

Regulation of OTC Drugs in Japan

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22 Oct. 2014



2nd APSMI General Assembly Meeting

Overview

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- ◆ Classes of OTC drugs
- ◆ Approval review
- ◆ Switch to OTC drugs
- ◆ Consultation service
- ◆ Prospects

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Classes of OTC drugs



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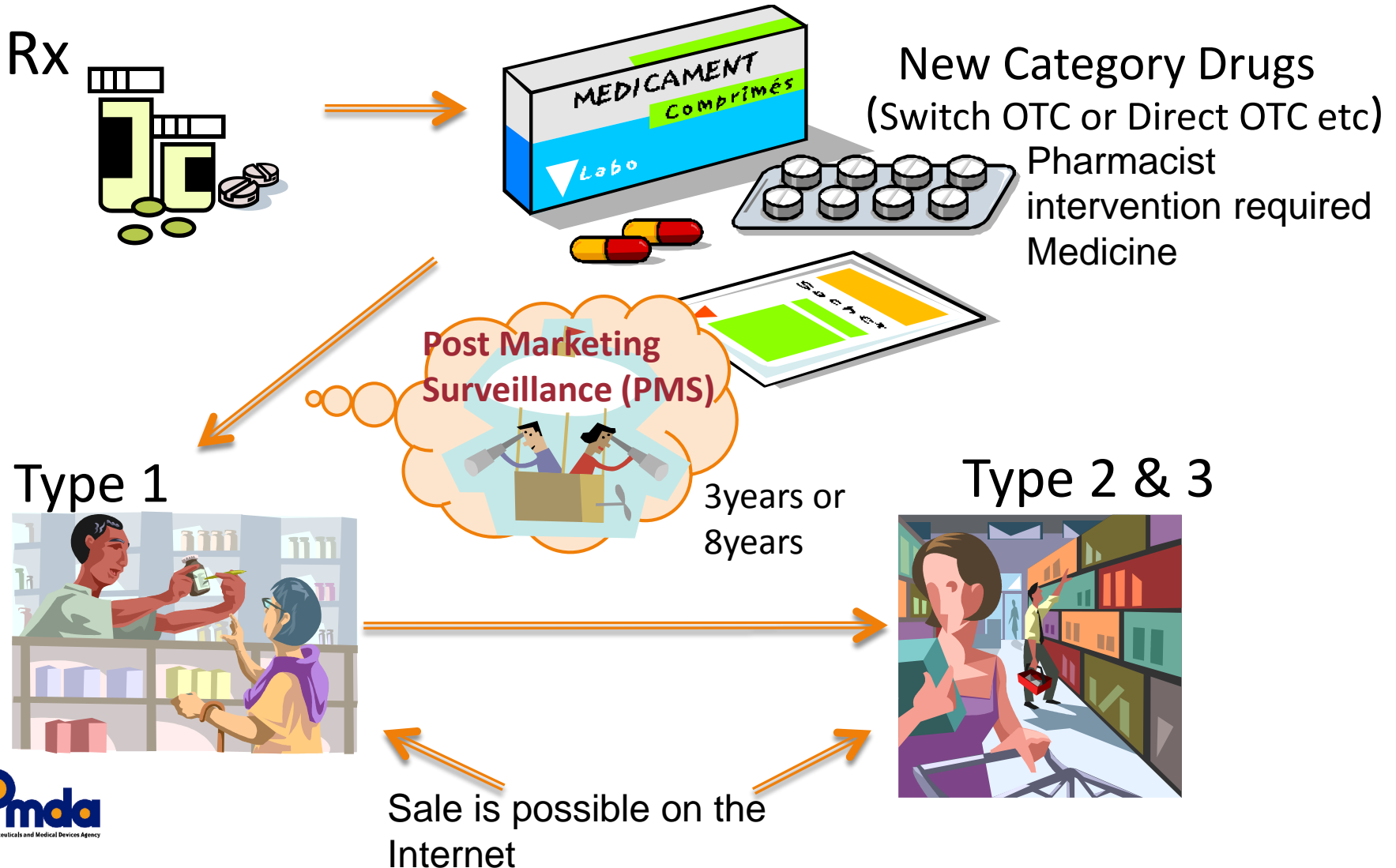
Class	Examples	Explanation about products	Consultation	Information provider
Type 1 (high potential risk)	H2-receptor antagonists, Minoxidil (Hair growing agent)	Requirement	Requirement	Pharmacists
Type 2 (less potential risk)	Cold medicines, anti-inflammatory analgesic agents, gastrointestinal drugs, 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

“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.

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

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Approval review of OTC drugs

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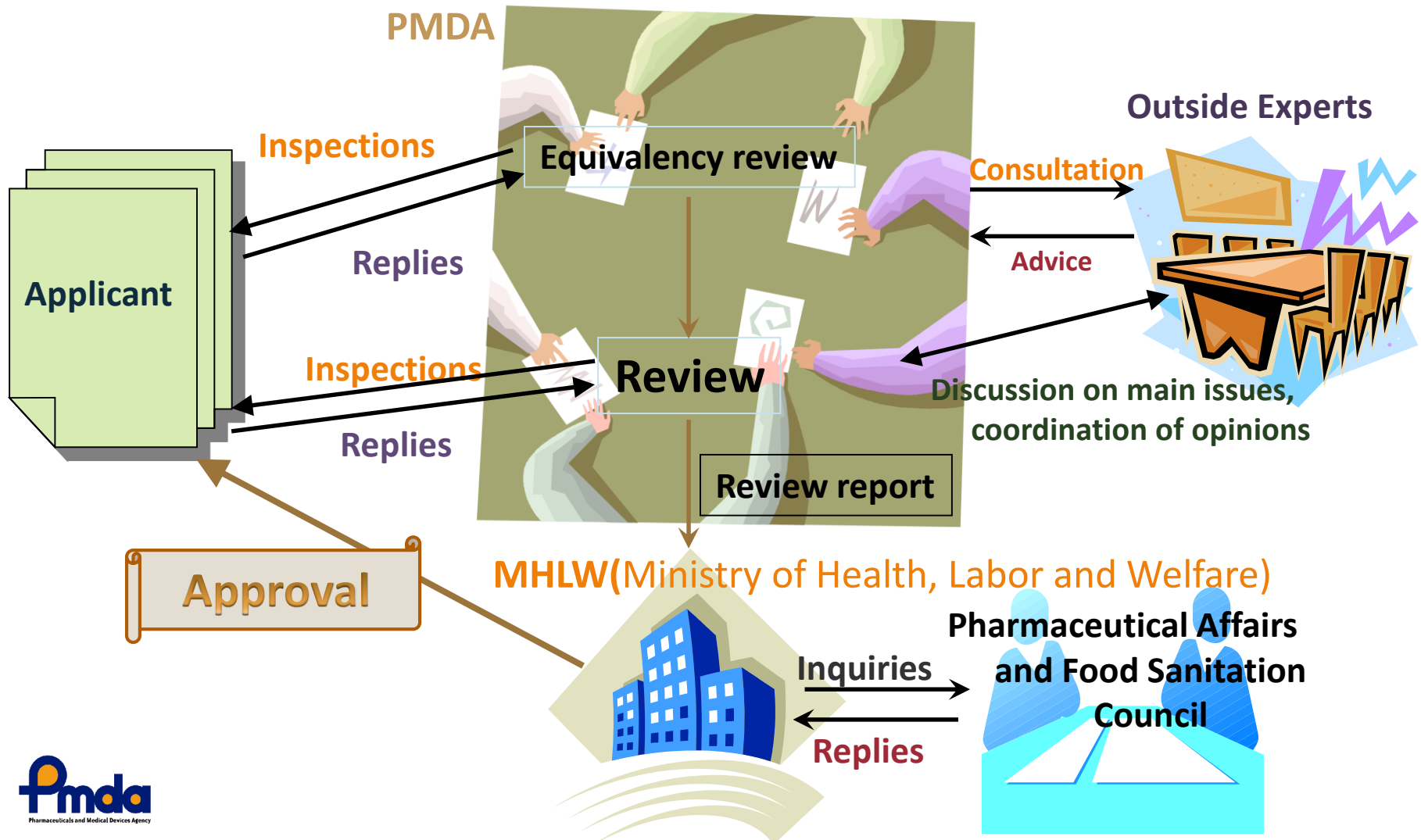
Is a product appropriate for as an OTC drug which is chosen and used by general consumer?

- ◆ 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

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The data requirements for OTC drug application

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Contents of the data submitted for application

A. Origin or background of its development, conditions of use in foreign countries	<ol style="list-style-type: none">1. Origin or background of development2. Conditions of use in foreign countries3. Special characteristics, comparisons with other drugs, etc.
B. Manufacturing methods, standards and test methods	<ol style="list-style-type: none">1. Chemical structure and physicochemical properties, etc.2. Manufacturing methods3. Standards and test methods
C. Stability	<ol style="list-style-type: none">1. Long-term storage tests2. Tests under severe conditions3. Accelerated tests
D. Pharmacological action	<ol style="list-style-type: none">1. Tests to support efficacy2. Secondary pharmacology, Safety pharmacology3. Other pharmacology
E. Absorption, distribution, metabolism, and excretion	<ol style="list-style-type: none">1. Absorption2. Distribution3. Metabolism4. Excretion5. Other ADME
F. Acute, subacute, and chronic toxicity, teratogenicity, and other type of toxicity	<ol style="list-style-type: none">1. Single dose toxicity2. Repeated dose toxicity3. Genotoxicity4. Carcinogenicity5. Reproductive toxicity6. Local irritation7. Other
G. Clinical studies	Clinical trial results

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Switching from Rx to OTC drugs

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- ◆ MHLW strongly supports switches from Rx to OTC drugs because...
 - ◆ It expands the selection of OTC drugs available to consumers for self-medication.
 - ◆ The public can use more effective drugs.
- ◆ However, it seems difficult to decide which active ingredients can be switched to OTC drugs...



System for accelerating the switch to OTC drugs

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- ◆ The Pharmaceutical Society of Japan made up the lists of prescription drug candidates which could be switched to OTC drugs based on efficacy and safety.
- ◆ Then, medical societies discuss the properties of active ingredients listed. The lists are issued generally every fiscal year from 2008.



List of candidates to switch to OTC drugs

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FY	Ingredient	Administrative Route	Notes
2009	Flurbiprofen Rebamipide Bendazac Clobetasone butyrate Tranilast Amlexanox Dexamethasone Fudosteine Alfacalcidol Calcitriol	External Internal External External Ophthalmic Nasal Oral mucosa Internal Internal Internal	Anti-inflammatory analgesic Gastrointestinal mucus protectant Anti-inflammatory analgesic Adrenal corticosteroid Allergy Allergy Adrenal corticosteroid Expectorant Vitamin D3 (osteoporosis) Vitamin D3 (osteoporosis)
2010	Domperidone Bepotastine besilate Olopatadine Cetirizine hydrochloride	Internal Internal Internal Internal	Prokinetic agent (nausea) Allergy Allergy Allergy
2012	Sodium hyaluronate	Ophthalmic drops	Artificial tears

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Simple Consultation



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- ◆ General questions about the OTC drug seeking to gain application:
 - ◆ The application category
 - ◆ whether a certain change will need to be submitted or registered
 - ◆ 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

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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

“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 potential OTC drugs

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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...



***Thank you for your
attention!***

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

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