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

First Announcement of GSCF/APSMI/TSMIA Joint Congress 2024

Self Care in Health Care: a Vision for Asia Pacific

Date: 13 – 15 November 2024

Venue: CENTARA GRAND & BANGKOK CONVENTION CENTRE AT CENTRALWORLD

Centara Grand & Bangkok Convention Center at Central World
999/99 Rama 1 Road, Pathumwan Bangkok 10330,Thailand

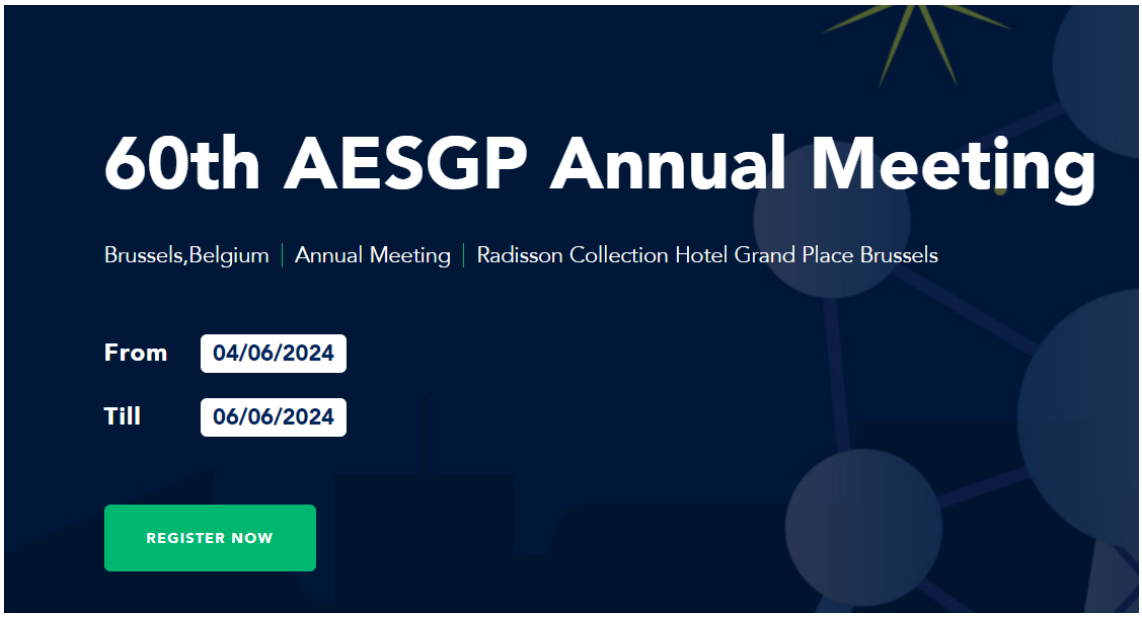
https://www.centarahotelsresorts.com/centaragrand/cgcw

Please save the date!

Details will be announced in the 2nd Announcement in March 2024.

For your reference:

https://aesgp.eu/events/60th-aesgp-annual-meeting



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APSMI NEWSLETTER
February 2024

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World Topics

Europe: EMA/CMDh: Nitrosamine Q&A Document revised

The EMA/CMDh nitrosamine Q&A document "Questions and answers for marketing authorization holders/applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products" was updated again in January 2024 and is now available in revision 20. Like the three appenices, the Q&A document is published on the EMA website and can be viewed under "Questions and answers".

Appendix 1 Acceptable intakes (AIs) established for N-nitrosamines
Appendix 2 Carcinogenic Potency Categorisation Approach for N-nitrosamines
Appendix 3 Enhanced Ames Test Conditions for N-nitrosamines

Q&A ver. 20 is available at the following URL:
https://www.ema.europa.eu/en/documents/referral/nitrosamines-emea-h-a53-1490-questions-answers-marketing-authorisation-holders-applicants-chmp-opinion-article-53-regulation-ec-no-726-2004-referral-nitrosamine-impurities-human-medicinal-products_en.pdf

Europe: Medicines And Cosmetics Industries Set To Pay At Least 80% Of Wastewater Treatment Costs

The pharmaceutical and cosmetics industries will have to bear at least 80% of the costs linked to cleaning harmful substances they discharge into urban wastewater, following an inter-institutional agreement reached in Brussels on January 29.

The two industries are jointly responsible for 92% of the toxic load in wastewaters, the European Commission maintained when launching its legislative proposal in October 2022.

Detailed information can be found in the following article:
Euronews.green (30th January 2024)
https://www.euronews.com/green/2024/01/30/pharma-and-cosmetics-industries-to-pay-for-wastewater-treatment

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Philippine: FDA to shorten review, approval process of generic drugs from 120 days to 45 days

On 13th February 2024, on the directive of President Ferdinand R. Marcos Jr., the Food and Drug Administration (FDA) is set to shorten the period of review and approval processes of applications of generic drugs from 120 days down to only 45 days.

"I'm on the verge of signing the memorandum circular for the facilitation of FRP for generic drug – it means it will shorten the 120 days to 45 days," FDA Director General Samual Zacate said in a Palace briefing on Tuesday after his sectoral meeting with the President aimed at streamlining the country's drug regulatory processes.

The FDA uses the Facilitated Review Pathway (FRP) as an alternate registration procedure, where they refer to the evaluations conducted by a reference drug regulatory agency overseas when making its own assessment.

The press release is available at the following URL:
https://pia.gov.ph/press-releases/2024/02/14/fda-to-shorten-review-approval-process-of-generic-drugs-from-120-days-to-45-days

Chinese Taipei: TFDA becomes the Associate Member of the ICMRA

On 21st February 2024, Taiwan Food and Drug Administration (TFDA) has officially joined an informal international group consisting of regulatory agencies that regulate medicines after the group approved its application to join.

TFDA said they have become an associate member of the International Coalition of Medicines Regulatory Authorities (ICMRA) after the ICMRA approved its application, filed in 2023, at a recent meeting in the statement.

TFDA Press Release:
https://www.fda.gov.tw/ENG/newsContent.aspx?id=30392

Relating Articles:
https://focustaiwan.tw/society/202402210008
https://www.taiwannews.com.tw/en/news/5099648