

APAC Harmonization: New Activities  
Indonesia Seminar 2014  
@Novotel Hotel, Mangga Dua, Jakarta, May 21, 2014

Japan Pharmaceutical Manufacturers Association  
(JPMA)  
Kozo Akasaka

What is APAC?

APAC = Asia Partnership Conference of  
Pharmaceutical Association

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Not

APEC = Asia-Pacific Economic Cooperation

# The initiation of Asia Partnership Conference of Pharmaceutical Association

2010年11月22日 (月)

来年4月に「第1回アジア連携会議(仮称)」-アジアの製薬団体と協力関係を強化

日本製薬工業協会の長谷川閑史会長(武田薬品社長)は18日、都内で記者会見し、アジアの製薬団体と協力関係を強化するため、来年4月に日本で「第1回アジア連携会議(仮称)」を開催すると発表した。中国・韓国・インドをはじめ、アジア12カ国・地域の国際製薬団体連合会(IFPMA)加盟13団体に参加を呼びかけ、各国が抱える問題・課題について共通認識を醸成したい考え。長谷川氏は「今後のアジアの重要性を考えると、アジア全体の意見をまとめ、グローバルの中に反映させていく必要がある。まずアジア各国で解決すべき問題について共通認識を持ち、解決に向けて共同歩調をとる努力をしていきたい」と語った。



製薬協・長谷川会長

初めての試みとなるアジア連携会議は、革新的な医薬品を、アジア各国の人々に速やかに届けることをミッションに掲げ、これを達成するために、解決すべき問題を共有するのが強い。長谷川氏は5月の就任会見で、新たな国際連携を推進する方針を示していたが、それを実行に移すことになった。

これまで、世界的な製薬団体の活動は、医薬品市場の大きい日米欧が中心だったが、長谷川氏は「アジア市場の重要性を考えると、日本だけでなく、アジアとして意見をまとめ、グローバルの中に反映させていく必要がある」と背景を説明。さらに、新興が著しいアジアのバイオベンチャーと、ネットワークを構築することで、将来的にはアジア製薬産業の発展を目指す構想を示した。

第1回会議では、まずアジア各国が医療環境、薬事制度、承認プロセス等の課題を持ち寄り、問題を共有化し、共通認識を醸成することを最大の目的と位置づけている。

【公募中の4未承認薬「3月末までに解決」】

一方、長谷川氏は、新薬創出加盟の恒久化実現を占う未承認薬・適応外薬への取り組みについて、未承認薬検討会議で開発申請のあった品目のうち、4品目の開発企業が見つからない現状に言及。「来年3月末までには、スポンサーを見つけて申請に応えたい」との方針を示した。

**PHARMA JAPAN WEB**  
THE ONLY ENGLISH PHARMACEUTICAL INDUSTRY NEWS SITE IN JAPAN

**JPMA to Organize Asian Liaison Conference<sup>TM</sup>(Nov.29.2010)**

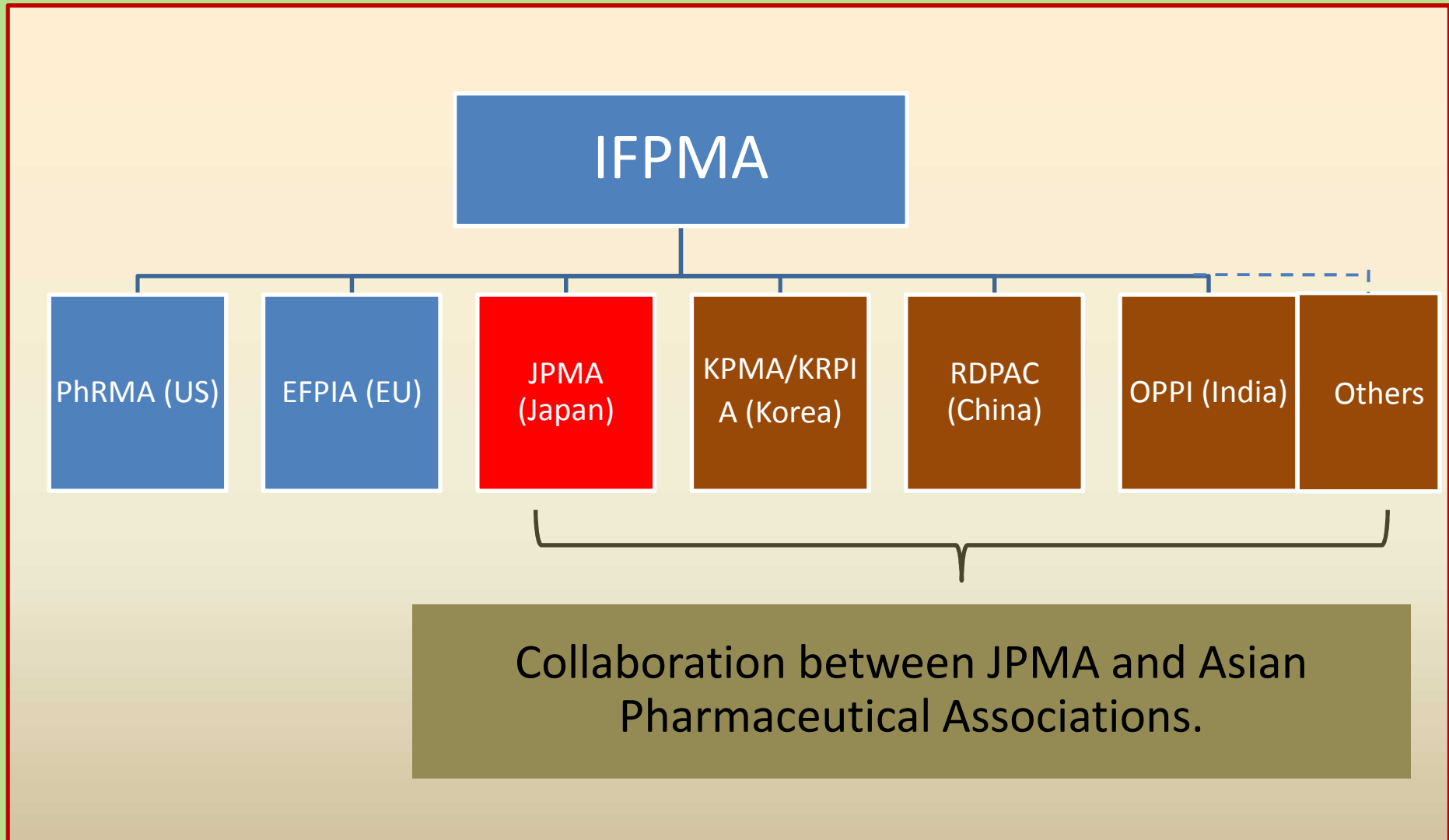
The JPMA (Japan Pharmaceutical Manufacturers Association) plans to create an Asian liaison conference<sup>TM</sup> inviting pharmaceutical industry associations from major Asian countries as members in order to establish closer relationships between industry organizations from Asian countries. The JPMA has invited 12 organizations affiliated with the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) from 11 countries/regions in Asia. It plans to host the first meeting in April 2011 in Tokyo. The conference will exchange opinions on a wide range of issues in order to promote the development of innovative drugs by drug companies in Asia. Establishing closer alliances with pharmaceutical industry organizations from Asian countries was one of the top-priority challenges listed by Yasuchika Hasegawa when he was elected JPMA chairman. Efforts to establish closer partnerships with China and South Korea have already been initiated, but the JPMA believes that it is essential for industry organizations from major Asian countries to share more information and cooperate more closely with each other as the importance of Asia increases in the development and marketing of drugs.

Mr. Hasegawa, Chairman of  
Japan Association of Corporate Executives



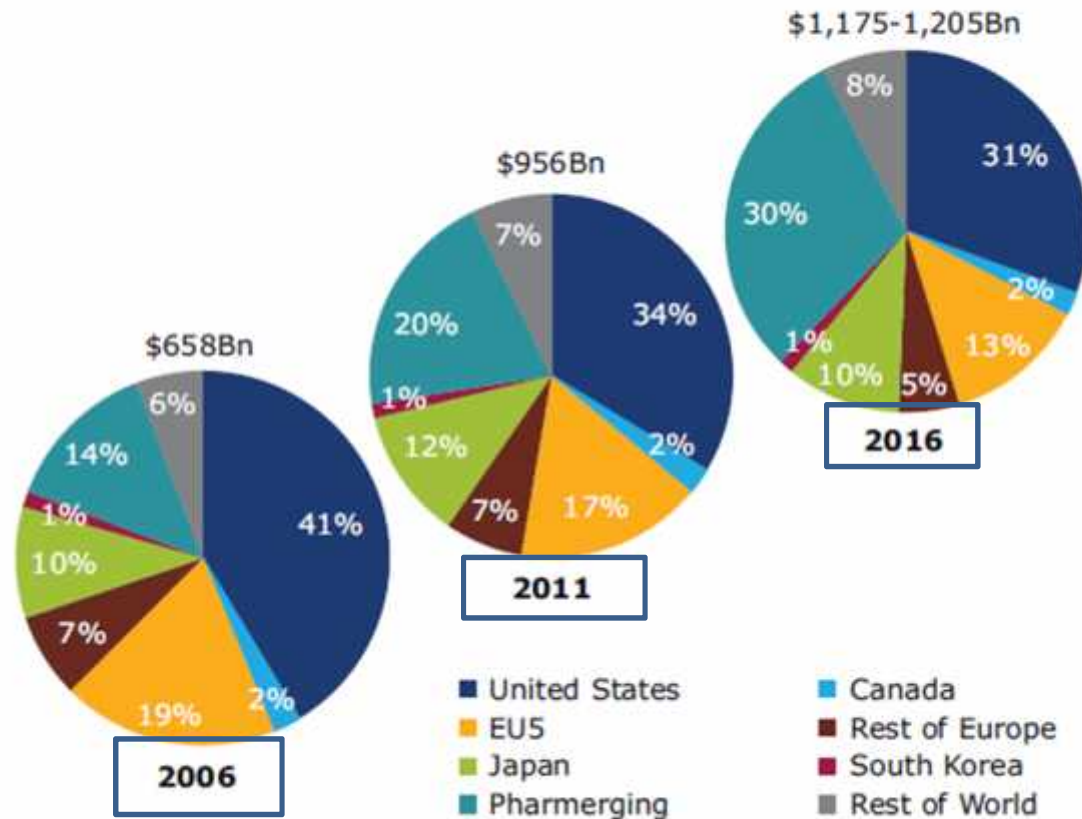
# Collaboration of JPMA

## New International Collaboration Framework



# Situation of Asia---World Pharmaceutical Market Overview(1)

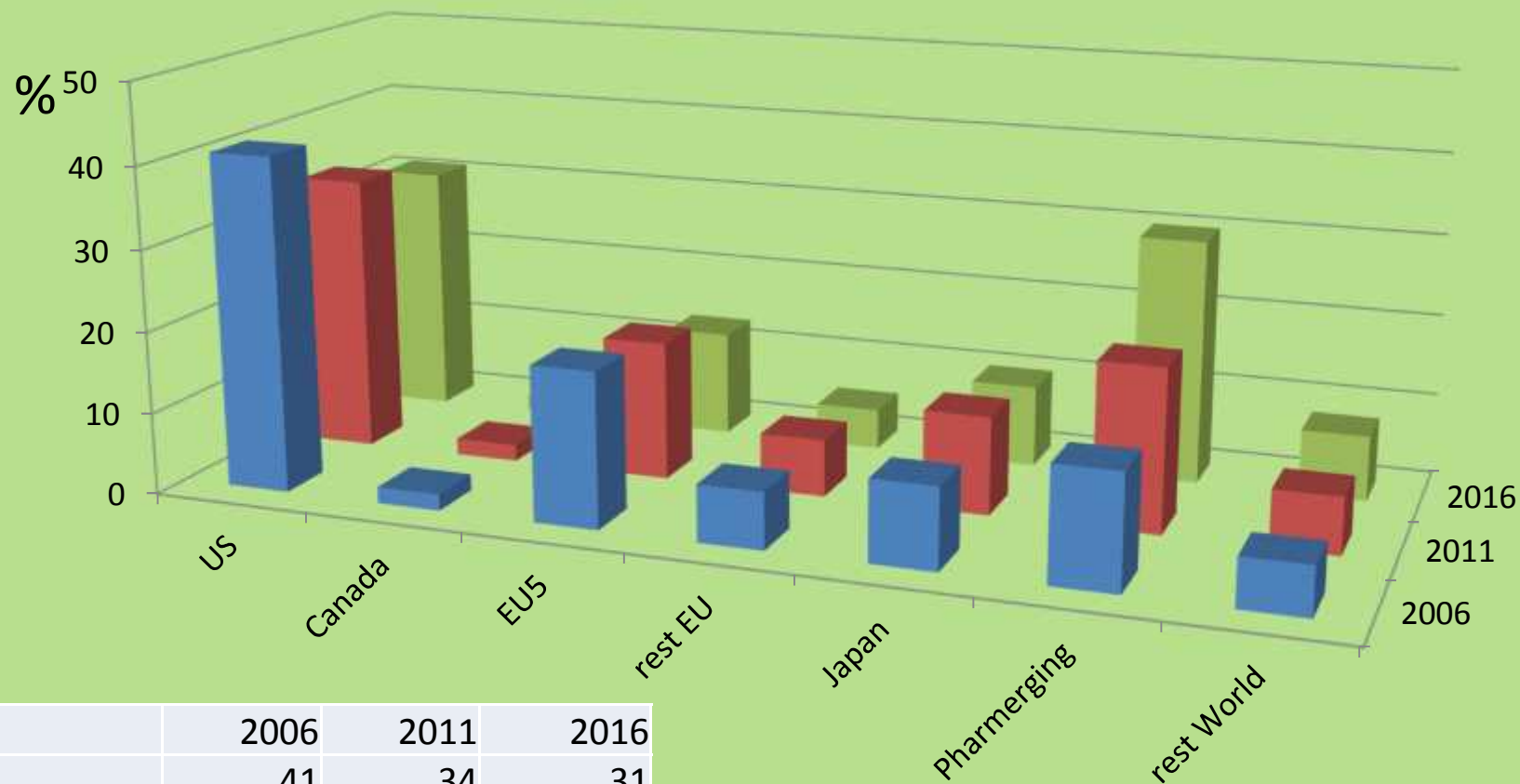
Spending by Geography



Source: IMS Market Prognosis, May 2012

- Developed markets will account for 57% of total spending, down from 73% in 2006.
- Japan will retain 10% of drug spending in 2016, essentially unchanged except for the impact of the biennial price cuts expected in 2012, 2014 and 2016.

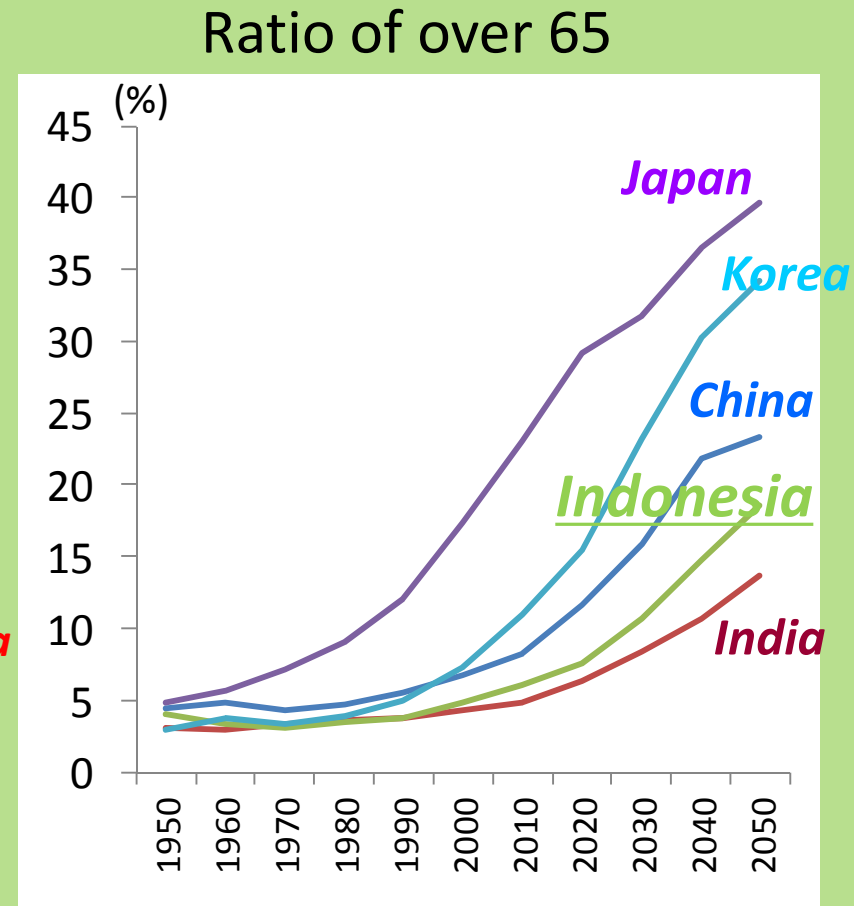
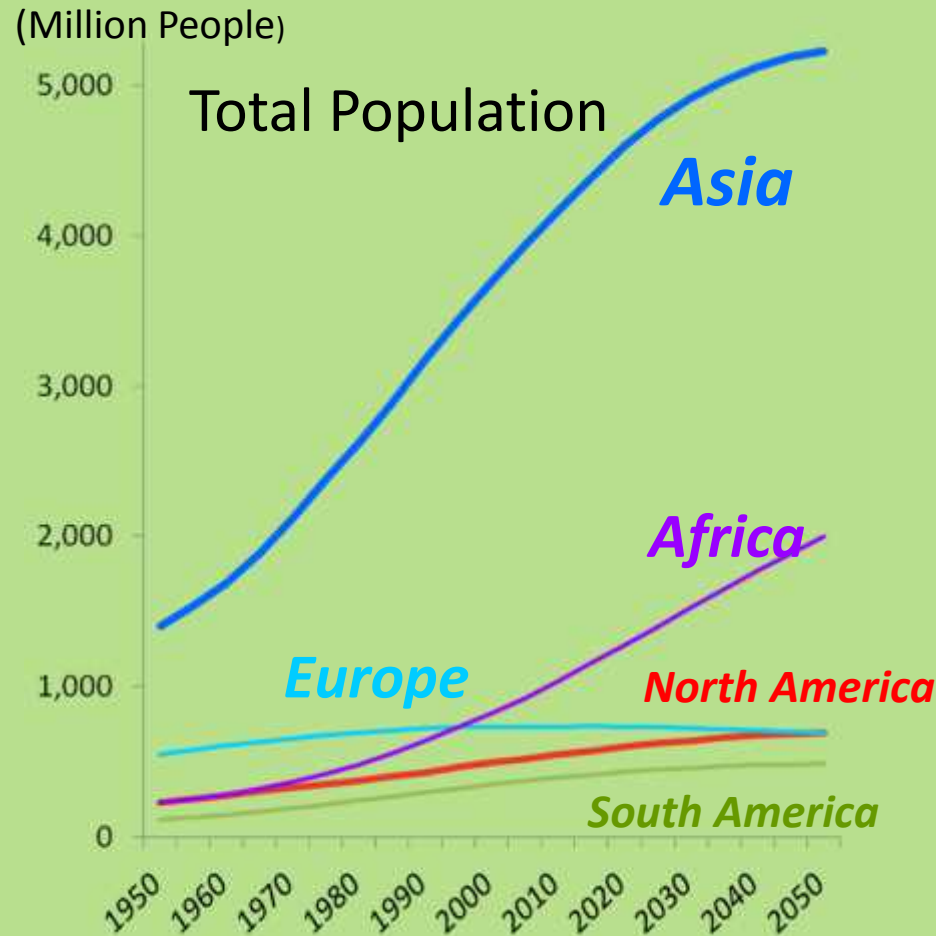
## World Pharmaceutical Market Overview (2)



	2006	2011	2016
US	41	34	31
Canada	2	2	2
EU5	19	17	13
rest EU	7	7	5
Japan	10	12	10
Pharmerging	14	20	30
rest World	6	7	8

**Pharmerging=**  
**India, China, Brazil, Mexico, Russia, Turkey**

# Growth of Population and Aging Society



(Source: "Census" and "Population projection" Statistics Bureau, Ministry of Internal Affairs and Communications and "Future population estimate of Japan" National Institute of Population and Social Security Research (estimate in December 2006))

## Many countries in Asia have positioned HC innovation and promotion of biotechnology as a key pillar and numerous bio-clusters have been established

	National Policy	Bio-cluster
Japan	“New Growth Strategy” developed in June 2010 positions HC innovation as Life Innovation and includes it as one of 7 national policies	Bio-cluster is being concentrated in line with Local Cluster Plan centering on special zones for structural reform and each local government.
South Korea	“Bio-Vision 2016” clearly sets a goal to strengthen competitiveness of bioindustry through the development and globalization	Total of 16 bio-clusters across 3 zones. International collaboration is being advanced
China	“Twelfth 5-year Plan (~2015)” designates seven sectors as strategic newly-emerging industries, one of which is biotechnology with biomedicine as its key field	Research institutions are cluster mainly in provincial cities. Lots of public investments are allocated
Singapore	Various measures such as Biopolis enhance functions as a hub for R&D/manufacturing of high-tech fields including semiconductors, information processing and biotechnology	Efforts typified by “Biopolis”




## continuation

<b>Thailand</b>	The National Science and Technology Strategic Plan (~2013) sets out funding measures in the field of pharmaceutical research, etc.	Efforts in line with the key strategies set out in the National Science and Technology Strategic Plan are under way (Efforts typified by Thailand Science Park)
<b>Taiwan</b>	Under the “Action Project for Six Emerging Industries” of Government, which includes biomedicine, establishment of public-private funding VCs and formulation of incubation centers continue. “Act on Development of Biomedical Industry” gives temporary tax breaks to bio-ventures.	With support from Government, bioclusters (mostly bio-incubation centers) and bio parks are being constructed.
<b>Malaysia</b>	The Tenth Malaysia Plan (~2015) named pharmaceuticals in “Development of Growing Industry,” the 7 <sup>th</sup> item among newly-identified 8 New Development Strategies, though it was left off the “12 National Key Economic Areas”	President Mahathir (then) advocated the concept of “BioValley Malaysia” in the early 2000s, which primarily focuses on food-field. Recent reporting indicates that clusters in the field of medicine have been further formulated centering on institutions of higher education
<b>India</b>	“Twelfth 5-year Plan (April 2012~),” which is under development, is expected to follow the previous 5-year Plan to maintain increased public investment in health care	The former 5-year Plan included the promotion of innovation through the creation of bioclusters in its 3 <sup>rd</sup> Action Plan. Currently, there are clusters in the BT field in 3 areas of India
<b>Hong Kong</b>	Same as China	Efforts typified by Hong Kong Science Park


# Significance of Collaborations in Asia

- 
- The economic center is moving to Asia, but the concept of a unified Asia is far from realization

- 
- Needed for Asia along with economic growth is to create a favorable environment

- 
- Drug development capabilities, innovative drugs can be originated in Asia, delivered to Asian economies

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- Improvement of QOL for Asian will further boosts national economies and develop societies

- 
- Pharmaceutical industry in Asia needs to work & grow together

# APAC Participating Economies

	Organization	Economy
<b>HKAPI</b>	The Hong Kong Association of the Pharmaceutical Industry	Hong Kong
<b>IPMG</b>	<b>International Pharmaceutical Manufacturer Group</b>	<b>Indonesia</b>
<b>IRPMA</b>	International Research-based Pharmaceutical Manufacturers Association	Taiwan
<b>KPMA</b>	Korea Pharmaceutical Manufacturers Association	Korea
<b>KRPIA</b>	Korean Research-based Pharmaceutical Industry Association	Korea
<b>OPPI</b>	Organization of Pharmaceutical Products of India	India
<b>PhAMA</b>	Pharmaceutical Association of Malaysia	Malaysia
<b>PHAP</b>	The Pharmaceutical and Healthcare Association of the Philippines	Philippines
<b>PReMA</b>	The Pharmaceutical Research and Manufacturers Association	Thailand
<b>RDPAC</b>	R&D-based Pharmaceutical Association in China	China
<b>SAPI</b>	Singapore Association of Pharmaceutical Industries	Singapore
<b>JPMA</b>	Japan Pharmaceutical Manufacturers Association	Japan

Guests: Exponent from PhRMA, EFPIA, IFPMA, Interpharma, FPMAJ, government (MHLW, PMDA, Malaysia, Singapore, Vietnam) and research institutes

# First APAC (2012. March 15, 16)



## Second APAC (2013. April.11&12)



# 革新的な医薬品をアジアの人々に速やかに届ける

## 各国政府・アカデミアとの連携に向けて

**APACとは**  
 Asia Partnership Center for Pharmaceutical Association  
 アジア製薬団体連携会議は、アジア太平洋地域に於ける革新的な医薬品を速やかに届けることを目的として、日本製薬工業協会 (JPIA) とアジア各国の製薬団体とが連携して設立された国際的な組織である。

APACの設立は、アジア太平洋地域に於ける革新的な医薬品を速やかに届けることを目的として、日本製薬工業協会 (JPIA) とアジア各国の製薬団体とが連携して設立された国際的な組織である。



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**第2回 APAC 主なプログラム**

- 10月24日 (月) 19:00-20:00 開会式
- 10月25日 (火) 09:00-12:00 第1セッション
- 10月25日 (火) 13:00-16:00 第2セッション
- 10月25日 (火) 17:00-19:00 第3セッション
- 10月26日 (水) 09:00-12:00 第4セッション
- 10月26日 (水) 13:00-16:00 第5セッション
- 10月26日 (水) 17:00-19:00 閉会式

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**第2回 APAC 各セッション**

- 第1セッション: 革新的な医薬品の開発と規制
- 第2セッション: 革新的な医薬品の臨床試験と承認
- 第3セッション: 革新的な医薬品のマーケティングと販売
- 第4セッション: 革新的な医薬品のアクセスと公平性
- 第5セッション: 革新的な医薬品の未来と展望



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日本製薬工業協会

www.jpma.or.jp

Second APAC article  
The Nikkei News Paper  
Apr. 26, 2013

# The Healthcare and Medical Strategy

## Understanding Among

- 1) Chief Cabinet Secretary
- 2) Minister of State for Information Technology (IT)
- 3) Minister of State for Science and Technology Policy
- 4) Minister of Public Managmt, Home Affairs Posts & Telecomn
- 5) Minister of Foreign Affairs
- 6) Minister of Education Science Sports and Culture
- 7) Minister of Health, Labor and Welfare
- 8) Minister of Economy, Trade and Industry
- and
- 9) Minister of Land, Infrastructure and Transportation

June 14, 2013

# The Healthcare and Medical Strategy

(June 14, 2013)

Page 19

1. Creation of novel technologies (R&D and practical application)
  - (2) R&D promotion in private sector

## ② Environmental development for Open Innovation

i) Provide financial support via various funds and other forms of assistances to small-to-medium-sized companies and ventures to foster the next-generation industries through promoting open innovation

ii) Toward advanced cooperation for creation of innovative new drugs, support efforts being made at the Asia Partnership Conference of Pharmaceutical Association (APAC) to promote creation of an open innovation platform through collaboration between industry, academia, government, and ventures of Asian countries

<http://www.kantei.go.jp/jp/singi/kenkouiryoku/pdf/senryaku.pdf>



## Mission of APAC

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

“We, people living in Asia to change Asia from inside” (1<sup>st</sup> APAC)

“Toward a cooperation with government and academia” (2<sup>nd</sup> APAC)

“Progressing towards a Strategic Roadmap for a Framework of Drug Discovery and Development in Asia”  
(3<sup>rd</sup> APAC)

## “We, people living in Asia to change Asia from inside”

Analysis and discussion on issues in Asian pharmaceutical markets

Agreement to the mission and the collaboration among Asian pharmaceutical associations

Select the issues APAC EWG work

- ➤ Regulations and Approval
- ➤ Drug Discovery Alliance

Participation of Government (MHLW, PMDA, etc)

## Agenda of 2<sup>nd</sup> APAC (2013. April.11&12)

### “Toward a cooperation with government authorities and academia”

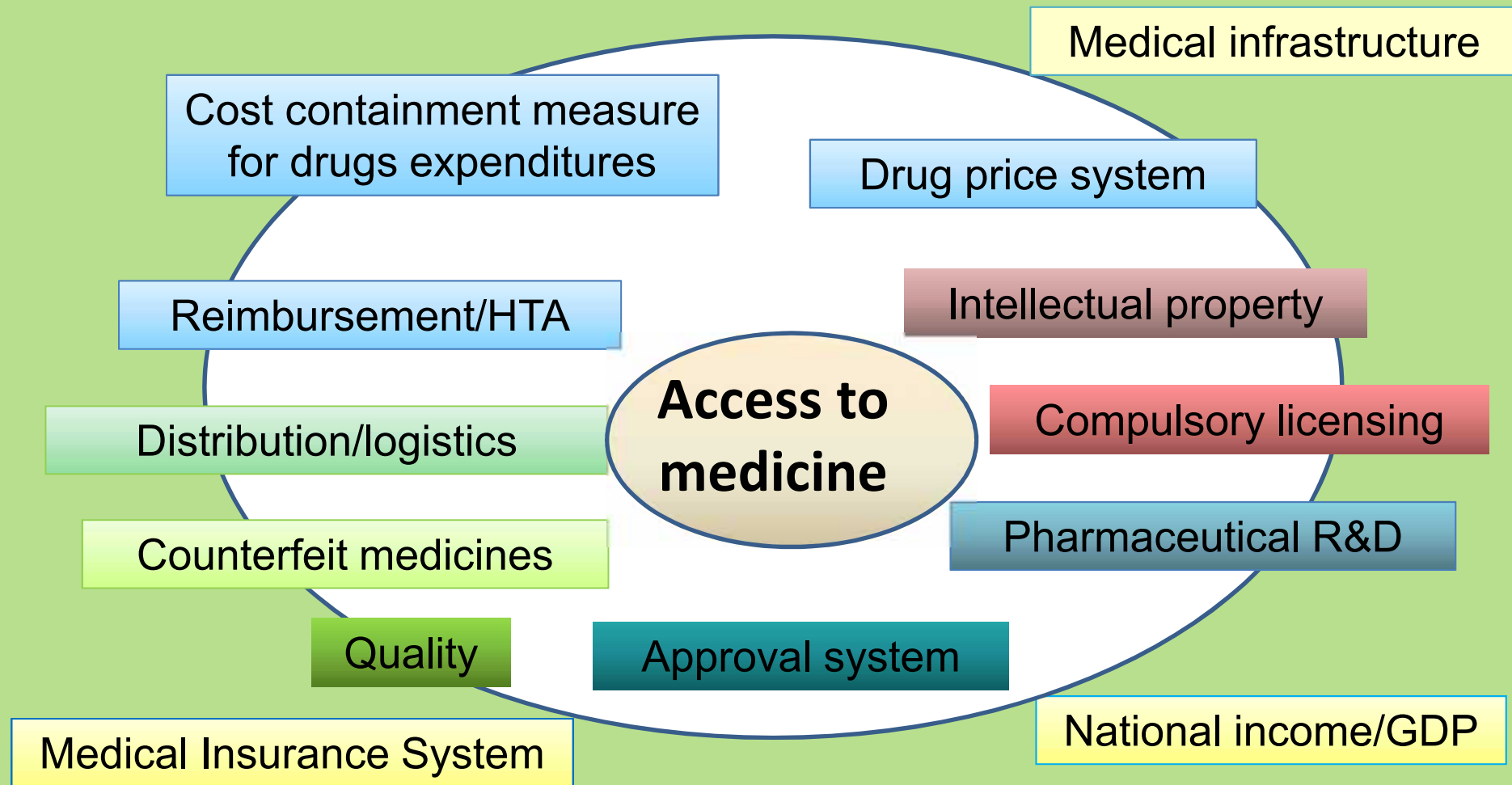
Review of issues and discussions on possible EWG

Review of progress of RA/DA EWGs

Panel Discussions for RA with regulators and for DA with research institutes from Asia

Key Note speech for UHC system in Japan, and The EU system for Regulation of Medicines

# Challenges and Issues in Access to Innovative Medicines in Asia



Source: 1<sup>st</sup> APAC (2012, 3.16)

# Healthcare Systems in Asia

	Financial Resource	Person Insured	Details
<b>Hong Kong</b>	Tax	Private insurance	Primary care provided at 100% self-payment or private insurance
<b>Indonesia</b>		Public officers /military personnel, regional health insurance	Workers' social security and insurance system for public officers cover 50.2% of the population (in 2007)
<b>Taiwan</b>		Universal care	Public universal HC system established in 1991
<b>Korea</b>	Social insurance	Universal care	Public universal HC system established in 1989
<b>India</b>		Insurance National /local public officers	Covers 5% of the population 90% of workers are uninsured
<b>Malaysia</b>		Insurance for Poverty group	No public HC insurance system. And Insurance system for the poor is available

## continuation

	Financial Resource	Person Insured	Details
<b>Philippines</b>		Universal Care	Public universal HC system established in 1995 but 1/3 of the population not insured.
<b>Thailand</b>	Tax	Universal Care	Public universal HC system (2002): combination of insurance for public officers, employee's health insurance and private insurance
<b>China</b>	Social insurance	Universal Care	1) Urban employees, 2) Urban residents 3) New villages Covers 95% of the population. Public universal HC system established in 2009.
<b>Singapore</b>	Health saving system		Minimal level of government involvement, compulsory saving system
<b>Japan</b>	Social insurance	Universal Care	Public universal HC system established in 1960. co-payment (15%)

Source: 1<sup>st</sup> APAC (2012, 3.16)

# Drug Pricing System in Asia



## **Major Issues to Discuss in APAC**

**Difficult to pick a theme to encompass some countries specific challenges**

**Need to comprehend and follow up the actual situation of each economy**

**Regulation/Approval and Drug Discovery as common themes to be addressed at the 1st APAC RTD**



# Agreements Reached at 1<sup>st</sup> APAC

**Goals:** Share information on the challenges faced in each economy and build a platform to transmit all necessary proposals to relevant stakeholders

## Topics Discussed in the Conference

### ◆ Regulations and Approvals

Prepare recommendations to realize **early submission and approval of NDA in Asia** and supply quality drug at global standards from Asia

### ◆ Drug Discovery Alliances

Promote open innovation in Asia in order to realize drug discovery that originates in Asia

### ◆ Actions

Form an APAC SC for planning a APAC meeting and oversee **WG for Regulations/Approvals and Drug Discovery Alliance**



1<sup>st</sup> meeting pic. in 2012

## Agreement Reached in the 2<sup>nd</sup> APAC

### ◆ General

Collaborate with the public sector, and academia in Asia to work toward the realization of our mission

### ◆ Regulations and Approvals

Establish a road map, aiming at speeding up and coordinating new drug applications and approvals in Asia

Work with the regulatory authorities of each economy

Ensure complementarity with existing regulatory harmonization initiatives in Asia

### ◆ Drug Discovery Alliances

Facilitate information exchange for collaboration, and dispatch a delegation for analysis of needs

Build networks and establish an environment for industry, the public sector, academia, and venture in Asia

Foster partnership and promote open innovation, participate in symposiums and conferences relating to drug discovery in Asia

# Updates on the Progress of Consideration Toward the 3rd APAC

## APAC-SC

- Vision of APAC & organization
- Expansion of participating associations, governments, and academia
- Cooperation with Governments,

## Regulations and Approvals EWG

- GRevP (Policy documents, collaboration with stakeholders)
- Harmonization of regulatory requirements for NDAs

## Drug Discovery Alliances EWG

- Building a platform for open innovation through bilateral discussions

# APAC 3

**“To Expedite the Launch of Innovative Medicines  
for the Peoples in Asia”**

<<Roadmap for Asia Origin Drug Discovery Infrastructure>>

**April 10th and 11th, 2014**

**Total participants: 304**

**(Industry, Government and Academia from  
Taiwan, Korea, Thai, Indonesia, Malaysia,  
China, Singapore, Vietnam, Myanmar,  
Philippines, Hong Kong and India)**

### Third APAC Program Day1: April 10

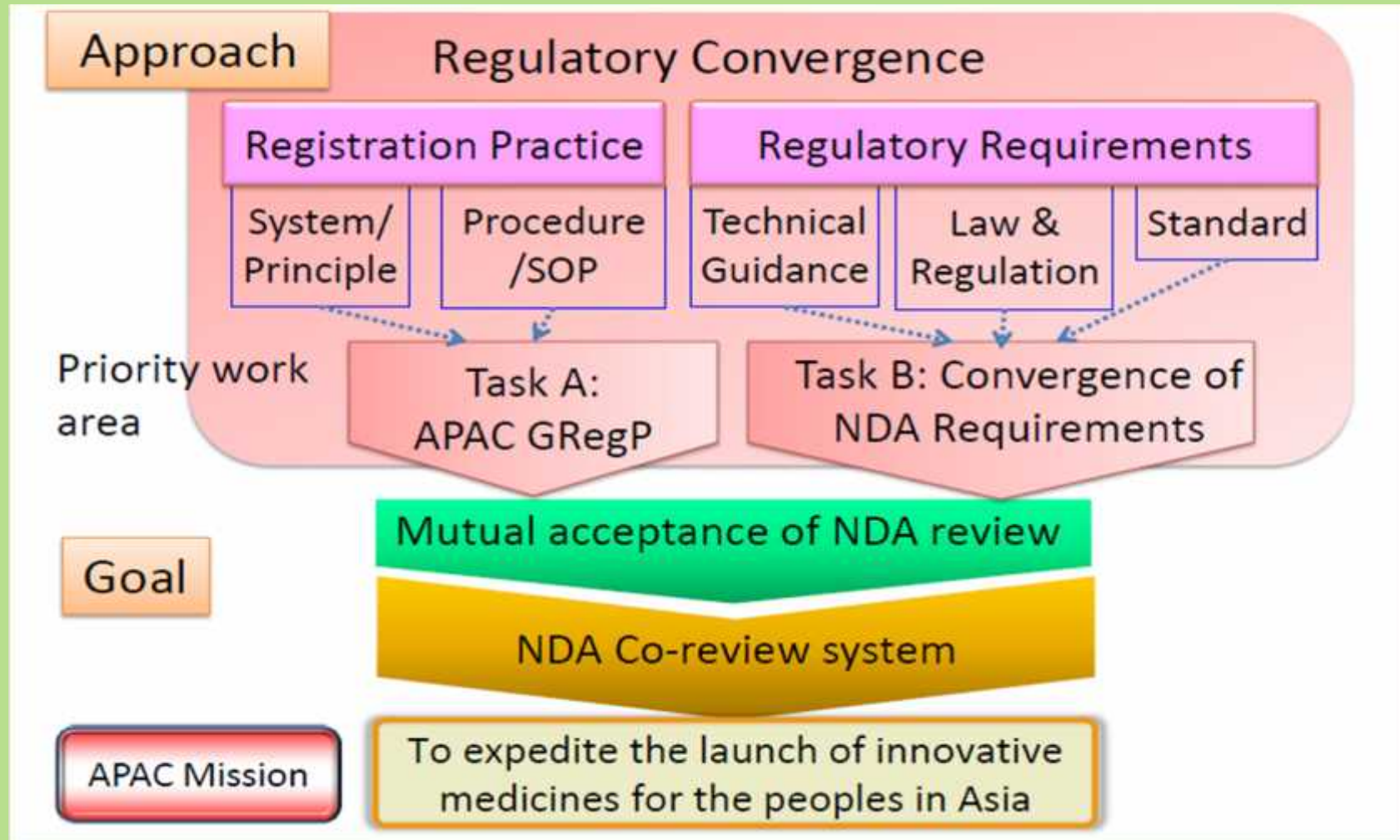
12:30 – 12:35	DG. Remarks: Tadaharu Goto (Director General, JPMA)
12:35 – 13:25	Regulations and Approvals – Expert Working Group Report,
13:25 – 14:15	Drug Discovery Alliance – Expert Working Group Report,
14:15 – 14:35	APAC Steering Committee Report,
14:35 – 14:45	Wrap-up: Masafumi Nogimori (Vice president, JPMA)
15:00 – 15:10	Opening Remarks: Isao Teshirogi (President, JPMA)
15:10 – 15:20	Guest Speech: Hiroto Izumi (Special Advisor to the Prime Minister)
15:20 – 16:20	“Pros and cons of the Utilization of HTA in Asia and its Future Direction”
16:20 – 16:40	Break
16:40 – 17:40	Intellectual Property in Asia: Current Status and Future Responses

## Day2: April 11

09:10 – 09:20	Guest Speech: Eduardo Pisani (IFPMA)
09:20 – 09:50	Keynote Address 1: “Global expansion of healthcare sector– Recent progresses and remaining challenges” Speaker: Hidehito Sekino (Director of Office for Global Expansion of Japanese Healthcare)
10:10 – 12:10	Panel Discussion 1: Regulations and Approvals – Expert Working Group “Collaboration between Regulatory Agencies and Industries to achieve regulatory convergence smoothly in Asia”
13:30 – 14:00	Keynote Address 2: “Challenges towards iPS cell therapy for Parkinson’s disease” Speaker: Jun Takahashi, Professor of Center for iPS Cell Research and Application, Kyoto University
14:00 – 16:00	Panel Discussion 2: Drug Discovery Alliance Expert Working Group “How can open innovation promote drug discovery in Asia”
16:20 – 16:50	Keynote Address 3. “GHIT, Challenge and the Possibility” Speaker: Shiro Konuma (Cabinet Secretariat)
16:50 – 17:10	Overall Wrap-up: Isao Teshirogi (President, JPMA)
17:10 – 17:30	Closing Remarks: Haruo Naito (Vice president, JPMA)

# Regulations and Approvals

## Goal and Approach



# Drug Discovery Alliances

FY2013

- ✓ Clarify definition  
APAC's open innovation
- ✓ Choose appropriate information sharing system for APAC
- ✓ Begin conducting networking opportunities at Bio conferences
- ✓ Continue with bilateral meetings with all countries

FY2014

- ✓ Conduct pilot trial for shared APAC information sharing system
- ✓ Expand networking opportunity from bilaterally to multilaterally
- ✓ Increase ratio of all members meeting

FY2020

Realize Asia originating drugs



# Point of consensus reached at the 3<sup>rd</sup> APAC

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Based on a relationship of mutual trust among Asian countries, develop a strategic roadmap for industry-academia-government collaboration to fulfill the mission of APAC and establish the framework needed to implement mission-driven activities.

## ◆ Regulations and approvals

To propose recommendations to the regulatory authorities of Asian countries for early submission and approval of NDAs in Asia. To address challenges to regulatory convergence for acceptance of new drug approvals granted by other regulatory authorities.

## ◆ Drug discovery Alliances

To continue developing opportunities for interaction bilaterally that meet the needs of each country, and through collaborations with government, academia and industry in each country develop a pan-Asia, drug-discovery open innovation platform.

## ◆ Others

The fourth APAC will be held in Tokyo.





Thank you very much!

Questions?  
To Parulian Simanjuntak  
(IPMG) or to me