

APSMI NEWSLETTER

March 2023

Contents:

World Topics:

- **USA:** Potential for removing phenylephrine from a monograph from OTC Monograph
- **UK:** Pholcodine OTCs Recalled in UK
- **UK:** MHRA reclassifies Cialis Together tablets to a Pharmacy medicine
- **Switzerland:** New Mobile technologies guidance document for human and veterinary medicinal products
- **Korea:** [New Bio-Health Industry Regulation Innovation Plan]
- **India:** Online drug sales, government considers tightening regulations





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

World Topics

USA: Potential for removing phenylephrine from a monograph from OTC Monograph

Nonprescription Drugs Advisory Committee (NDAC) will discuss whether data supports oral phenylephrine's GRASE as nasal decongestant on 23rd April 2023.

Detail information is available at the following article:

<https://hbw.pharmaintelligence.informa.com/RS153451/Asking-Advisors-About-Phenylephrine-Efficacy-May-Portend-FDA-Taking-Streamlined-Monograph-Steps>

UK: Pholcodine OTCs Recalled in UK

The Medicines and Healthcare products Regulatory Agency (MHRA) released an advice for healthcare professionals regarding the withdrawal of pholcodine-containing medicines from the market on 14th March 2023 alongside a review conducted by the European Medicines Agency, which also concluded that the benefits did not outweigh the risks.

The press release can be obtained at the following URL:

<https://www.gov.uk/drug-safety-update/pholcodine-containing-cough-and-cold-medicines-withdrawal-from-uk-market-as-a-precautionary-measure>

UK: MHRA reclassifies Cialis Together tablets to a Pharmacy medicine

Following advice from the Commission on Human Medicines, the Medicines and Healthcare products Regulatory Agency (MHRA) has reclassified Cialis Together so that it can now be made available for purchase over the counter, without a prescription on 14th March 2023.

The press release can be obtained at the following URL:

<https://www.gov.uk/government/news/mhra-reclassifies-cialis-together-tablets-to-a-pharmacy-medicine>

Switzerland: New Mobile technologies guidance document for human and veterinary medicinal products

The Swiss Agency for Therapeutic Products (Swissmedic) released new regulations on the use of QR codes on packaging and in medicinal product information on 1st March 2023.

The guideline is available at the following URL:

<https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/authorisations/>



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

information/neue-wl-mobile-technologien-ham-tam.html

Korea: 「New Bio-Health Industry Regulation Innovation Plan」

The Ministry of Health and Welfare, led by Minister Cho KyooHong, announced the New Bio-Health Industry Regulation Innovation Plan at the Third Regulatory Innovation Strategy Meeting on 2nd March 2023.

Detail information is available in English at the following URL:

https://www.mohw.go.kr/eng/nw/nw0101vw.jsp?PAR_MENU_ID=1007&MENU_ID=100701&page=1&CONT_SEQ=375337

India: Online drug sales, government considers tightening regulations

India's Ministry of Health and Family Welfare is considering tightening regulations on the sale of medicines online.

Detail information is available at the following article:

<https://www.ndtv.com/india-news/centre-considers-banning-online-drug-stores-over-data-misuse-report-3858324>