

APSMI NEWSLETTER

August 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

Latin America: AMLAC was established

On 26 April 2023, the heads of the health agencies of Colombia, Cuba and Mexico, specifically the National Institute for Surveillance of Drugs and Food (INVIMA) of Colombia, the Center for the State Control of Medicines, Equipment, and Medical Devices (CECMED) of Cuba, and Federal Commission for the Protection against Sanitary Risks (COFEPRIS) of Mexico, signed the Acapulco Declaration for the creation of AMLAC (Agencia Reguladora de Medicamentos y Dispositivos Médicos de Latinoamérica y el Caribe), the Latin America and Caribbean Medicines and Medical Devices Regulatory Agency.

The current status of AMLAC membership is as follows.

- ◆ Membership (10 countries): Mexico, Colombia, Cuba, Bolivia, Dominican Republic, Dominica, Ecuador, El Salvador, Honduras, Jamaica
- ◆ Under consideration (3 countries): Argentina, Brazil, Chile

Detail information can be obtained at the following URLs:

Ministry of Foreign Affairs, Republic of Cuba WEBSITE:

<https://cubaminrex.cu/en/colombia-mexico-and-cuba-promote-creation-regulatory-agency-drugs-and-medical-devices-latin-america>

South Centre WEBSITE:

<https://www.southcentre.int/policy-brief-120-11-july-2023/>

GABI(GENERICS AND BIOSIMILARS INITIATIVE) WEBSITE:

<https://www.gabionline.net/policies-legislation/amlac-regulatory-agency-for-medicines-in-latin-america-and-the-caribbean-established>

PAGB: Publishes Report “The Economic Impact of OTC Products in the UK”

On 12 July 2023, the Proprietary Association of Great Britain (PAGB) published a report “THE ECONOMIC IMPACT OF OVER-THE-COUNTER PRODUCTS IN THE UK”.

The report explains that for every £1 consumers spend in his £3.3bn OTC market today, it delivers the following economic benefits:



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- ◆ The OTC sector contributes £1 to the economy in wages and exports.
- ◆ Workplace absenteeism is avoided, saving the economy £5.40.
- ◆ NHS saves him £1.90 on prescription and consultation costs.

The report (37 pages in English) is available at the following URL:

<https://www.pagb.co.uk/content/uploads/2023/07/20230712-Frontier-PAGB-OTC-Impact-Report-v1-0.pdf>

MHRA: Proposed reverse switch for codeine-containing syrup drugs

On 18 July 2023, the UK Medicines and Healthcare products Regulatory Agency (MHRA) launched a public consultation to propose a reverse switch of codeine-containing syrups to prescription drugs, opinion on 15 August Completed recruitment.

The proposal (16 pages in English) is available from the MHRA website:

<https://www.gov.uk/government/consultations/mhra-public-consultation-on-the-proposal-to-make-codeine-linctus-available-as-a-prescription-only-medicine-pom>

US FDA: Warning letters sent to 10 foreign over-the-counter drug manufacturers and 2 US companies US FDA Issues Warning Letters to Manufacturers of Pediatric Homeopathic OTC Drugs

The US Food and Drug Administration (FDA) sent warning letters to ten foreign over-the-counter drugmakers for failing to test raw materials susceptible for Diethylene Glycol (DEG) and Ethylene Glycol (EG) contamination; some of these letters also took the companies to task for ignoring the agency's requests for written records. FDA also handed two warning letters to domestic drugmakers for failure to comply with requests for records.

12 companies sent warning letters:

- India (4): Daxal Cosmetics, Skyline Herbals, Suhan Aerosol, Orchid Lifesciences
- Korea (3): LCC Limited, Sangleaf Pharm, KM Pharmaceuticals
- Portugal (1): Fancystage Unipessoal
- Canada (1): Avaria Health and Beauty Corp
- Turkey (1): Tan Alize Kozmetik
- U.S. (2): Cergomex Imports, GTP International



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Detail information can be obtained by the following article of RAPS:

<https://www.raps.org/news-and-articles/news-articles/2023/8/fda-issues-blitz-of-warning-letters-over-testing-v>

Each warning letter can be available at the following US FDA website :

<https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters>

Event

APSMI: 5th Self-CARER Meeting

On 18-20 September 2023, the 5th Self-CARER Meeting (Self-Medication Collaborative ASIAN Regulator Expert Roundtable) will be held in Taipei. The meeting is sponsored by Asia-Pacific Self-Medication Association (APSMI).