

APSMI NEWSLETTER

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ASIA-PACIFIC SELF-MEDICATION INDUSTRY
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World Topics

EMA:EU Pilot Produces First Electronic Product Information

EU regulators have published the first electronic product information (ePI) documents under their pilot initiative to allow the transition to an electronic information system for medicines approved at both national and EU level.

The ePIs are available at the following portal site:

<https://plm-portal.ema.europa.eu/ePIAll/>

Malaysia: Guideline for Facilitated Registration Pathway (FRP) , Revision 1, 2023

16 November 2023, the National Pharmaceutical Regulatory Agency (NPRA) of Malaysia updated its guideline on approval pathways for medicines that have already received authorization in certain overseas territories. NPRA's changes include the addition of new reference regulatory agencies and the shortening of approval timelines.

The revised guideline is available at the following URL:

https://np.ra.gov.my/easyarticles/images/users/1047/Direktif/Lampiran-A_FRP-Guidelines_Revision-1_2023.pdf

This matter is introduced in detail in the following article in RAPS newspaper:

<https://www.raps.org/News-and-Articles/News-Articles/2023/11/Asia-Pacific-Roundup-Malaysia%E2%80%99s-NPRA-updates-regul>

Event

Asia-Pacific Self-Care Regional Congress

GSCF and APSMI will jointly hold "Asia-Pacific Self-Care Regional Congress (Tentative name)" in Bangkok in November 2024.

The first announcement is to be released by the end of January 2024.



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*Wishing you good health, happiness, and good cheer in the coming year.
Have a wonderful Christmas and New Year ahead!*



Asia-Pacific Self-Medication Industry

