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Developing indicators and method of drug classification according to Thai law

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Objective: This study aimed to develop suitable criteria, indicators and the method of drug classification according to the Drug Act, B.E.2510 (A.D.1967) and its amendments.
Methods: A 7-step study was carried out by first analyzing the Act, related laws, and minutes of the Drug Committee, followed by organizing the experts meeting and conducting an in-depth interview with knowledgeable persons involved in drug law and regulations. After collecting enough essential information and valuable opinions, the appropriate criteria and indicators for the drug classification as well as practical method of the classification were developed. Finally, all created tools were tested to ensure their validity.
Results: Five criteria including safety, related disease and diagnosis, administration, abuse/misuse and novelty were created. Under these five criteria, there are 16 indicators used for suitably classifying registered drugs in Thailand into three categories as special control drugs, dangerous drugs and over-the-counter (OTC) drugs.
Conclusion: The newly developed criteria with indicators and the method of drug classification can be effectively used to classify registered drugs in Thailand.

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Introduction

From reviewing drug acts of other countries, some classify registered drugs into 2 categories, including prescription and non-prescription/over-the-counter drugs such as U.S.A. Malaysia, Philippines; while some classify into 3, including prescription only medicines (POM), pharmacy medicines (PM) and general sale list (GSL), such as countries in European Union, Singapore, Sri Lanka. Among these countries, the main criteria used for drug classification are toxicity, risk, necessity, novelty, affordability, misuse or abuse, etc.[1-5] The Drug Act, B.E.2510 and its amendments is enforced to balance between drug business and consumer protection in Thailand. This act classifies registered drugs in several aspects; modern & traditional medicines; internal & external use medicines; herbal medicines & ready-packed medicines; specially-controlled medicines, dangerous medicines & OTC medicines. All of these comply to another features of the law such as registration, advertisement, labeling, selling report, etc. [6-8] Classifying to specially-controlled, dangerous & OTC medicine is the classification which focuses mainly on toxicity & misuse/abuse. This classification is vital to the enforcement of the Drug Act B.E.2510 & its amendments. [6-8] Nevertheless, there is no obvious criteria, indicators & method of the registered drug classification in Thailand before.[9] Consequently, the objective of this study is to develop the mentioned tools in order that the drug control system will be more efficient & more practical leading to better consumer protection.

Methods

Seven steps were conducted in this study. (1) Reviewing drug classification in Thailand by scrutinizing & analyzing the Drug Act B.E.2510 and its amendments, the Ministerial Regulations, the Ministerial Notifications, and the minutes of Drug Committee meetings. (2) Reviewing drug classification in other countries. (3) Organizing the experts meeting for first draft of concept paper. (4) In-depth interviewing knowledgeable persons for valuable opinions. (5) Developing criteria, indicators & method of the registered drug classification. (6) Testing the invented tool by random sampling 86 items of drug from the Thai National Essential Drug List and (7) Improving the invented tool.

Results

Drug classifying situation: Under the Drug Act B.E.2510 & its amendments, the registered drugs in Thailand are classified in several aspects. In the aspect which focuses on the level of toxicity & the opportunity of misuse/abuse, they will be classified into 3 categories including specially-controlled, dangerous and OTC medicines. Specially-controlled

medicines must be prescribed by physicians and should be dispensed by pharmacists, while dangerous medicines can be dispensed by pharmacists without prescription and OTC medicines can be available for self-medication of the general people. Notwithstanding, they're not obviously specified in the Drug Act B.E.2510 & its amendments unlikely to classifying psychotropic substances and narcotic drugs in the Psychotropic Substances Act B.E.2518 and the Narcotics Act B.E.2522, respectively. [5] [9] [10] In the past, though most of registered medicines in Thailand were classified in the list of the Ministerial Notifications but some of them were not in the list. Subsequently, the Minister issued the notifications listing items of non-dangerous and non-specially-controlled ready-packed medicines. This Ministerial Notification affected more extensive lists of drugs which can be sold in second-class drugstore (without pharmacist). Non-dangerous and non-specially-controlled ready-packed medicines then appears not different from OTC medicine and they can be advertised directly to consumers by law.The Drug Committee has the duty to propose drug classification to the Minister. The committee always uses other countries' information with applying to the Thai context in consideration for drug classification.[9] [12] Reasons for each category of the classification can be demonstrated in Table 1.

Table 1 Reasons for each category of the classification

Drug categories	Reasons for classifying to the relevant category
Specially-controlled medicines (Prescription medicines)	- Used for fatal diseases which need diagnosis & prescription from expert - With high danger or risk - Prone to abuse or misuse which effects personal health or community - Must be prescribed by doctor and dispensed by pharmacist
Dangerous medicines (Pharmacy medicines)	- Used for frequent ailments which can be primarily diagnosed by pharmacist - With moderate danger or risk - May be abused or misused but not fatal - Cannot be used by ordinary people
OTC medicines	- Used for frequent ailments which can be easily diagnosed by ordinary people - Used for temporary or minor ailments - Can be used easily - With high safety and low risk - Not prone to abuse or misuse

Criteria and indicators of drug classification: The researchers listed the potential criteria from discussion after reviewing, expert meeting and in-depth interviewing, they were related disease/symptom, danger/risk/safety, abuse/misuse, accessibility, people's ability to decide, etc**.** Finally, the researchers develop 16 indicators from 5 criteria including Safety, Related Disease and Diagnosis, Administration, Abuse / Misuse and Novelty.

Developing Method for Drug Classification: The researchers had developed the method of drug classification by utilizing the above criteria & indicators, this process comprised of 4 or 5 steps as following:

Step 1 Focus on 4 indicators including (1) Dosage form - injection (2) Novelty – new drug (3) Withdrawal effect - positive and (4) Stability – less than 1 year. If "yes" in 1 – 4 items, that medicine will be classified as specially-controlled medicine or prescription only medicine (POM) but if "no" in every items, that medicine will be passed to the next step.

Step 2 Focus on 5 indicators including (5) Without direct toxicity (6) Side effect - trivial & can be healed by ending that medication (7) Rare case of drug interaction (8) Used for minor or temporary ailments Used for mild or temporary ailments and (9) Self diagnosed by ordinary people. If "yes" in every items, that medicine will be passed to the step 3a but if "no" in 1 – 5 items, it will be passed to the step 3b.

Step 3a Focus on 6 indicators including (10) Dependence (11) Habit forming & affect bad health which's not severe (12) Misuse & affect only personal health (13) Mode of administration – complicate & need suggestion (14) Drug resistance – leading to not severe case and (15) Drug tolerance**.** If "no" in every items, that medicine will be passed to the step 4 but if "yes" in 1 – 6 items, it will be passed to the step 3b.

Step 3b Focus on another 6 indicators including (10) Low therapeutic index or Low margin of Safety (11) With direct toxicity & need to be cured by doctor (12) Reported incidence of serious adverse effect at important organ more than 10% (13) Reported incidence of fatal allergy or idiosyncrasy that need special care (14) Used for chronic diseases or severe communicable diseases or fatal diseases and (15) Need doctors, dentists or veterinarian to diagnose that related disease. If "yes" in 1 – 6 items, that medicine will be classified as POM but if "no" in every items, it will be classified as dangerous medicine or pharmacy medicine (PM).

Step 4 From step 3a, the medicine with "no" in every items will be passed to this step. The last indicator will be use to consider, (16) Limited packing size with small amount in ready package. If "yes", that medicine will be classified as OTC medicine or general sale list (GSL) but if "no" it will be classified as dangerous medicine or PM.(Diagram 1)

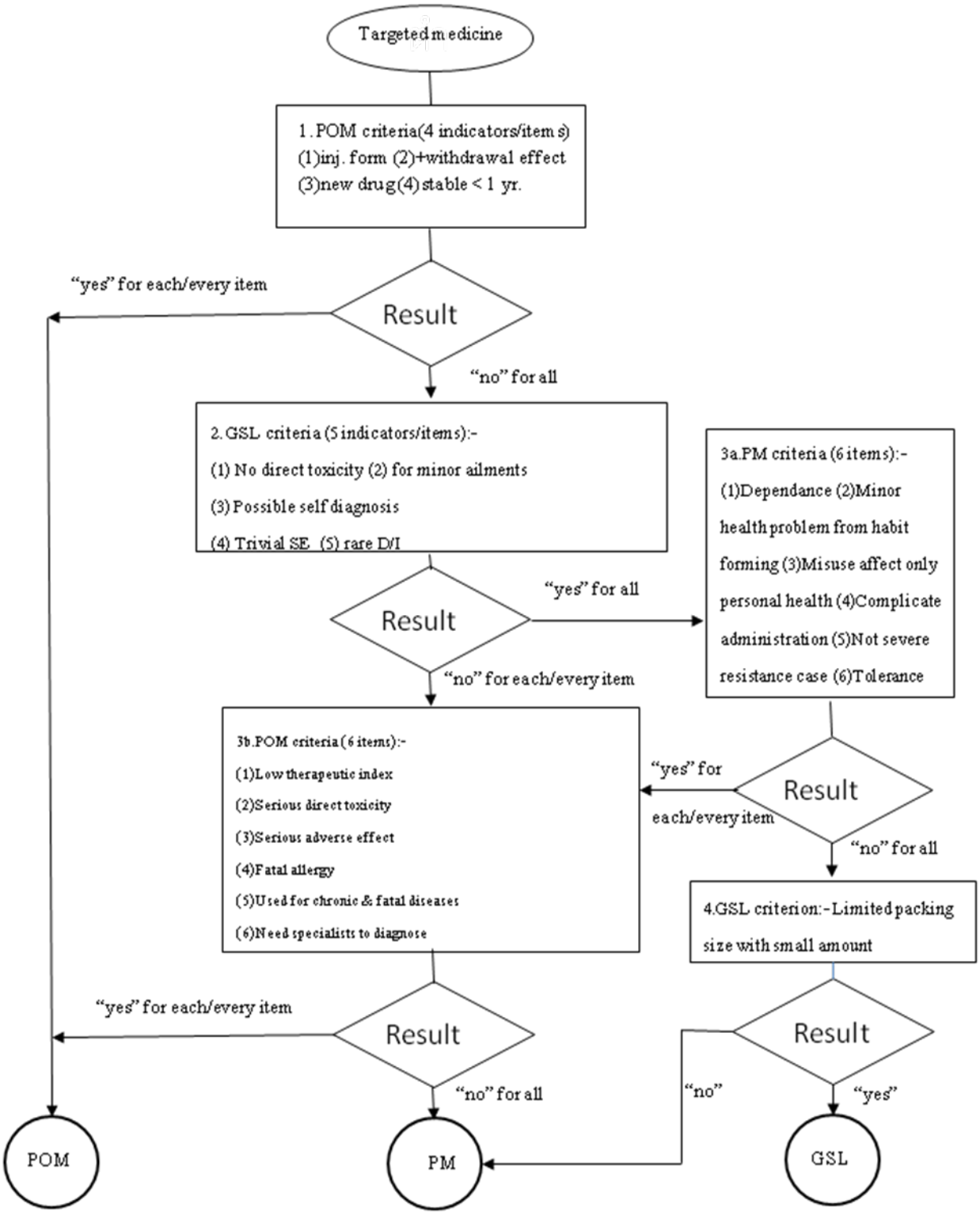

Diagram 1 Drug Classification Guideline

Discussion

The criteria with indicators and the method of drug classification which was developed by the researchers can be used for classifying registered drugs in Thailand more obviously. Nonetheless, utilizing this tool must be under apparent and acceptable standard value. Moreover, the tool must be generalized and can be easily traceable.

Conclusion

There are 2 options for specifying the standard value of drug classification: (1) specify in accordance with international standard and (2) if there is no international standard, it should be specified by Thai experts under the approval of the Drug Committee. Any option must be considered along the appropriateness of the country context or the consumers' benefit. Applying computer technology to the method of drug classification would be interesting suggestion.

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