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

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	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)	ОТС	ОТС	1996	ОТС	?	2006	d-OTC 1985	d-OTC

Source: AESGP Data Base, APSMI Country Report 2016

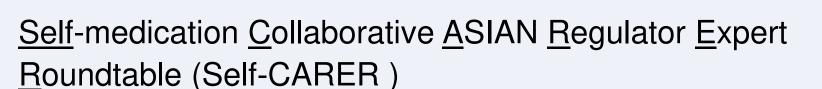
OTC: currently available as OTC drugs, if and when switched is unknown. d-OTC: direct OTC, approved first as OTC

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



- 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)





