

Pharmaceutical Market and Regulatory Environment in Asia (PMRE)

Staying Current with market & regulatory
environment

Tomoyuki Otsuka
PMRE Task Force Lead

Agenda

What is Pharmaceutical Market and Regulatory Environment Report (PMRE)?

How was it created?

Where can we find it?

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APAC mission is to expedite the launch of innovative medicines for the peoples in Asia, through a holistic scope

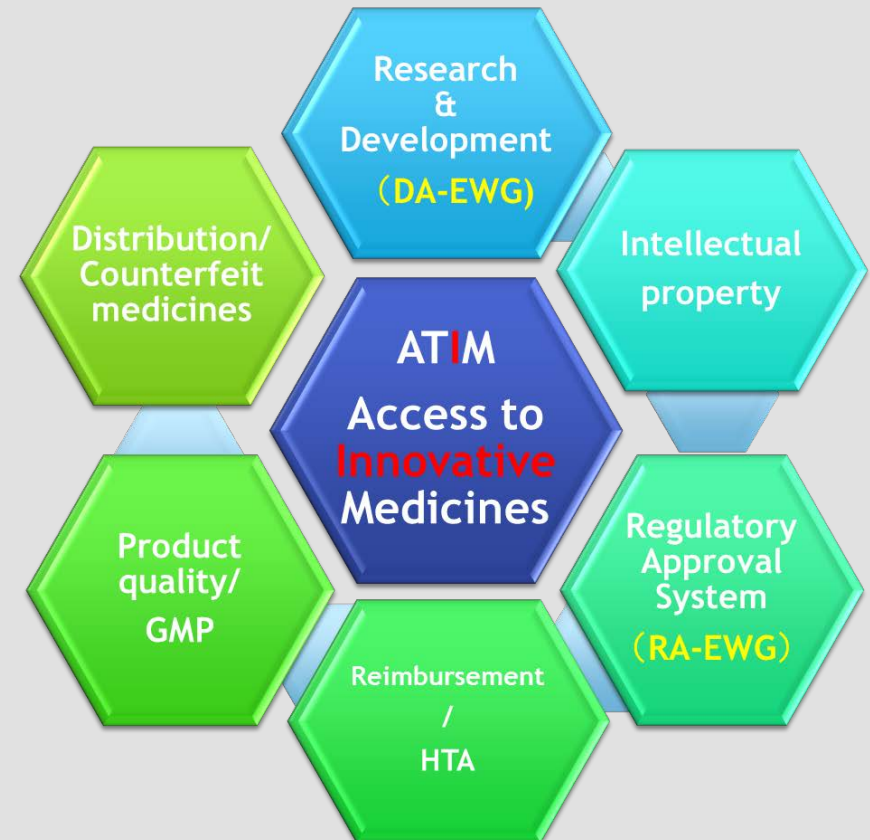
MISSION

To expedite the launch of innovative medicines for the peoples in Asia



SCOPE

to improve Access to Innovative Medicines (ATIM)



APAC merged Analysis report with JPMA Asia comparative report to a new comprehensive report



2011~

Regulatory

**Analysis
Report**



2019 ~

**Pharmaceutical
Market and
Regulatory
Environment
(PMRE)**



**Regulatory +
Market
Asia**

**comparative
report**



Comprehensive report will

**Contribute to the
achievement of APAC
Mission**

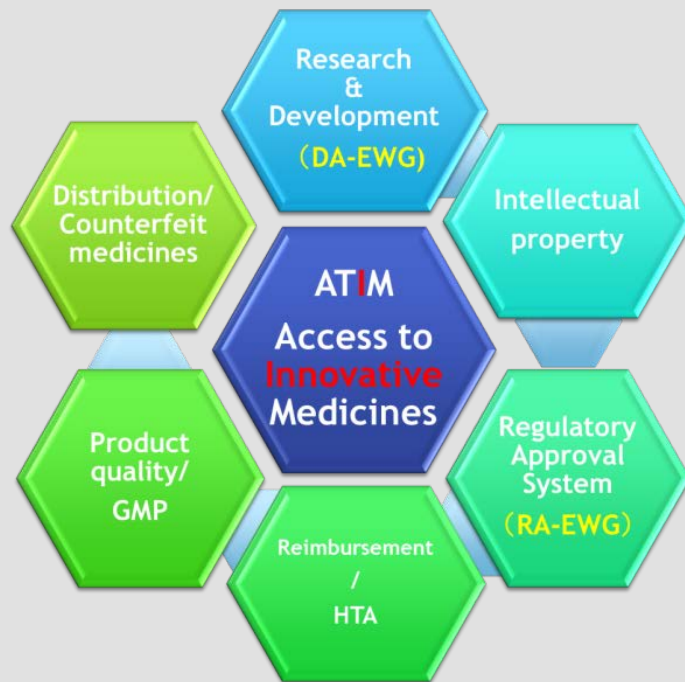
**Add value for APAC member
associations and their
members**

**Differentiate APAC as a fact-
based platform**

The content of the report: PMRE broadly covers various elements on pharmaceutical market & regulatory environment

SCOPE :

to improve Access to
Innovative Medicines
(ATIM)



MARKET

- Market & Distribution
- Healthcare Funding and Pricing
- Intellectual Property
- Pharmaceutical Trade

REGULATORY

- IND/CTA
- NDA
- Clinical Trials
- Manufacturing
- Post-approval

Examples of insights: PMRE makes it easier to compare regulations in each economy for future APAC collaboration

	HKAPI	IPMG	IRPMA	JPMA	KPBMA/ KRPIA	OPPI	PHAMA	PHAP	PREMA	RDPAC PHIRDA	SAPI	PG
Centralized logistic Management	NA	NA	YES	YES	YES	YES	In Progress	In Progress	NA	YES	YES	NA
Patent term extension	NA	NA	YES	YES	YES	NA	NA	NA	NA	YES	YES	NA
Priority review.	NA with exceptions	YES	YES	YES	YES	NA	YES	YES	YES	YES	YES	In Progress

Note: The YES/NA or In progress in this chart is for illustrative purpose. Please refer to the PMRE report for the full information.

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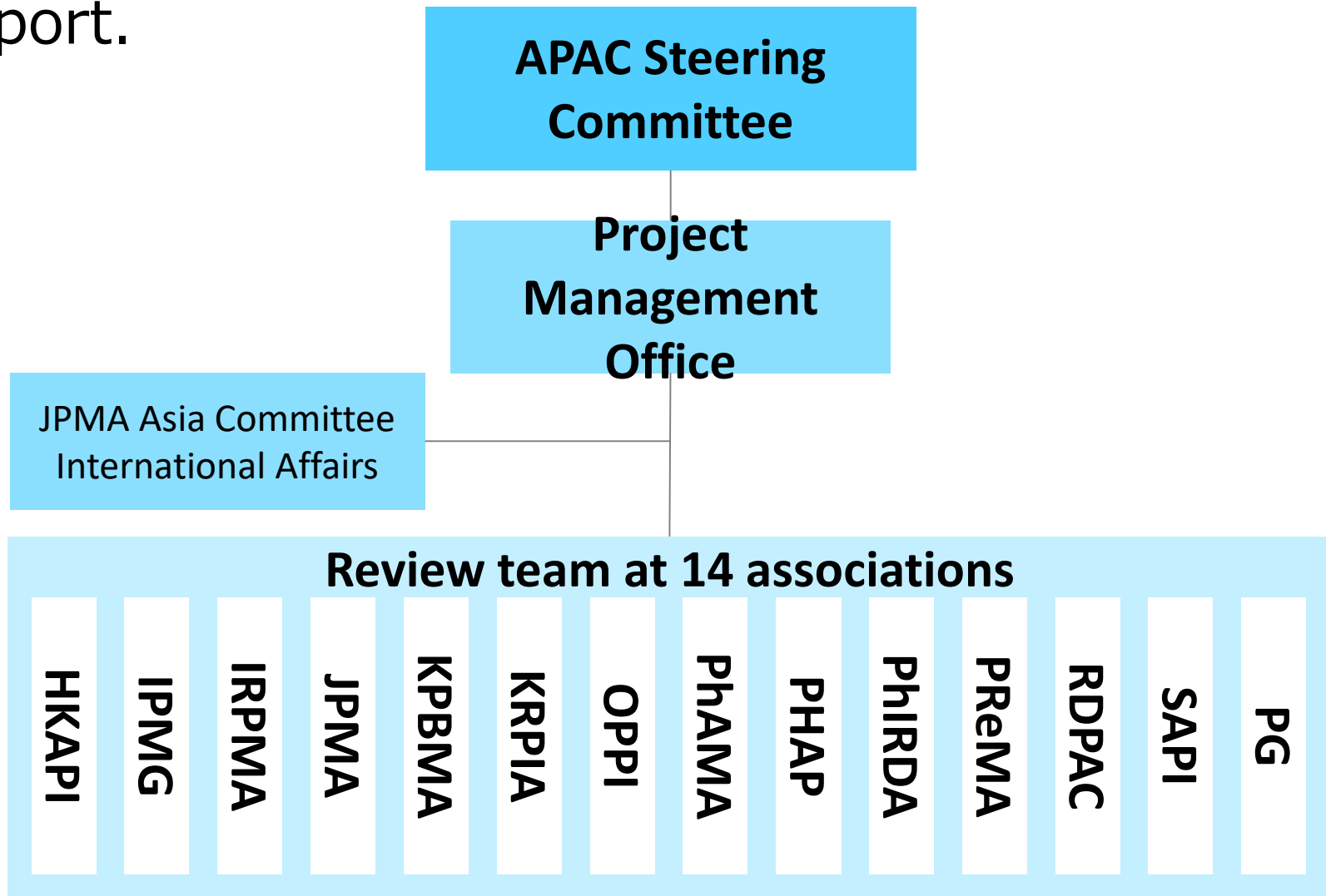


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14 associations and their 100+ members contributed to the new PMRE report.



Special Thanks to authors & reviewers



HKAPI	The Hong Kong Association of the Pharmaceutical Industry Sabrina Chan, Karen Yuen
IPMG	International Pharmaceutical Manufacturers Group Parulian Simanjuntak, Agustina Tjandra
IRPMA	International Research-Based Pharmaceutical Manufacturers Association Heather Lin, Linda Wu
JPMA	Japan Pharmaceutical Manufacturers Association Asia Committee of International Affairs, Code Compliance Committee, Intellectual Property Committee, Pharmaceutical Industrial Policy Committee, Quality & Technology Committee, Regulatory Affairs Committee
KPBMA	Korea Pharmaceutical and Bio-pharma Manufacturers Association Seogkyu Yoon
KRPIA	Korean Research-based Pharmaceutical Industry Association Mijin Jung, Youngju Kang
OPPI	Organization of Pharmaceutical Producers of India Sanjit Singh Lamba, Ajay kumar Sharma , Nitika Garg
PhAMA	Pharmaceutical Association of Malaysia Alice Chee, Shi Hao Lim
PHAP	Pharmaceutical and Healthcare Association of the Philippines Teodoro Padilla, Richard Simon Binos, Emeline Bautista
PHIRDA	China Pharmaceutical Innovation and Research Development Association Xiaoti Lu, Yuanlin Yang
PReMA	Pharmaceutical Research & Manufacturers Association Busakorn Lerswatanasivalee
RDPAC	China Association of Enterprise with Foreign Investment R&D-based Pharmaceutical Association Committee, Sara Wang
SAPI	Singapore Association of Pharmaceutical Industries Christina Teo, Kum Cheun Wong
PG	Pharma Group (Vietnam)

PMO
Lead: Otsuka
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Where to access it digitally? PMRE will be available at APAC member site



<https://apac-asia.com/>



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ABOUT US

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NEWS

OUR WORKING GROUPS



APAC

Asia Partnership Conference
of Pharmaceutical Associations

To expedite the launch of innovative medicines
for the peoples in Asia.





Thank you!