

Convergence of OTC Drug Regulation in Asia-Pacific

Toshi Tominaga, Ph. D., Secretary-General, Asia-Pacific Self-Medication Industry (APSMI)

Year of Rx to OTC Switch

Disharmonies in OTC Regulation

1. Categorization of OTC drugs
2. Data required for approval application and 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	OTC	1985	OTC	OTC
Loratadine	1993	2002	1994-96	2005	2011	2017	2013	OTC
Cimetidine	1994	1995	1995	OTC	?	1997	OTC	OTC
Omeprazole	2004	2003	2010	OTC	2018	Rx	Rx	OTC
Triamcinolone (Mouth Ulcer)	OTC	OTC	1996	OTC	?	2006	OTC	?

Source: AESGP Data Base, APSMI Country Report
OTC: switched year unknown, Rx: not yet switched

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)



Jakarta, Oct. 2018

Collaboration for
Regulatory Harmonization. Best Practice, Work-Sharing



Taipei, March 2018

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

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

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

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