APSMI Newsletter

Spring and Summer 2020

CONTENTS

1. Chinese Taipei

1) TFDA endorsed the OTC policy and started communication with stakeholders

An OTC policy was proposed at the end of 2019 which reviewed the current regulatory status and trending in self-medication. In this policy:

- It emphasizes the importance of self-medication and OTC value.
- Also responsibilities among different stakeholders are identified and communicated, including better OTC regulations by TFDA, de-list of OTC from NHI reimbursement, implementation of consumer education from

national education systems with cooperation within Educational department and healthcare professionals.

2) TFDA announced OTC new drug guidance

After 2-year communication with TFDA, TFDA announced the registration guidance for OTC new drug on 30 August. The guidance mainly to waive the clinical/non-clinical studies for those OTC products (classified as new combination, new dosage form, new recommended dose and new strength in Taiwan) with more than 10-year approval evidence in foreign countries (10 major countries).

3) Flexible management for registration during COVID 19 period

Due to the lock down in many countries during COVID 19, many administrative processes have been impacted and could delay the submission or approval of the product license.

Industry has proposed to TFDA for flexible management. On 4 May, the Pharmaceutical Affairs Section and GMP section (TFDA) aligned on the regulatory flexibility in product registration/renewal/variation.

- Accept e-signature and scanned copy (original copy should be archived)
- Allow submit non-legalized document to get approval (conditionally) and supplement the legalized document within 1 year.
- Allow certain flexibility in response deadline (case-by-case)
- Encourage e-submission and company chop can be waived.
- Provide Point of Contact info for urgent communication

2. Indonesia

1) REGULATION UPDATE

A National Agency for Drug and Food Control (NADFC) Regulation No. 8 of 2020 on Control of Online Sales of Drugs and Food

- Drugs and food in this NADFC Regulation include: Drug, Traditional medicine, Health supplement, Cosmetic, Food

B Government Regulation No. 31 of 2019 and Regulation Of The Minister Of Religion 26 of 2019 on Stages of the Halal Certification on OTC products

- The stages of the obligation to be certified halal for OTC (green dot and blue dot) starting from October 17, 2021 to October 17, 2029

C National Agency for Drug and Food Control (NADFC) Regulation No. 19 of 2020 on Follow-up drug and food control.

- Category of Findings in Production Facilities, Distribution Facilities, Pharmaceutical Service Facilities, and Pharmaceutical Electronic system operators : Minor, Major and Critical findings

D Draft Constitution Of Drug And Food Control

- Only 2 drug classification OTC & Prescription
  Now, OTC have 2 categories (greed dot and blue dot)
- Ministry Of Health's Draft Regulation : Switches Rx to OTC
- The Ministry Of Health's Draft Regulation : Drug Stores

2) **ACTIVITIES TO PROMOTE SELFCARE**

- **GEMA CERMAT (Gerakan Masyarakat Cerdas Menggunakan Obat)**
  The society movement to be smart for the use of medicines

➢ Guideline of society movement to be smart for the use of medicines (Published July, 2020)

The society movement to be smart for the use of medicines activities include efforts to increase knowledge and skills, as well as changes in people's behavior in choosing, obtain, use, store and dispose of drugs properly**, includes over-the-counter drugs for self-medication, as well as prescription drugs.**

3. Japan

1) Japanese government's move to promote Rx-to-OTC switching

The Cabinet of the Japanese government decided to execute a regulatory reform plan based on the recommendation made in July 2020 by the Council for Promotion of Regulatory Reform. The Reform Plan contains a part that refers specifically to promotion of self-medication and especially to Rx-to-OTC switch. The Cabinet has designated the Ministry of Health, Labor and Welfare (MHLW) as responsible for executing the reform, within the fiscal year 2020 (by March 2011).

The salient points about the reform are summarized as follows;

- MHLW should establish a cross-sectional division within the Ministry to promote self-medication as well as Rx-to-OTC switch.

- The Evaluation Committee, which lies in the center of the nation's current Rx-to-OTC switch scheme, should undergo a major change, so that it promotes but not hinders switching.
- OTC in-vitro diagnostics (OTCIVDs) should be promoted simultaneously and similarly to OTC drugs.

2) Petition to revise Self-Medication Tax Deduction for 2021

Mr. Hitoshi Shibata, Chairman of the Japan Federation of Self-Medication Industries (JFSMI) submitted a petition to reform the tax system to Mr. Nobukatsu Kato, Minister of Health labor and Welfare with the representative of Japan Pharmaceutical Manufacturers Association (JPMA), on July 17, 2020.

The petition summarizes itself into the following;

- expansion of the products (OTC medicines) that enjoys the tax deduction status,
- simplification of the filing process for the deduction,
- easing of the lower and upper limits to the deductible expense for OTC drugs, and
- prolongation of the sun-setting of the system.

Mr. Hitoshi Shibata, Chair of JSMIA handed the petition to Mr. Manabu Yoshida, Director-General, Health Policy Bureau, MHLW.

3) COVID-19

Japan Self Medication Industry (JSMI) served as a contact point for the Japanese Ministry of Health, Labor and Welfare (MHLW) to procure urgently-needed hand sanitizers, gargle agents and alcohol for disinfection to be sent to Wuhan, China in January 2020. Japan's OTC industry supplied a total of hundreds of requested products, mostly for free. The products were collected to the JSMI office in Tokyo and sent to the airport for charter flights.

As regulatory flexibility during the pandemic period, Japan's Pharmaceuticals and Medical Devices Agency (PMDA) allowed submission

of dossier without the company seal and alternative communication routes such as e-mail besides usually employed Fax. PMDA also published Q&A regarding measures to be taken when protocol deviation in clinical trials is unavoidable under the circumstances.

4. Korea

1) Abolition of a way of approval for OTC product

Ministry of Food and Drug Safety (MFDS), the authority granting marketing authorization of medicinal products in Korea, announced that a policy that has enabled OTC product to be approved in easier ways will be abolished in the near future. The policy is that an applicant can get approval of OTC product without safety & efficacy data (e.g. nonclinical data and clinical data), if the OTC product is approved and being marketed as OTC product in advanced countries (e.g. USA, EU, Japan).

2) Policy on promoting OTC

Though MFDS plans to strengthen its regulation over OTC as mentioned above on one hand, the Ministry is, on the other hand, is requested to make policies which can promote OTC products, as OTC products are required for self-care,. As one of the promotion measures, MFDS plans to expand the OTC monograph.

While the safety and efficacy of the OTC products are not as easily proven with clinical data as those of prescription drugs, expansion of OTC monographs can facilitate approval of OTC products for the applicants.

The main issue of expanding OTC monograph is also safety and efficacy of the products. Expanded OTC monograph should guarantee the category of OTC products' safety and efficacy. The Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA) has researched how OTC monograph should be changed, and suggested to MFDS several ways of expanding OTC monograph, in terms of the ingredients, strength, dosage types, and therapeutic areas.