

Convergence of OTC Drug Regulation in Asia-Pacific

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Year of Rx to OTC Switch

- Disharmonies in OTC Regulation**
1. Categorization of OTC drugs
 2. Data required for approval & review process
 3. Monograph and Approval Standards
 4. Advertisement pre-Authorization
 5. Rx to OTC Switch
 6. ICH Guidelines Application

	UK	USA	Australia	China	Chinese -Taipei	Japan	Korea	Thailand
Ibuprofen (oral)	1983	1984	1989	OTC	2018 (400mg)	1985	d-OTC 1997	d-OTC
Loratadine	1993	2002	1994-96	2005	2011	2017	2013	d-OTC
Cimetidine	1994	1995	1995	OTC	Rx	1997	Rx	d-OTC
Omeprazole	2004	2003	2010	OTC	2018	Rx	Rx	d-OTC
Triamcinolone (Mouth Ulcer)	OTC	OTC	1996	OTC	?	2006	d-OTC 1985	d-OTC

Region	Sales (Billion USD)	Market Share (%)
Asia-Pacific	33	32
North America	29	28
Europe	29	25
Total	118	100

Source: AESGP Data Base, APSMI Country Report 2016
 OTC: currently available as OTC drugs, if and when switched is unknown. d-OTC: direct OTC, approved first as OTC

Industry's Efforts



Asia-Pacific Self-Medication Industry (APSMI)

- Industry's Conference to contribute to the development of OTC industries and to promote responsible Self-Medication in Asia-Pacific
- Established in 2010
- Participating OTC Manufacturers' Associations; China (CNMA), Taiwan (TPMMA), Korea (KPBMA), Indonesia (G.P. Farmasi), Japan (JFSMI), Philippines (CHAP), Thailand (TSMIA)

Regulators' Initiative



Self-medication Collaborative ASIAN Regulator Expert Roundtable (Self-CARER)

- A Platform for regulators to optimize OTC regulation in Asia-Pacific.
- Informal meeting since 2014
- Participating regulatory agencies in 2018 Taipei meeting: Chinese Taipei, India, Indonesia, Japan, Malaysia, Myanmar, New Zealand, Singapore, Thailand, Vietnam (10 countries)



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Collaboration for Regulatory Harmonization. Best Practice, Work-Sharing



Taipei, March 2018