

APSMI NEWSLETTER

September 2023

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ASIA-PACIFIC SELF-MEDICATION INDUSTRY
ITOHPIA IWAMOTOCHO 1-CHOME BLDG. 4TH FLOOR
1-8-15, IWAMOTOCHO, CHIYODA-KU, TOKYO 101-0032, JAPAN

World Topics

US FDA: NDAC unanimously voted on the ineffectiveness of PE as a nasal decongestant

A non-prescription drugs advisory committee (NDAC) of the U.S. Food and Drug Administration (FDA) held a committee meeting from September 11th to 12th regarding the ingredient "phenylephrine," which is commonly added to over-the-counter anti-allergy and cold medicines. It was unanimously approved that this form is ineffective.

Detail information can be obtained at the following URLs:

<https://www.fda.gov/media/171972/download>

September 11-12, 2023 Nonprescription Drugs Advisory Committee Meeting (fda.gov)

<https://www.fda.gov/advisory-committees/advisory-committee-calendar/updated-september-11-12-2023-meeting-nonprescription-drugs-advisory-committee-meeting-announcement#event-materials>

UPDATED: September 11-12, 2023: Meeting of the Nonprescription Drugs Advisory Committee Meeting Announcement - 09/11/2023 | FDA

<https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-results-recent-advisory-committee-meeting-oral-phenylephrine>

FDA clarifies results of recent advisory committee meeting on oral phenylephrine | FDA

YouTube : Meeting of the Nonprescription Drugs Advisory Committee (NDAC)

Sept. 11, 2023

https://www.youtube.com/watch?v=DF916_xGj24

September 11-12, 2023 Meeting of the Nonprescription Drugs Advisory Committee (NDAC)
- Day 1 – YouTube

Sept. 12, 2023

<https://www.youtube.com/watch?v=aUyuzjInGfA>

September 11-12, 2023 Meeting of the Nonprescription Drugs Advisory Committee (NDAC)
- Day 2 - YouTube



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Event

APSMI: the 5th Self-CARER Meeting & the 13th APSMI BM

From September 18th to 20th, 2023, the 5th Self-CARER Conference and 13th APSMI Board of Directors Meeting were held in Taipei as a hybrid web-based meeting.

Dr. Padma Kamath, GSCF, and Mr. Christopher Humphrey, EU-ABC, kindly made presentation as invited speakers at the Open Session, the 5th Self-CARER Meeting:

a. 5th Self-CARER Conference

Thirty-nine (39) regulators from 8 countries/region (Japan, Thailand, Chinese Taipei, South Korea, Vietnam, Malaysia, Indonesia, and the Philippines) participated (36 in-person, 3 online), and held a three-day seminar on OTC drug administration.

Day 1 (September 18th P.M.): Self-CARER University

Session 1: Policy, eco-systems, emerging issues and stakeholders

Session 2: Simplified product registration & Switch evaluation process

Session 3: Digital Transformation in Self-CARE

Day 2 (September 19th Full Day): Self-CARER Closed Session

- ◆ Regulatory Update

- ◆ Round Table Discussion

Theme 1: Opportunity and challenge for OTC registration simplification

Theme 2: Opportunity and challenge for switch

Theme 3: Opportunity and challenge for OTC e-labeling

Day 3 (September 20th A.M.): Self-CARER Open Session

- ◆ Welcome speech: Future perspective for self care in Taiwan

(Dr. Wu Shou-Mei, Taiwan FDA)

- ◆ Keynote speech (Ms. Sylvia Tsai, Chair, APSMI)

- ◆ Global trends in OTC regulation (Dr. Padma Kamath, GSCF)

- ◆ Driving selfcare towards sustainable health system and resiliency

(Mr. Christopher Humphrey, EU-ASEAN Business Council)

- ◆ Key learning from Self-CARER University

(Ms. Worasuda Yoongthong, Thai FDA)

- ◆ Self-CARER meeting outcome (Mr. Naoyuki Yasuda, PMDA)



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b. 13th APSMI Board of Directors Meeting

Seven (7) new members joined APSMI at the 13th APSMI BM as follows:

1. Healthcare Committee under American Chamber of Commerce in Vietnam(Am-Cham Vietnam), Vietnam
2. Sanofi Consumer Healthcare ASEA (Sanofi CHC ASEA), Singapore
3. Procter & Gamble International Operations SA SG Branch(P&G), Singapore
4. Kenvue, Singapore
5. PT. Konimex, Indonesia
6. ROHTO Pharmaceutical Co.,Ltd. (ROHTO), Japan
7. Haleon, Singapore