Thailand
Food &
Drug
Administration

Thailand's experience in developing the Reclassification guideline

Ms.Charunee Krisanaphan
Pharmacist, Senior Professional level
Standards and Regulations Division, Bureau of Drug Control
Thai Food and Drug Administration

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Outlines

- Definition
- Existed guideline
- Process of developing guideline
- Reclassification guideline
- Challenges
- Opportunities

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Definition

Drug Acts B.E. 2510 and amendments

Modern drug

Traditional drug

Dangerous drug

Special controlled drug

Ready packed drug

Household medicine

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Classification of drug

- 2 Principles
  - Safety
    - Higher risk drug – Prescribing and Dispensing
  - Accessibility
    - Hospital
    - Pharmacy/Drug Store

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	Thailand	Australia	UK
Hospital /Physician	Special controlled drug	Prescription only	Prescription only
Pharmacy /Pharmacist	Dangerous drug	Pharmacist only	Pharmacy medicines
Pharmacy/ Health care professional	Ready packed drug	Pharmacy medicine	
Any outlet	Household medicine	OTC	General sale list

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Existed guideline

Criteria for Household medicine-1

- Dangerous drug or Ready packed in Thailand at least 5 years
- Frequent used by the public/ needs for Health problems
- Treat the minor illness (self-assessment) with short term used
- Easy administration
- Good safety profile and less potential for drug abuse

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Existed guideline

Criteria for Household medicine-2

- Less general toxicity , no reproductive toxicity and non carcinogenicity
- Low risk in Type A ADR and very Low risk in Type B ADR
- Not for treatment high risk /chronic disease such as diabetes, tuberculosis, cancer, heart, lung, etc.
- Stable drug

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Process of developing guideline

- Review reclassification guideline from other countries
- Draft a guideline
- Public hearing
- Revise the guideline
- Propose to Drug committee for approval
- Formal announcement and implement
- Seminar/Workshop for industry

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Reclassification guideline

A. Scope

B. Definition

C. Required documents

1. Product information
2. Symptoms or disease information
3. Efficacy and Safety information (Summary)
4. Efficacy and Safety information (Full report)

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Required documents – Part I-Product information

1. Characteristics of Active ingredient
   - Chemical properties and stability data
   - Pharmacological properties
2. Proposed detailed of drug
   - Type and Contents of active ingredient per unit dose
   - Indication and dose administration
   - Label and product information
   - Package size

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Required documents – Part I-Product information

3. Registered detailed of drug

-Name of the product

-Registration number

-Name and contents of active ingredients

-Dosage form

-Indication

- Dose and administration

- Contraindication Precaution Warning

-Package size

-Shelf life and storage condition

-Approved label and drug information

4. Status of registration in other countries

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Required documents – Part II Symptoms or disease information

1. Epidemiology and disease
2. Sign and Symptom
3. Diagnosis and undesirable effects if misdiagnosis
4. Disease prevention
5. Reference

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Required documents – Part III Efficacy and Safety information

1. Non-clinical and clinical overview
2. Safety data
   - Summary of ADR type A and type B (PSUR from Thailand and/or foreign data)
   - Safety data in Vulnerable groups
   - Risk assessment of drug safety or safety concern
   - Risk assessment of drug overdose
   - Food-Drug interaction, Drug interaction
   - Misuse and/or Abuse
   - Cost-effectiveness (if available)
3. Clinical data

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Opportunities

- Guideline
- Company could request for reclassification
- People access to drug

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Challenges

- Reliable information
- PIL (ASEAN harmonization)
- Irrational used of drug
  - Microbial resistant

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Thank you for your attentions