharmacopoeia

• To use as key reference to justify whether those interphase products fall under definition of Drug under Article 4(2) of Drug Act B.E 2510

• To use as key reference to approve specification and control methods of any drugs where listed in official monograph applicable to new submission of MAA or Variation
Process for updating recognized Official Pharmacopoeia

1. Review by Sub-Committee or Working Group when new version of well recognized pharmacopoeia is publicly available
2. Seek public consultation from all stakeholders
3. Submit draft of Ministerial Notification to be reviewed by Drug Committee for their positive opinion
4. Prepare Ministerial Notification as recommended by Drug Committee for official endorsement by Minister
5. Publish in Royal Thai gazette
Criteria in recognition of pharmacopoeia

• Updated version of official pharmacopoeia
• Providing good reference to new and more precise analytical methods
• Providing important specification and control method to minimize risk
• Containing not too sophisticated methods to burden local industry
• Available and accessible in English version
Thank you for kind attention