

Update on JP-TW OTC drugs WG

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Objective

The objective of Japan-Taiwan OTC WG is to improve mutual understanding of OTC drugs regulation and regulatory environment with regard to OTC drugs in Japan and Taiwan.

Items being discussed

1. Regulatory Updates
2. Bilateral Cooperation
 - Monograph proposal from Japan
 - Comparison of each system
 - Workshop proposal in next April

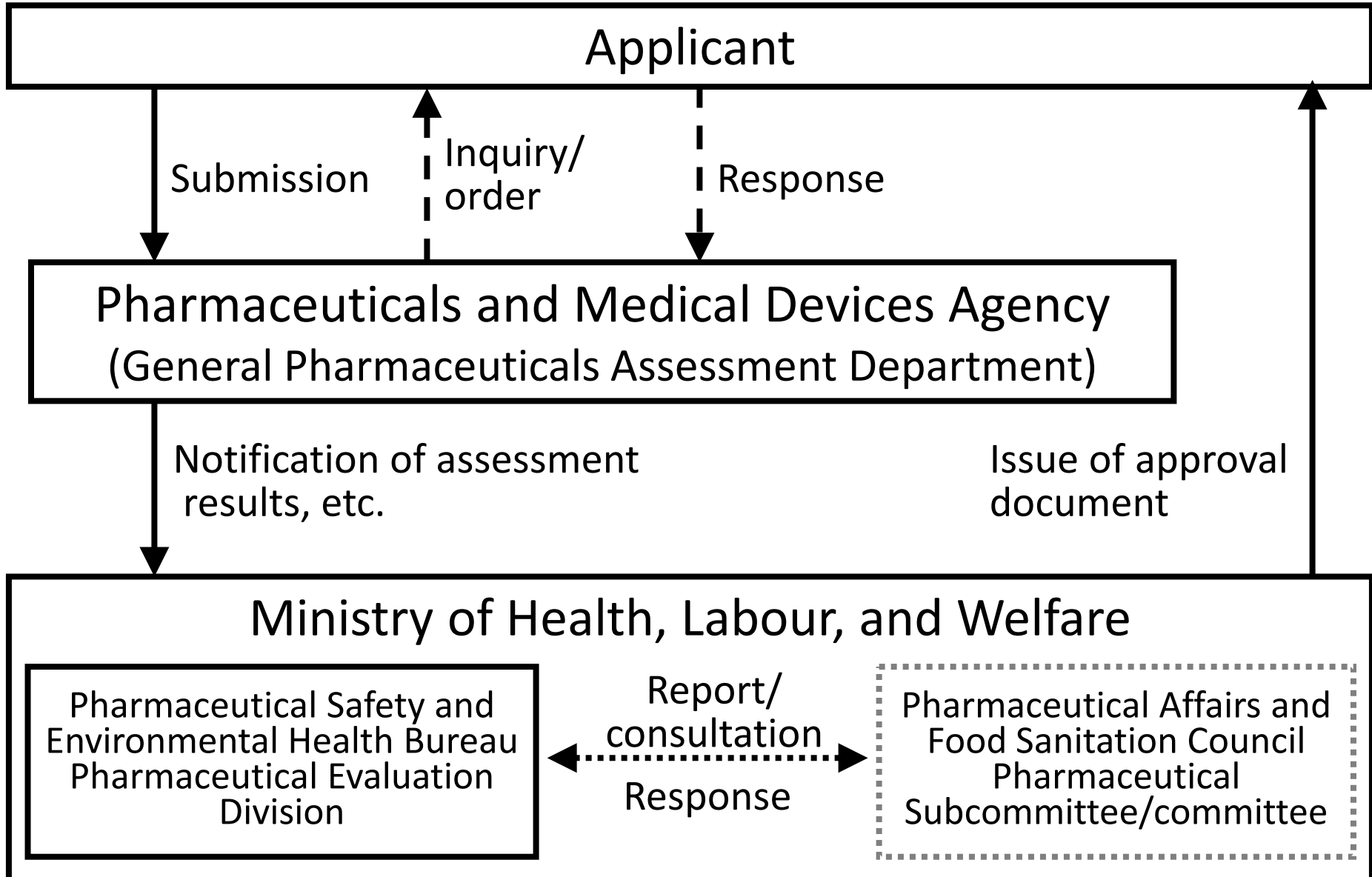
Monograph proposal from Japan

- A list of 25 items proposed from Japan to Taiwan to be included in Taiwan's monograph.
- Priority, utility for consumers and regulatory feasibility were considered to make the list.
- Classification of items by Taiwan would be useful as a next step.
- Mutual understanding of the monograph systems would also help discussion.

Overview & update of Japan's monograph system

Simplification of approval assessment

– Expansion and review of items approved by the governor–



OTC pharmaceuticals (about 11,000 items)

Approved by the minister

- ❑ Pharmaceuticals not applicable to the standards for approval by the governor

Approved by the governor

- ❑ Pharmaceuticals applicable to the standards for approval by the governor
 - ❑ Standards for approval by the governor are prepared for the following efficacy groups (15 efficacy groups):
 - Cold remedy
 - Antipyretic and analgesic
 - Antitussive and expectorant
 - Gastrointestinal medicine
 - Laxative
 - Antivertiginous drugs
 - Ophthalmologic drugs
 - Preparations with vitamin as primary agent
 - Enema agent
 - Anthelmintic
 - Nasal drug for rhinitis
 - Oral agent for rhinitis
 - External agent for hemorrhoids
 - Drugs for athlete's foot and ringworm
 - Antipruritic and anti-inflammatory
- (about 4,500 items)

Period required for approval assessment

Due to the approval standard, the **assessment period is shorter** than the period of approval by the minister.

- Approval by the minister : 7.0 months
- Approval by the governor : 2 to 3 months

Expansion and review of items approved by the governor

<Advantages>

- Citizens : Expansion of items that meet the needs
- PMDA : Faster assessment of items in new areas due to reductions in the assessment of OTC pharmaceuticals
- Companies : Reduction in burden of development, faster product making

Commenced review on the approval standards of antipyretics and analgesics, etc



Reform of four standards were implemented last year for **cold remedies**, **antipyretics and analgesics**, **antitussives and expectorants**, **oral drugs for rhinitis**.

Type	Reform of approval standard
<u>Cold remedies</u>	March 25, 2015
<u>Antipyretics and analgesics</u>	March 25, 2015
<u>Antitussives and expectorants</u>	March 25, 2015
<u>Oral drugs for rhinitis</u>	March 25, 2015

Cold remedy

- Added active ingredients (Ibuprofen, etc.)
- Review of compounding rules
- Review of dose and administration
- Easy-to-understand expression of efficacy

Antipyretics and analgesic

- Added active ingredients (Ibuprofen, etc.)
- Review of compounding rules
- Review of dose and administration
- Easy-to-understand expression of efficacy

Antitussive and expectorant

- Added active ingredients (Bromhexine hydrochloride, etc.)
- Review of compounding rules
- Review of dose and administration
- Easy-to-understand expression of efficacy

Oral drug for rhinitis

- Added active ingredients (Mequitazine, etc.)
- Review of compounding rules
- Review of dose and administration

Inclusion of new components based on precedents for approval

Organization and changes (dose form, etc.) according to official documents such as JP 16

OTC pharmaceuticals

- From the handling policies of regional proposals (cabinet decision on December 22, 2015)
- From the regulatory reform implementation plan (cabinet decision on June 2, 2016)

○ Expansion of items approved by the governor

- General Chinese medicine preparation (in fiscal 2016)
- Pure crude drug (in fiscal 2017)

○ Review of the expressions of efficacy and indication

(translate to expressions easily understood by the consumers' point of view)

Thank you for your attention!

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