APSMI Newsletter

Spring and Summer 2021

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1. Chinese Taipei

1) Stand alone "Medical Device Act" was established and effective on 1st May

Medical Device was governed under Pharmaceutical Affairs Act in the past decades. Considering the different characteristics of medical device from pharmaceutical products, TFDA referred to the regulations in EU, ASEAN, China and Korea to work on a separated regulatory framework for medical device from Pharmaceutical Affairs Act and the new Medical Device Act was effective on 1st May 2021.

The key differences of the new Act from the past regulations are:

1. Criteria of medical device classification is based on risk.
2. To add "Software" in the product scope (SaMD): in order to catch up the medical and consumer needs in digital application for diagnosis, treatment and self-care, a clearer regulatory framework is established to govern the new type of digital products.

3. In addition to the manufacturers (including software development house), importers/exporters or retails, the types of Medical Device firms include the businesses which engage in the rental, or repair of medical devices.

4. Require “qualified technical person” for a medical device firm.

5. To allow new type of channel (eCommerce/Distance sales and Vending machine) for specific items in the Act.

6. Mandatory GMP, GDP (implemented by stage), UDI labeling (implemented by stage) and Track and Trace management (for specific classifications).

7. Allow certain Class I items to be marketed via “Listing” procedure.

8. Simplify the advertisement process by prolonging the approval period from 1 year to 3 years.

2. Japan

1) Tax Break for OTC expense to be expanded

Japanese Government will increase the number of OTC drugs eligible for tax deduction (1,830 to 3,280) from 2022 to be slightly reduced to 3,230 in 2026.

Japan’s Self-Medication Tax Deduction System currently lists about 1,830 OTC drugs as eligible for deduction. These drugs contain one of 89 ingredients switched from Rx. A purchase of the products is partially reimbursed in the form of tax break.

As reported in the previous issue of APSMI Newsletter, the Japanese government will extend the System, which would otherwise sun-set 2021 year-end for another 5 years (2022 to 2026). Besides, about 1,450 new OTC products will become eligible from 2022. The “newcomers” were determined not by the ingredients, but by the efficacy categories; those in anti-inflammatory/analgesic, anti-tussive/expectorant, and anti-nasal allergy were newly listed. Cold medicines and anti-histaminergic agents fall in the categories. OTC drugs in these categories have more users with larger market sizes than those in other categories. Subsidizing their purchase should, therefore, help reduce the country’s medical expenditure.

Four ingredients currently eligible for deduction, contained in the total of 50 OTC vitamins, cardiotonic agents, calcium agents, and gargles, will be, however, removed from the list in 2026, on the ground that the products should be used carefully and that the effect to reduce medical expenditure is small.

2) Health Ministry establishes Self-Care / Self-Medication Promotion Office

In order to promote self-care / self-medication, Japan's Ministry of Health, Labor, and Welfare (MHLW) established in its organization a unit responsible to coordinate various activities in the Ministry in April 2021.

Because self-care / self-medication has many facets, multiple departments in the Ministry are involved; i.e. those responsible for drug regulation, industry promotion, health insurance, and health policies. Self-care/ self-medication cannot be effectively promoted without coordinating the activities of these departments. The newly created Office is expected to function as the control tower.

More specifically, the Office plans to formulate a package of policies to promote self-care/ self-medication, implemented across the Ministry. The policy package includes, but is not limited to, measures to facilitate Rx-to-OTC switch and to incentivize health care professionals to assist self-care/ self-medication. The Office also functions as the contact point of the Ministry for external communication and public relations. Promulgation of the Self-Medication Tax Deduction System mentioned above, for example, will be one of the Office's responsibilities.

The Office created its consultatory organ, Expert Committee on Self-Medication Promotion, comprised of experts outside the Ministry, in order to acquire suggestions widely from multiple stakeholders.

3. Korea

1) Drug Impurities Management Plan

On July 27th 2021, Korean Ministry of Food and Drug Safety (MFDS) announced Drug Impurities Management Plan for OTCs. The new rule goes into effect from October 15th, 2021.

The new rule applies to finished drugs listed in the OTC Monograph and raw materials and finished drugs listed in the Pharmacopeia (OTC), but not to products undergoing regulatory review. The rule requires the manufacturer to submit a possibility assessment table for nitroso-compound impurities. Possible contamination by N-Nitrosodimethylamine (NDMA) and other nitroso-compounds is evaluated. If the product is imported from abroad, evaluation by the overseas manufacturer can be used.

When a manufacturer notifies MFDS on their starting manufacture of the listed raw materials or finished drug, it must submit the assessment table. Also when the manufacturer changes the manufacturing method, process, etc. it must conduct a risk assessment anew and manage the safety of the product on its own.

4. Thailand

1) **ASEAN Good Registration Management (GRM): Application to Self-Care healthcare industry**

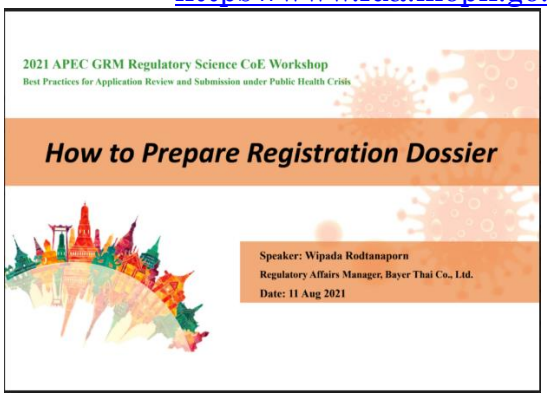
TSMIA view that self-care products have played important roles during Covid-19 pandemic in Thailand & ASEAN countries, such as support basic healthcare of citizen during lock-down, and importantly in personal hygiene & protection area. It is important that ASEAN & Thailand apply the GRM principle during public health crises, such as Regulatory Flexibility & Digitalization in developing the best practices for application review and submission, it will make the people in our countries access to important pharmaceuticals and innovation faster to cope with the crises, including for their self-care.

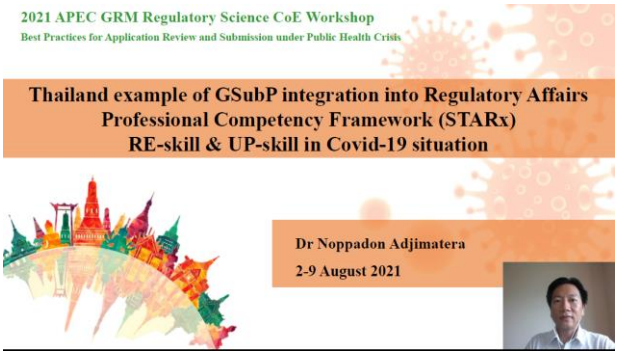
TSMIA has continued partnership with Thai FDA in supporting the APEC Good Registration Management (GRM) Regulatory Science Center of Excellence since 2019. This year the 2021 GRM workshop is arranged during Aug 2-11, 2021 via "virtual meeting", with the theme on *Best Practices for Application Review and Submission under Public Health Crises.* TSMIA has delivered 2 lectures for the workshop

- **Self-learning session:** *Thailand example in GSubP integration into Regulatory Affairs Professional Competency Framework (STARx) reskill/upskill in COVID-19 situation* (by Dr. Noppadon Adjimatera, TSMIA)
- **Workshop session:** *"How to Prepare Application Dossier and Support Tool"* with case studies on e-submission/e-documentations (by Ms. Wipada Rodtanaporn, TSMIA)

More information on GRM Workshop can be found in this website including presentation material

- https://www.fda.moph.go.th/Pages/GRMThailand/download.html





2) **Telepharmacy & E-pharmacy regulatory development in Thailand**

Since 2020-2021, Thailand Government has embraced e-Health initiatives especially key during the Covid-19 emergency due to significantly disrupted off-line healthcare services. Thailand Ministry of Public Health (MoPH) has introduced the "Medicine dispensing near your home" program

in government hospitals nationwide, where medicines will be delivered to neighborhood pharmacy stores with the aim to reduce congestion at hospitals and support Covid-19 management.

With more societal need on tele/e-Health, pioneer regulations are issued by HPC Councils (Telepharmacy Guideline for Pharmacists, Telemedicine Guideline for Medical Doctors) and MoPH (Telemedicine Guideline for Healthcare Institutions) following this successful program. Telepharmacy is typically involving the drug dispensing to patient house and online-consultation, but still need the physical drugstore presences. Telemedicine is the medical service over online platform, starting from consultation, diagnosis and eventually medicine dispensing/delivery (which incorporate the Telepharmacy element), and this could be viewed by patient like "E-pharmacy" through consumer-interface of application (but with the doctor diagnosis online etc.) to fulfil the telemedicine definition.

The concept of a true e-pharmacy is still a challenge with Drug Act BE2510, which currently prohibits medicine selling outside physical drugstore. TSMIA has worked via the "Telepharmacy taskforce" to draft the Thailand Telepharmacy Proposal (comprising of e-Pharmacy) with the view of international best practices (UK, Singapore, Philippines), which has been presented to FDA.

Currently Thai FDA is researching the e-Pharmacy framework & regulatory strategy, and TSMIA is working closely with the Telepharmacy taskforce and Thai FDA on this matter. More update will be presented in due course.