

15/April/2013

日露医療フォーラム(分科会)



Market overview and the industry issues and challenges in 2013

**Chair of JPMA International Affairs Committee
Eisai Co., Ltd.
Yutaka Tsuchiya**

Agenda

1. General information

2. Key issues for JPMA

- Ensuring compliance in industry
- life science budget and the “Control Tower function”
- Corporate tax and R&D tax credit
- Pricing

3. International cooperation

Abe administration

Japanese Prime Minister Shinzo Abe focuses on stimulating Japan economy, and appears “Abenomics” with his 3 key agenda;

1. Bold financial policy
 - 2 percent inflation target
2. Rapid and active fiscal policy
 - “Emergency Economic Stimulus Measures”
3. Growth strategy for promoting private investment
 - relaxation of regulations

JPMA and FPMAJ



FPMAJ

Federation of Pharmaceutical
Manufacturers' Associations of
Japan

JPMA

Generic

OTC

vaccine

...

Japan Pharmaceutical Manufacturers
Associations

-Joining 70 R&D pharma companies

President: Dr Isao Teshirogi (Shionogi)

Including 14 associations and local associations

Key Issues for JPMA towards FY2013



1. Ensuring compliance in our industry
2. Further enhancement of measures to develop the R&D based pharmaceutical industry
 - Strengthening of “Control Tower function” of science and technology/medical policies and unification of budgets among the ministries and increase of life science-related budgets
 - Improvement of tax system related R&D to strengthen international competitiveness.
 - Full implementation of the new drug price system: “New Premium System for the Promotion of Innovative Drug and Resolution of Off-Label Use (New Premium System)”
3. Further promotion of international contribution and co-operations

Ensuring Compliance and Code of Practice

- Thoroughness of 'JPMA Charter of Business Activities' and 'Compliance Program Guideline'.
- 'JPMA's Code of Practice' in preparation to be effective from April 2013.
- Promotion of understanding 'Transparency Guideline in relation to Medical Organizations' enacting in April 2013.

Scope of disclosure;

1. Research and Development expenses; Joint research, Clinical study, ADR, Post-marketing surveillance, etc.
2. Academic research support expenses; Donations, Co-sponsored academia conference, etc.
3. Manuscript/Writing fees; Fees for lectures, etc.
4. Information provision-related expenses; Lecture meeting expenses, etc.
5. Expenses for hospitality as social courtesy

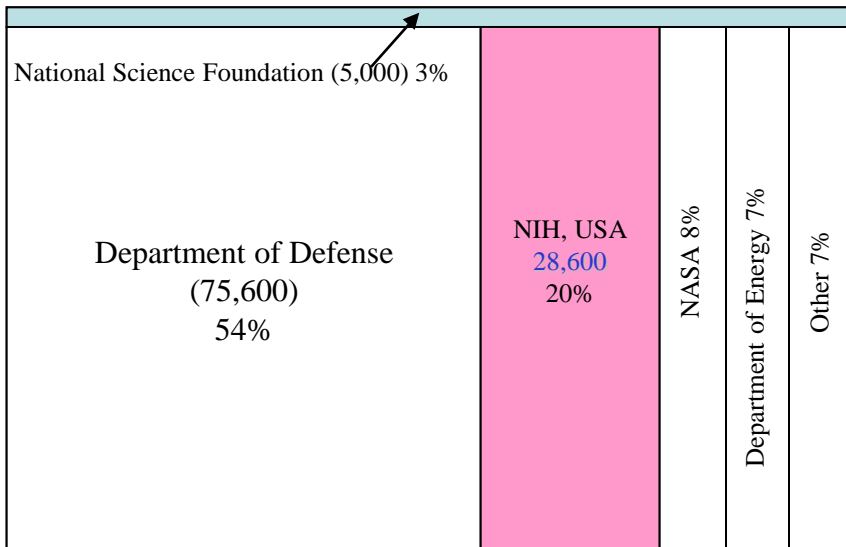
Control Tower Function for science & Technology policy and budget allocation

Shortage of budget amounts and deficiency in strategic/focused distribution, duplication of various measures and lack of collaboration

Distribution structure for science and technology budgets (comparison between Japan and USA)

Framework of USA R&D budget
13.95 trillion yen; 2010

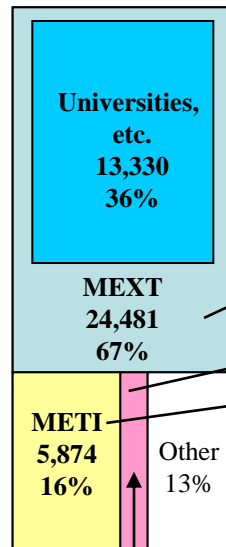
100 M yen



Framework of Japan's R&D budget
3.64 trillion yen; FY2011

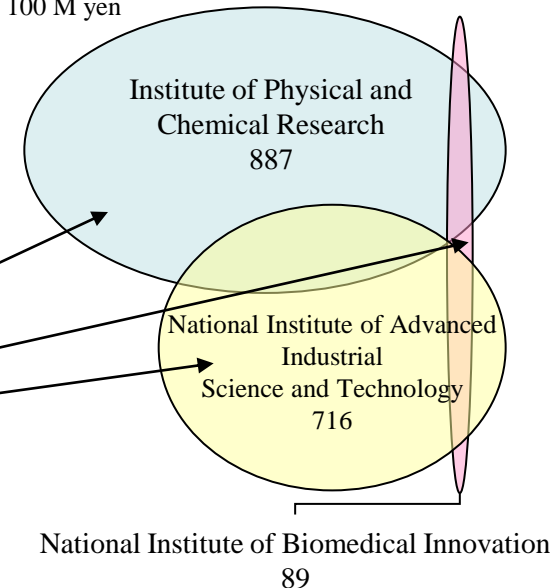
Academic research

Commercial research



Comparison of various government institutions

100 M yen



Source: based on FY 2011 budget plan of each research institutions

Source*: AAAS Analysis of R&D, Japan: Created by the Ministry of Economy, Trade and Industry (METI) based on Council for Science and Technology Policy records
Origin: Industrial Structure Council Industrial Science Technology Policy Committee/Research and Development Subcommittee reports

Ref: FY2009 Life Science Budget 346.1 billion yen

Source: February 20, 2009 Council for Science and Technology Policy records

Establish "control tower function" to allow "further enhancement of related budgets" and "efficient investment in budgets through elimination/integration of similar measurements!"

JPMA's requests for a tax system to promote R&D Investment and Increase of R&D tax relief

- Perpetuation of 30% upper limit of R&D tax credit (max 30% of the corporate tax)
 - Abe cabinet confirmed that maximum 30% of corporate tax (current 20%) can be offset by R&D investment in FY2013-14, along with its "Emergency Economic Stimulus Measures"
- Further Reduction of Corporate Tax Rate
- Other major proposal
 - Introduction of Innovation Box
 - Introduction of Angel Tax System for Corporations

Comparison of Corporate tax rate and R&D tax credit



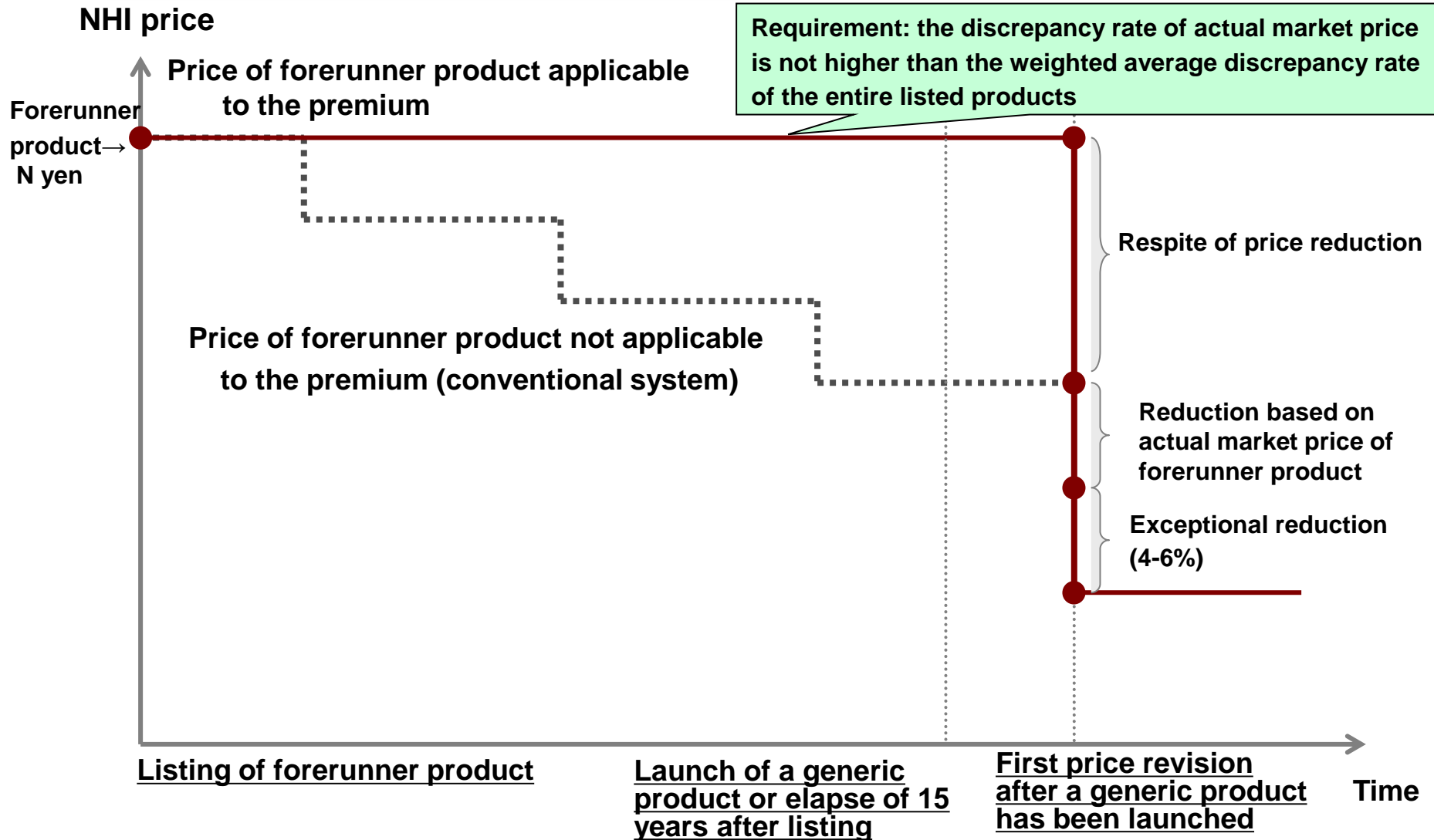
~	Effective Corporate Tax Rate	R&D tax credit			Changes in R&D tax credit	
		The value of tax credit ([] is for small and middle sized firm)	Max credit	Carry-over period		
Japan	38.01% (Tokyo)	8-10% of total R&D spending [12% of total R&D spending]	+ 5% of amount of increase or a certain rate of excess of 10% of the sales	Main part: 20% of amount of tax, Additional part: 10% of amount of tax (total of 30% max)	Allowed carry-over period, usually for 1 yr (only for 2009 and 2010, until 2011 and 2012, respectively)	
US	40.8%	20% of amount of excess of basis, or 14% of 50% of average research spending in the last 3 terms		75% of amount of tax	20 yrs	• Propose increase the tax credit rate to 17% (currently 14%)
France	33.33%	30% of total R&D spending (if above 1.1bn euro, then 5% of total R&D spending)		none	3 yrs (refund the remaining amount)	• Reduce of corporate tax rate to 15% if the profit is attributed to patents
UK	24% Reduce tax rate to 23% from FY2013 , and 21% from FY2014	Amount to 7.2% of total R&D spending [Amount to 30% of total R&D spending]		[£7.5m in each project]	Indefinite	<ul style="list-style-type: none"> • Increase premium credit rate (large firm: 125%→130%, small and middle sized firm: 150%→175%) from 2008 • In small and middle sized firm, further increase to 200% (from FY2011) and to 225% (from FY2012) • In the Financial Act 2012, proposed to transfer to the above the line credit from the current system • Patent Box system (Reduce of corporate tax rate to 10% if the profit is attributed to patents) come into force from FY2013.
China	25%	Amount to 12.5% of total R&D spending		None	5 yrs Taxable income (if amount of additional deductible expense is used, carry-over applies to the amount)	• Established the premium credit rate to the R&D spending from Jan 2008
S. Korea	22%	total R&D spending × (apply the lowest whichever 6% or 3% +50% of (R&D spending/sales amount) <or, 20%*> [25% of total R&D spending <or, 30%*>] ※if specific industry/R&D related to technologies	or 40% of amount of increase [50% of amount of increase]	none	5 yrs	• R&D spending for cutting edge technologies, increase tax credit rate to 20% (usually 3~6% from 2010)
Singapore	17%	Amount to 25.5% of total R&D spending		-	-	• Established the premium credit rate of 250% to the R&D spending as "credit for productivity and innovation" from 2011

Appropriate Reward for Innovation

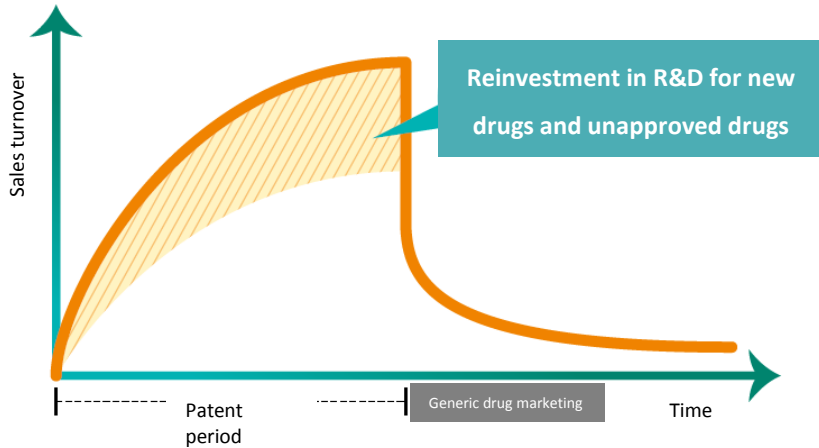
- Trial period of “[New Premium System for the Promotion of Innovative Drug and Resolution of Off-Label Use \(New Premium System\)](#)” introduced in 2010 was extended to 2012 and 2013, on the recommendation of a government advisory panel (Chu-i-kyo)
- New Premium System is expected to stimulate R&D pharmaceutical companies to develop new drugs/indications which are currently available in Japan only through off-label use.
- JPMA propose to make the premium system permanent.

*Chyu-i-kyo: Central Social Insurance Medical Council

Conventional system and New Premium System (since 2010)



New Premium System for the Promotion of Innovative Drug and Resolution of Off-Label Use

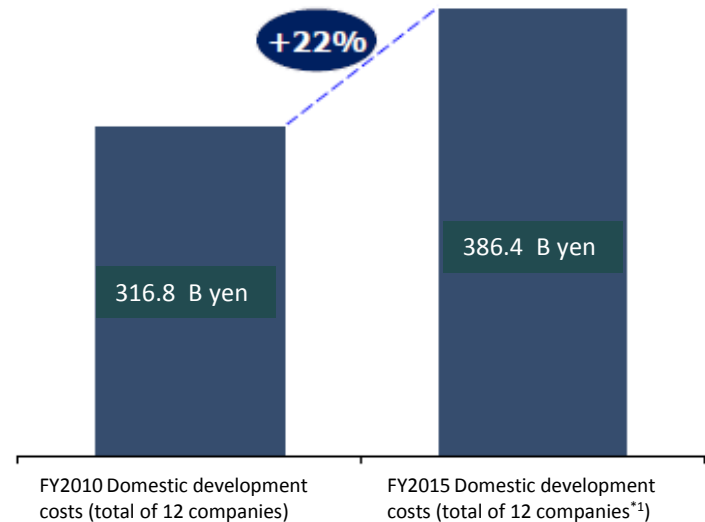


Shifts in sales turnover of drugs subject to the “premium to promote the development of new drugs and eliminate off-label use” (image)

To immediately respond to the needs of citizens/patients and medical professionals...

- Accelerate innovative new drug development
- Respond to unmet medical needs
- Eliminate unapproved drugs/off-label drugs and drug lag

Changes in domestic development costs
(Totals from 12 out of 15 companies that responded to a survey)



Source: August 24, 2011 Central Social Insurance Medical Council; Special Committee on Drug Prices records

- Actions to accelerate/vitalize new drug development in Japan

Full adoption/perpetuation of the New Premium System to vitalize creation of innovative new drugs!

Asia Partnership Conference of Pharmaceutical Associations (APAC)



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

Organization (12 association/11 economies)		Economies
HKAPI	<i>The Hong Kong Association of the Pharmaceutical Industry</i>	Hong Kong
IPMG	<i>International Pharmaceutical Manufacturer Group</i>	Indonesia
IRPMA	<i>International Research-based Pharmaceutical Manufacturers Association</i>	Taiwan
KPMA	<i>Korea Pharmaceutical Manufacturers Association</i>	Korea
KRPIA	<i>Korean Research-based Pharmaceutical Industry Association</i>	Korea
OPPI	<i>Organization of Pharmaceutical Products of India</i>	India
PhAMA	<i>Pharmaceutical Association of Malaysia</i>	Malaysia
PHPA	<i>The Pharmaceutical and Healthcare Association of the Philippines</i>	Philippines
PReMA	<i>The Pharmaceutical Research and Manufacturers Association</i>	Thailand
RDPAC	<i>R&D-based Pharmaceutical Association in China</i>	China
SAPI	<i>Singapore Association of Pharmaceutical Industries</i>	Singapore
JPMA	<i>Japan Pharmaceutical Manufacturers Association</i>	Japan

Guests: Representatives from PhRMA, EFPIA, IFPMA, interpharma, FPMAJ, MHLW and PMDA

Asia Partnership Conference of Pharmaceutical Associations (APAC)

Goals

Share information regarding the challenges faced in each economy and build a platform to transmit all necessary proposals of APAC as necessary

Topics discussed at the Conference

◆ Regulations and approvals

Offer recommendations to realize **early submission and approval of NDAs in Asia** and Stable supply of quality drug at global standards

◆ Drug discovery alliances

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

APAC will be held annually

2nd APAC meeting held 11-12 April 2013.



1st meeting in 2012

Further international co-operation

Bilateral annual meetings with industry associations and/or local governments:



JPMA and DoH, ABPI
(17th meeting in Nov 2012)



JPMA and AIPM
(Jun 2012~)



JPMA and LEEM with CEPS,
HAS
(20th meeting in Feb 2013)



MHLW, PMDA, JPMA,
MoHW, KFDA, HIRA, KPMA
(10th meeting in Jun 2012)



JPMA and VFA
(9th meeting in Nov 2012)



MHLW, PMDA, JPMA, NHFPC
(MoH), CFDA (SFDA), RDPAC
(7th meeting in 2013)



JPMA and EFPIA
(Feb 2012~)



MHLW, PMDA, JPMA,
Taiwan-FDA, CDE, industry
association (7th meeting in 2011)

Thank you for your attention