Regulation of OTC Drugs in Japan

Takatoshi Nakamura

Office Director
Office of OTC/Generic Drugs
Pharmaceuticals and Medical Devices Agency

Overview

- Classes of OTC drugs
- Approval review
- Consultation service
- Prospects

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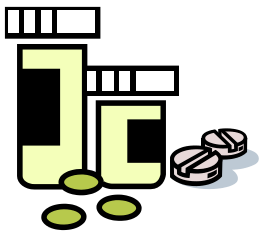
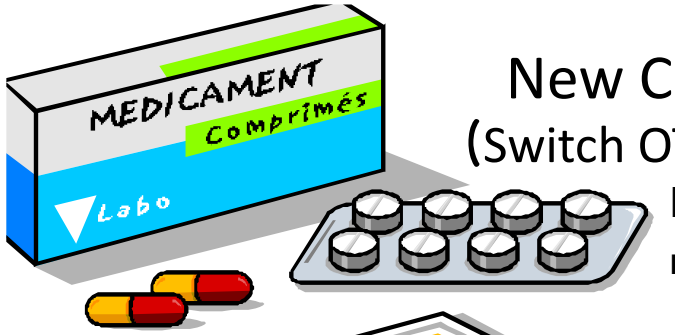
How a drug gets OTC status and relation to class of an OTC drug

Rx





New Category Drugs
(Switch OTC or Direct OTC etc)
Pharmacist intervention required Medicine

Post Marketing Surveillance (PMS)

3years or 8years

Type 1

Type 2 & 3

Sale is possible on the Internet

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“New Category drugs”

- This category drugs differ from OTC drugs. It is the category that followed ethical drugs.
- This category drugs needs face to face provision of information and instruction based on pharmaceutical knowledge by pharmacists for proper use.
- The drugs that have newly become available as non-prescription one(these risks of dealing as OTC drugs are undefined) and powerful drugs classified into this category.

Classes of OTC drugs

Class	Examples	Explanation about products	Consultation	Information provider
Type 1 (high potential risk)	H2-receptor antagonists, Minoxidil (Hair growing agent)	Requirement	Requirement	Pharmacists
Type 2 (less potential risk)	Cold medicines, anti-inflammatory analgesic agents, gastrointestinal drugs, etc.	Preferably	Requirement	Pharmacists or qualified drug sellers
Type 3 (relatively low risk)	Vitamin B or C tablets, intestinal remedy, digestive agents, etc.	Not-requirement	Requirement	Pharmacists or qualified drug sellers

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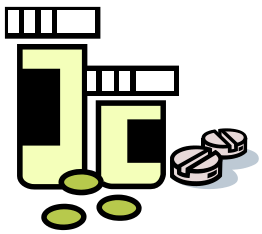

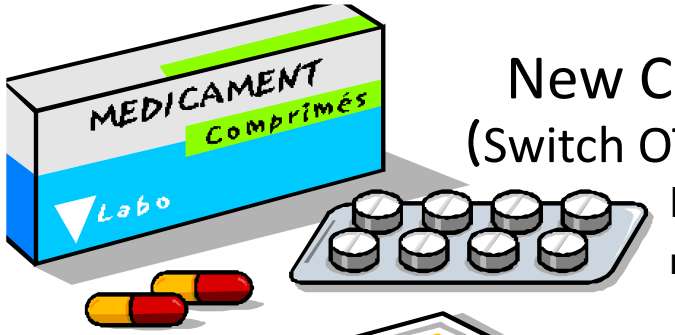

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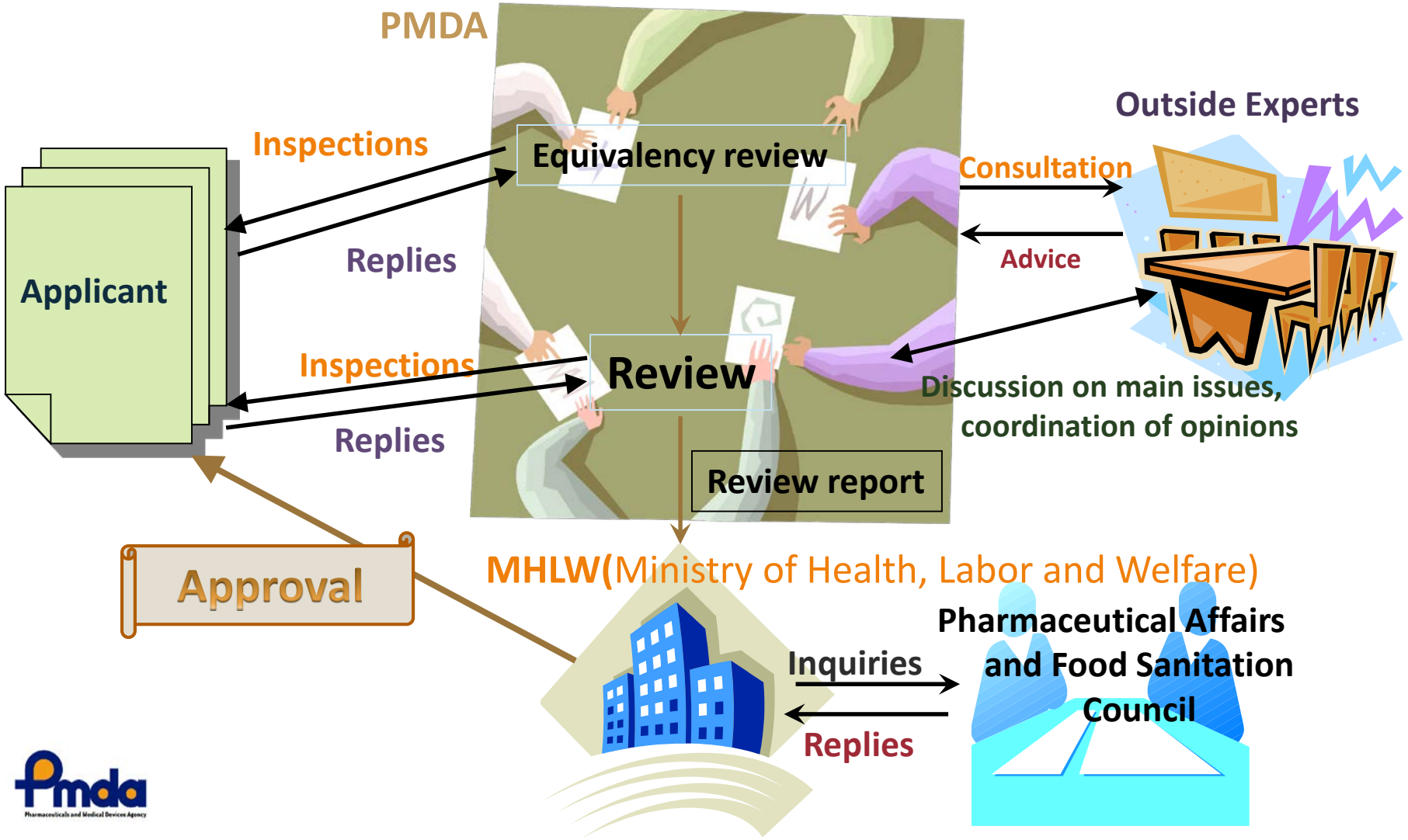
Approval review of OTC drugs

Is a product appropriate for as an OTC drug which is chosen and used by general consumer?

- Active ingredients
  - have assured the efficacy and safety
- Indications
  - for common symptoms and disorders that are easily recognizable by ordinary consumer
- Dosage and administration, formulation
  - easy and safe to use
  - no misuse and abuse potential

Approval review process for new OTC drugs



The data requirements for OTC drug application

Contents of the data submitted for application	
A. Origin or background of its development, conditions of use in foreign countries	1. Origin or background of development 2. Conditions of use in foreign countries 3. Special characteristics, comparisons with other drugs, etc.
B. Manufacturing methods, standards and test methods	1. Chemical structure and physicochemical properties, etc. 2. Manufacturing methods 3. Standards and test methods
C. Stability	1. Long-term storage tests 2. Tests under severe conditions 3. Accelerated tests
D. Pharmacological action	1. Tests to support efficacy 2. Secondary pharmacology, Safety pharmacology 3. Other pharmacology
E. Absorption, distribution, metabolism, and excretion	1. Absorption 2. Distribution 3. Metabolism 4. Excretion 5. Other ADME
F. Acute, subacute, and chronic toxicity, teratogenicity, and other type of toxicity	1. Single dose toxicity 2. Repeated dose toxicity 3. Genotoxicity 4. Carcinogenicity 5. Reproductive toxicity 6. Local irritation 7. Other
G. Clinical studies	Clinical trial results

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Simple Consultation

- General questions about the OTC drug seeking to gain application:
  - The application category
  - whether a certain change will need to be submitted or registrated
  - quality or quantity of additives, …etc
- However, this is a short consultation insufficient to finalize the product as an OTC drug.
- Applicants are eager for a new different type of consultation service.

Consultation service for OTC drugs

Type	Content	Frequency (each time)
Submission consultation of new drug seeking approval as OTC drug or switching to OTC drug	Give some advice about package of data for new OTC drug application (ex. Efficacy and safety data as Rx, information of the product in abroad)	Once a month (120 min)
Protocols of clinical trial	Give some advice about clinical trial protocols for OTC drugs focusing on assessment criteria such as primary end points and inclusion criteria	Once a month (60 min)
Suitability as an OTC drugs	Give some advice about suitability as a possible OTC drugs at the early stage of its development (ex. Indication, dosage, direction, value of combination preparation, new inactive ingredient)	4 times per month (30 min)

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Future potentials of OTC drugs 1

"Self-medication involves the use of medicinal products by the consumer to treat self-recognized disorders or symptoms, or the intermittent or continued use of a medication prescribed by a physician for chronic or recurring disease or symptoms. In practice, it also includes use of the medication of family members, especially where the treatment of children or the elderly is involved."

(WHO: Guidelines for the Regulatory Assessment of Medicinal Products for use in Self-medication, 2000)

Future potentials of OTC drugs 2

For example…

- Prevent the onset of symptom in metabolic-syndrome or allergy…
- Improvement of quality of life : hair growing agent, nicotine-replacement therapy, insomnia, obesity
- Easy self-check kit
- Remedy for minor symptom : to prevent infection of wounds and injuries, treatment of recurrent thrush, recurrent cold sores…

Future Cooperation

- Discussion on the further collaboration ways
- International cooperation within the framework of APSMI
- Possibility for Regulator-Industry Joint WG on OTC regulation including Asian region

Thank you for your attention!

Website(English):http://www.pmda.go.jp/english/index.html