ASIA-PACIFIC SELF-MEDICATION INDUSTRY
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APSMI NEWSLETTER
April 2023

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World Topics

Asia: E-labeling position paper adopted at the 12th APAC

The 12th Asia Partnership Conference of Pharmaceutical Associations (APAC) (organized and hosted by JPMA) was held in Tokyo on 18 April 2023.

APAC e-labeling position paper for early implementation of e-labeling in Asian countries and for a unified approach was adopted.

The APAC E-labeling position paper is available at the following URL:

https://apac-asia.com/images/elabeling/APAC_e-Labeling_PositionPaper.pdf

The program and PPTs of the 12th APAC are available at the following URL:

https://12th-apac.com/index.html

Malaysia: E-labeling guideline was issued

E-labeling guideline was issued by the National Pharmaceutical Regulatory Agency (NPRA) of Malaysia on April 11, 2023 (It is not a mandatory requirement).

The Implementation schedule is explained in detail in the presentation materials for the 12th APAC mentioned above.

The guideline is available at the following URL:

In Malay:

https://www.npra.gov.my/index.php/en/directive-general/1527484-direktif-berkenaan-pelaksanaan-electronic-labelling-e-labelling-ke-atas-produk-farmaseutikal-di-malaysia.html

English translation:

https://www.npra.gov.my/easyarticles/images/users/1047/Lampiran-A-Guideline-on-E-Labelling-for-Pharmaceutical-Products-in-Malaysia.pdf

WHO: Alert of the risk of anaphylactic reactions who have taken pholcodine containing products was issued

On 31 March 2023, The World Health Organization (WHO) issued an alert to health-care professionals and regulatory authorities of the risk of anaphylactic reactions in people who have taken pholcodine-containing products at least 12 months prior to surgical procedures involving the administration of general anaesthesia with neuromuscular blocking agents (NMBAs).

The alert is available at the fooling URL:

Prior use of pholcodine-containing cough and cold remedies and risk of perioperative anaphylactic reactions to neuromuscular blocking agents (NMBAs) (who.int)

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WHO: proposes updated excipient GMPs in wake of contaminated cough syrup

WHO recently proposed updated guidance to assist pharmaceutical manufacturers in assessing the quality of excipients after child deaths were reported in several countries linked to contaminated cough syrups containing unacceptable levels of diethylene glycol (DEG) and ethylene glycol (EG) in their formulations.

The guideline is available at the following URL:

https://cdn.who.int/media/docs/default-source/health-products-policy-and-standards/qas23_921_gmp_for_excipients_pharmaceutical_products_public-consultation.pdf?sfvrsn=c9ef88da_3

USA: "Over-the-Counter (OTC) Drug Review on OTC Monograph Reform in the CARES Act" and "Draft Guidance for Over-the-Counter Monograph Order Requests (OTC-OMORs): Format and Content" were issued

The US FDA has published a review on OTC Monograph Reform in the CARES Act on 12 April 2023.

In addition, US FDA released "Draft Guidance for Over-the-Counter Monograph Order Requests (OTC-OMORs): Format and Content" on 13 April 2023.

The review is available at the following URL:

https://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/over-counter-otc-drug-review-otc-monograph-reform-cares-act

The draft guidance is available at the following URL:

https://www.federalregister.gov/documents/2023/04/13/2023-07767/over-the-counter-monograph-order-requests-format-and-content-draft-guidance-for-industry