APSMI Newsletter

Autumn and Winter 2020

CONTENTS

1. Japan

1) Symposium for Self-Medication Day 2020

On November 5, 2020 Japan Self-Medication Industry, supported by Japan Federation of Self-Medication Industries, held on-Symposium for Self-Medication Day 2020. The Symposium consisted of Keynote Speech "What is yet untapped value of OTC drugs?", by Dr. Ataru Igarashi, Associate Professor, University of Tokyo, experts' comments and panel discussion.

Dr. Igarashi reported on his studies on replacement of prescription drugs with switched OTC drugs in the Japanese medical scene and on its economic effects. The Speech was followed by academicians' comments as well as a panel discussion with representatives from the business community, clinics, and health insurers. All the speakers agree on the value of OTC drugs.

2) Self-Medication Tax Deduction prolonged for another 5 years

On December 21, 2020 the Cabinet of the Japanese Government adopted the Fiscal 2021 Tax Reform Guidelines. The Guideline gives Japan's Self-Medication Tax Deduction System, to sunset at the end of 2021, another 5 years of existence till the end of 2016.

The current system applies to the costs for OTC drugs reclassified from prescription drugs since 1983. Under the revised Deduction System starting from 2022, the scope will be expanded to include some non-switched ingredients. The Government will soon convene an advisory group to determine eligible ingredients. As another measure to encourage the use of the System, evidential documents accompany the deduction application will be reduced.

3) Rx-to-OTC Switching Evaluation Committee Reform

Based on a top-down instruction from the Cabinet of the Japanese Government, the Ministry of Health, Labor and Welfare (MHLW) has been in the process of reforming Rx-to-OTC Switching Evaluation Committee. The Committee was established to promote reclassification, but has been effectively hindering the process, as the Government's Reform Council asserts. The Reform is due March 2011. The Ministry and the Evaluation Committee have agreed so far on the following changes.

- The Evaluation Committee will not recommend on the final switch-ability of particular ingredients, but consider the challenges and suggest measures to realize proposed switching.
- The membership of the Evaluation Committee will be changed to have the OTC manufacturing and distributing industries represented. The Committee currently consists of health care professionals and consumer representatives.

2. Korea

1) Policy on promoting OTC – expanding OTC monograph

In December 2020, MFDS announced major improvement in drug approval policy through an online forum including OTC promotion policy.

- Until now, it could only be used for monograph drugs if the ingredients were listed in the designated pharmacopeia (i.e. KP, USP, EP, JP, etc) but in the improved policy, it can be used if it has already been evaluated in other drugs or have undergone separate review of the data specification and test method before.
- And some new ingredients and preparation will be added as below.

Specification	Present	Ingredients listed in the designated pharmacopeia (i.e. KP, USP, EP, JP, etc.)	Improvement	Ingredients used in approved drugs or have been reviewed for data specification and test method before
Ingredients		Newly established		Add new ingredients: Mecobalamin, Cobamamid, Dried yeast, etc.
Preparation		Newly established		Add new preparation: Oral jelly, Orally disintegrating tablet, Orally disintegrating film, etc.

MFDS will collect more opinion on this improvement from the industry and revise the regulation.

3. Philippines

1) Dialogue with FDA to allow e-commerce for OTC products held Nov. 9, 2020

FDA requires online platforms i.e. Lazada, Shopee, to have a physical drugstore in order to operate through e-commerce. Big chain drugstores like Watsons and Mercury have valid Licenses issued by FDA to allow online selling and delivery. Based on Administrative Order 2020-0017, all establishments shall not have a virtual office. Absence of physical office upon inspection, without permission or approval from the FDA shall be a ground for disapproval of application or revocation of LTO.

CHAP has proposed to remove the requirement on the physical store particularly for Lazada and Shopee since the Marketing Authorization Holders still have responsibility on the products sold through these platforms. FDA has yet to issue a regulation on e-commerce guidelines. CHAP has acknowledged that both sellers and marketplaces are jointly responsible on the products being sold. The discussion is ongoing and is closely monitored by CHAP.

2) FDA proposes the Draft Philippine Variation Guidelines

The proposed Variation Guidelines does not provide a scope of drug classification. CHAP proposed to have a separate variation guideline for Home Remedy (HR), Pharmacy Only Medicines (POM) and Over-the-Counter (OTC) drug products with proposed timelines of 3-20 working days depending if Notification, Minor or Major Variation. CHAP awaits the final version of the Philippine Variation Guidelines to be issued by FDA.

3) FDA proposes updated Citizen's Charter

The requirements for OTC remain to be based on National Guidelines with proposed working days of 130 days. CHAP proposed for a lifetime validity of registration as well as simplified requirements based on the proven safety and efficacy of OTC products. FDA has yet to finalize the Citizen's Charter

https://ww2.fda.gov.ph/attachments/article/685873/FDA%20Citizen's%20Charter%20CDRR.pdf