



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

APSMI NEWSLETTER

December 2022

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APSMI Website updated

APSMI Website has been updated to reflect the results of the 12th APSMI Board of Directors Meeting which was held in Bangkok on 28th November 2022:

Updated contents:

[Open Site]

- ◆ Activities
- ◆ Board of Directors

[Member Site]

- ◆ APSMI Master Plan 2023 – 2025
- ◆ Board of Directors
- ◆ Documents and minutes of the 12th Board of Directors Meeting

World Topics

1. ICH Assembly Meeting

The Assembly of the International Council for Harmonisation (ICH) met in-person on the 15 - 16 November 2022, in Incheon, Republic of Korea in parallel of meetings of ten Working Groups, and preceded by meetings of the ICH Management Committee and the MedDRA Management Committee.

The meeting provided an important opportunity to advance work of ICH's thirty-three Working Groups and key activities including training.

The ICH Assembly also welcomed DPM, Tunisia as a new ICH Observer, bringing ICH to a total of 20 Members and 36 Observers.

Press release of the meeting is available at the following URL:

<https://www.ich.org/pressrelease/press-release-ich-assembly-meeting-incheon-republic-korea-november-2022>

2. CHPA

The Consumer Healthcare Products Association (CHPA) released findings from its 2022 Over-The-Counter (OTC) Value Study, once again showing that self-care with OTC medicines not only benefits individuals but also benefits the entire healthcare system



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on 1st december 2022. This year's study found that on average, every dollar spent on OTC medicines saves the U.S. healthcare system \$7.33, resulting in an overall annual savings of \$167.1 billion.

The full report is available at the following URL:

<https://www.chpa.org/news/2022/12/value-created-otc-medicines-generates-billions-savings-us-healthcare-system>

3. EMA

EMA recommends withdrawal of pholcodine medicines from EU market on 2nd December 2022.

EMA's safety committee, PRAC, has concluded its review of medicines containing pholcodine, which are used in adults and children to treat non-productive (dry) cough and, in combination with other active substances, for the treatment of symptoms of cold and flu, and has recommended the revocation of the EU marketing authorizations for these medicines.

Detail information is available at the following URL:

https://www.ema.europa.eu/en/documents/referral/pholcodine-containing-medicinal-products-article-107i-referral-ema-recommends-withdrawal-pholcodine_en.pdf

4. USA

Public comment on the proposed rule of 'Nonprescription Drug Product With an Additional Condition for Nonprescription Use (ACNU)' closed on 25th November 2022, with 182 comments submitted.

The submitted comments are available at the following URL:

<https://www.regulations.gov/docket/FDA-2021-N-0862/comments?sortBy=postedDate&sortDirection=desc>

5. The 9th Thailand – Japan Symposium

The 9th Thailand – Japan Symposium (hosted by Thai-FDA and PMDA) will be held in Bangkok on 17th January 2023.

Detail information is available at the following URL:

<https://sites.google.com/view/9ththailand-japansymposium/home>