



April 17, 2012



Making Japan a globally competitive pharmaceutical center of excellence

Gary M. Winer

Vice Chairman, Japan Based Exec Com-PhRMA

President, Representative Director, Abbott Japan Co. Ltd.

Dennis M. Erb

Chairman, PhRMA Japan's Science and Regulatory Leadership Forum

Vice President, Head of Japan Development, MSD K.K.

Japan has achieved the best healthcare outcomes

Results of international comparison of health indicators



Overall rating		
1	Japan	A
2	Switzerland	A
3	Italy	A
4	Norway	B
5	Finland	B
6	Sweden	B
7	France	B
8	Australia	B
9	Germany	B
10	Canada	B
11	Netherlands	C
12	Belgium	C
13	Austria	C
14	UK	C
15	Ireland	D
16	Denmark	D
17	US	D

11 indicators and rating for Japan

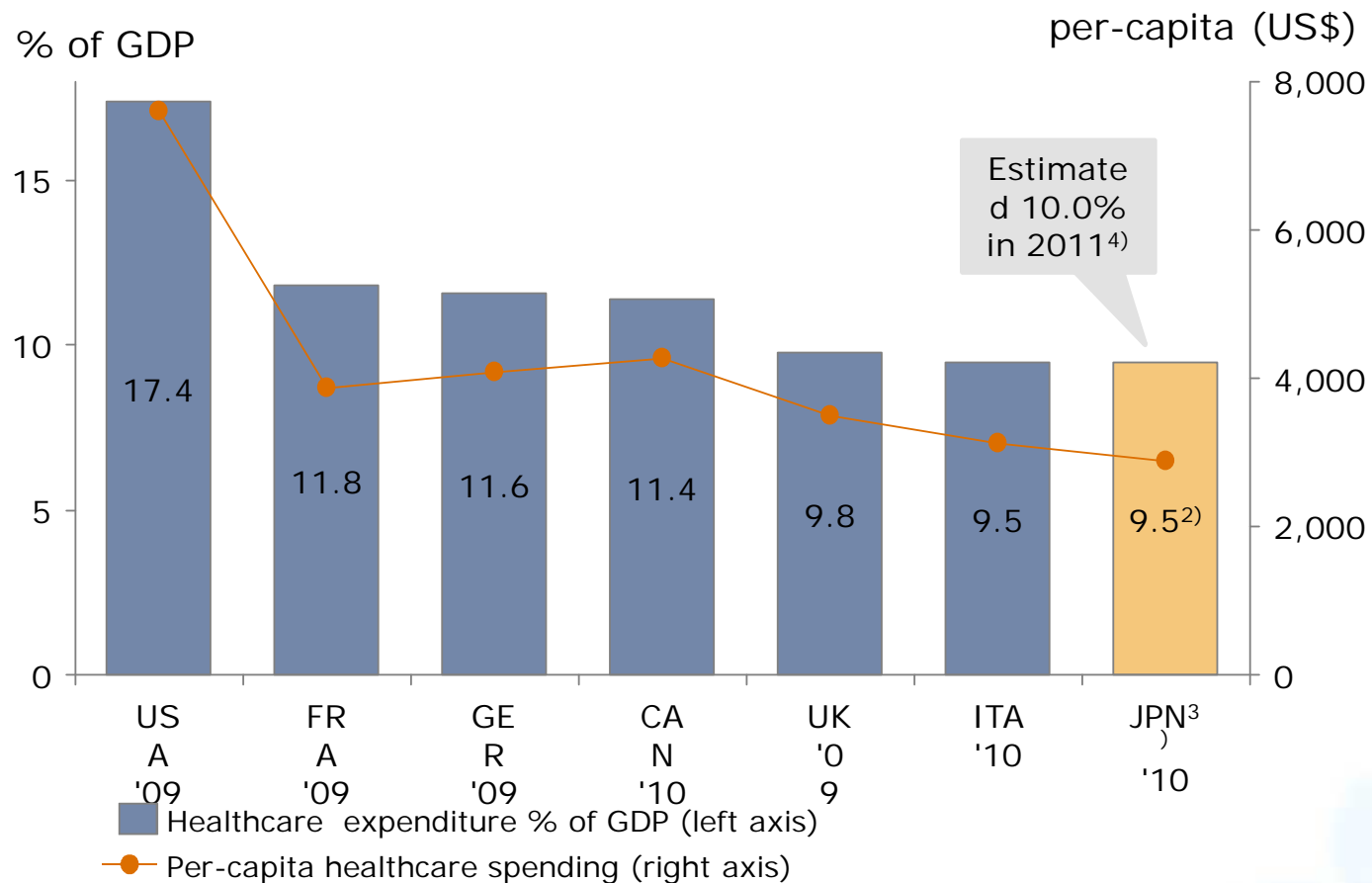
Indicators	Rating ¹
Life expectancy	A
Self-Reported Health Status	D
Premature Mortality	A
Mortality Due to Cancer	A
Mortality Due to Circulatory Diseases	A
Mortality Due to Respiratory Diseases	C
Mortality Due to Diabetes	A
Mortality Due to Musculoskeletal System Diseases	A
Mortality Due to Mental Disorders	A
Infant Mortality	A
Mortality Due to Medical Misadventures	A

1. A country receives a report card rating of "A" on a given indicator if its score is in the top quartile; a "B" if its score is in the second quartile; a "C" if its score is in the third quartile; and a "D" if its score is in the bottom quartile
 Source: Conference Board of Canada based on OECD Health Data 2009

The level of healthcare spending is the lowest in the G7 countries



National healthcare spending as Per-cent of GDP and Per-capita spending¹⁾ (2009 or 2010)



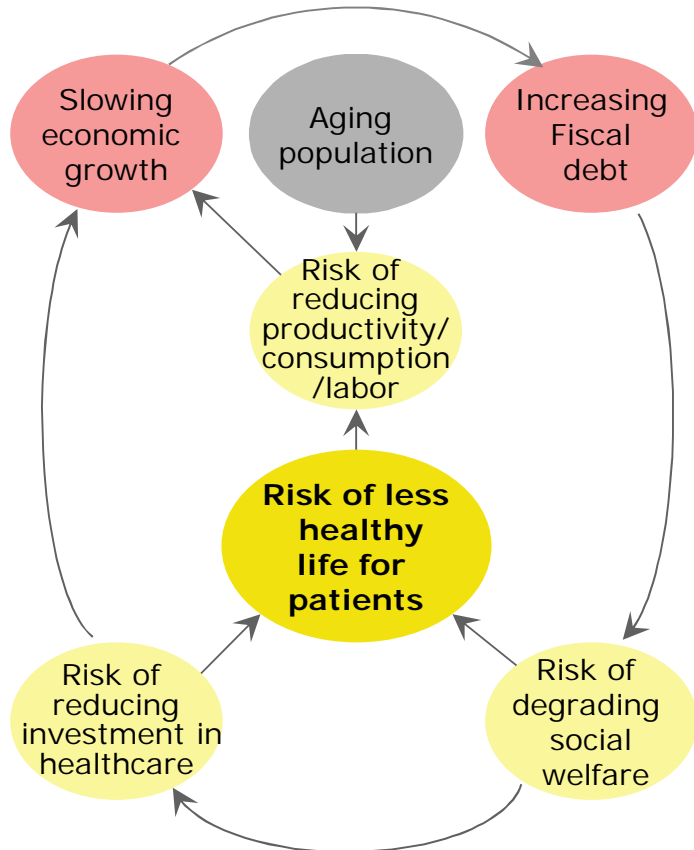
1. OECD Health Data 2011; 2. Estimate figure for 2010 based on data published by MHLW since latest OECD date for Japan is those of 2008; 3. Per-capita spending for Japan is as of 2008; 4. Estimate based on actual data for April-September 2011 published by MHLW

Investment in healthcare will generate virtuous cycle for socio-economic enhancement in Japan



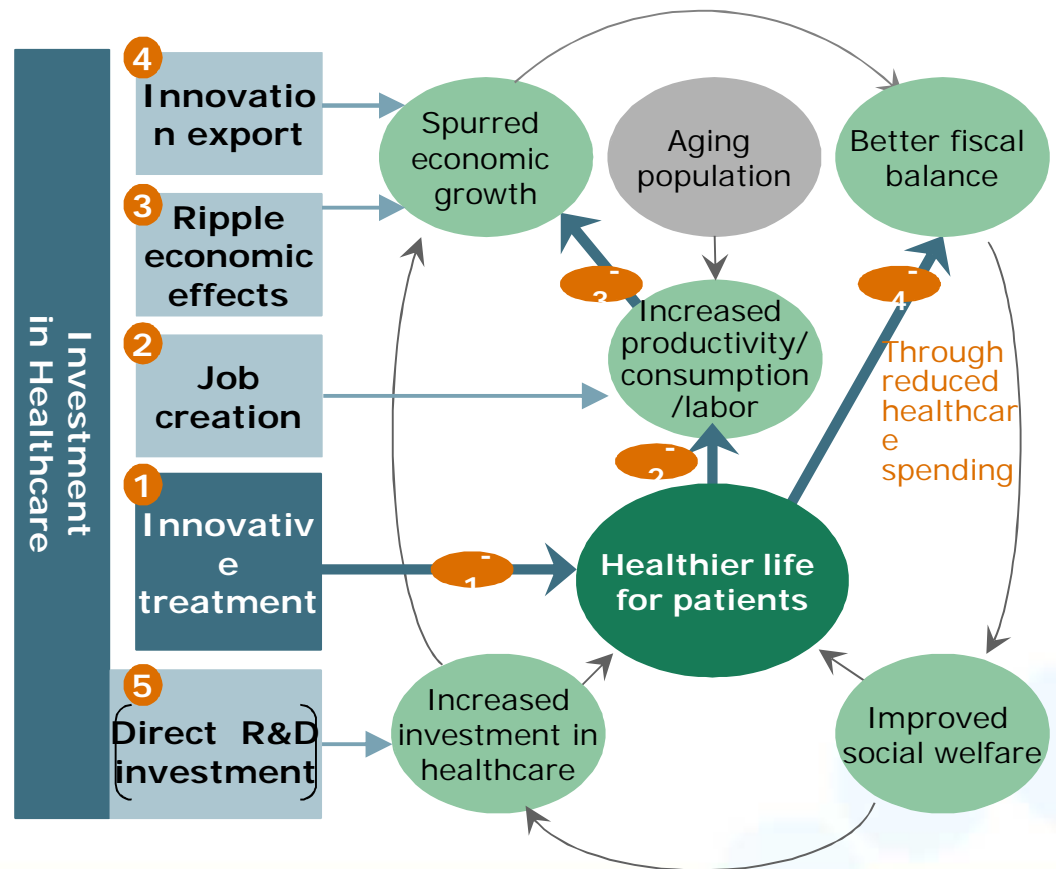
Potential risk in Japan

Economic/demographic trend could drive social anxiety



Expected impact of investment in healthcare

Realize healthier life for patients, contributing to betterment of society/economy

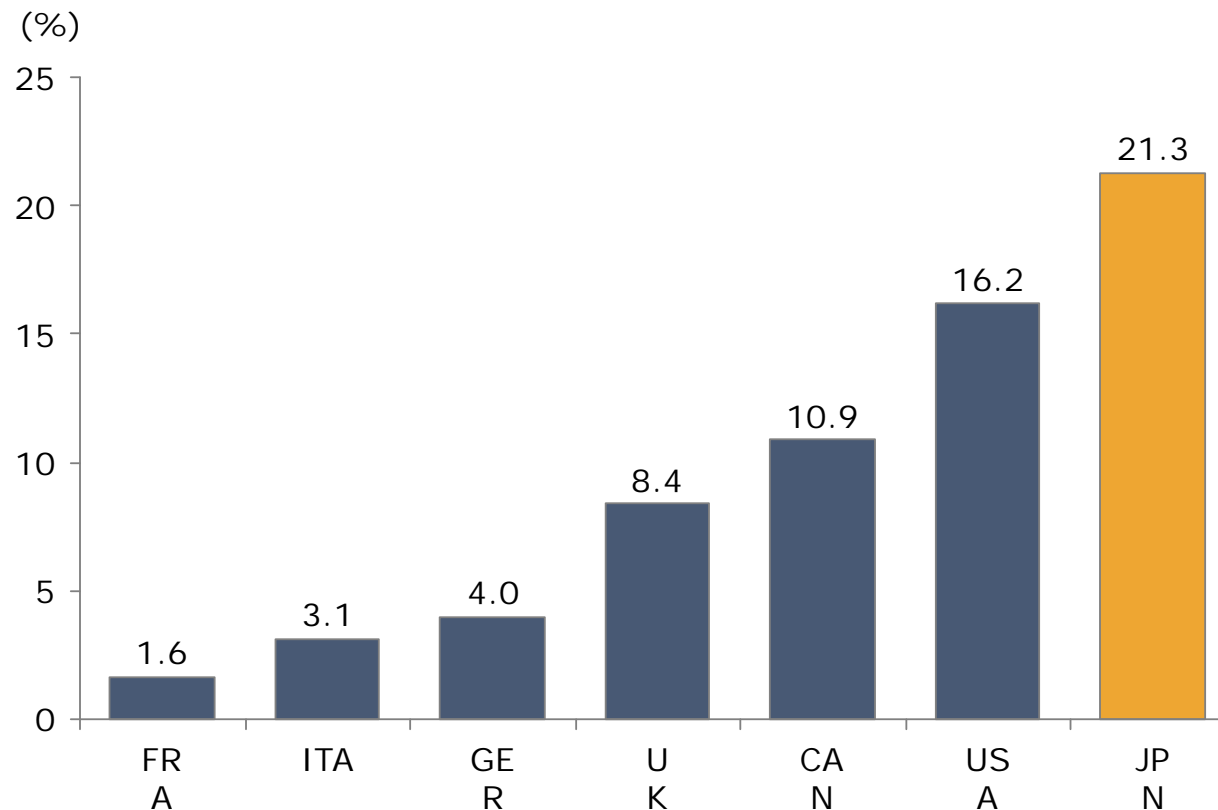


Productivity increase of the elderly brings considerable economic benefits to Japan

P/RMA

Japan has the highest rate of over 65 employment rate

Over 65 years old employment rate¹⁾ (2010)



1. Number of over 65 in employment divided by total over 65 population
Source: OECD (2010)

Investment in healthcare helps create jobs further activating economy in Japan



Industry		no. of job created ('000, 2009.3-10.3)	Total no. of employees ('000, 2010)
1. Social Welfare	Nursing care & other social welfare	270	3,010
	Healthcare	240	3,490
2. Hotel/Restaurant services		150	3,880
3. Daily services/Leisure		110	2,370
4. Wholesale/Retail		70	10,600
5. Academic/Specialized services		70	1,990
6. Other services		10	4,430
7. Information/Communication		20	1,890
8. Education		40	2,850
9. Transport/Postal Service		180	3,540
10. Agriculture/Forestry		250	2,170
11. Manufacturing		310	10,580
12. Construction		330	4,890
Total: All industries		350	62,100

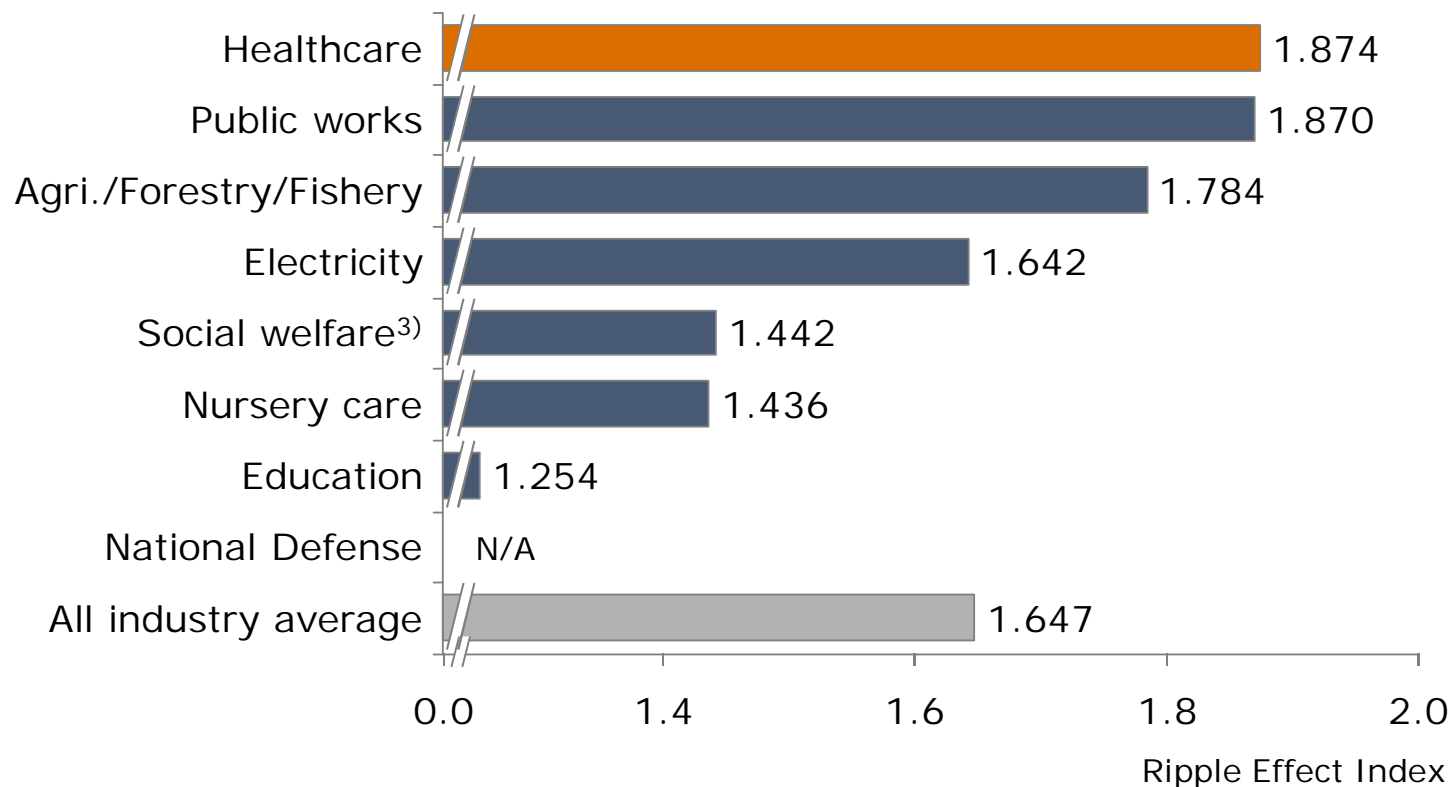
Source: Labor force survey by Statistics Bureau of Ministry of Internal Affairs & Communication

Healthcare generates higher ripple economic effects than other major sectors in Japan



Ripple Effect Index (2005)¹⁾

(Comparison among 8 largest industries in terms of national spending allocation²⁾)



1. The ripple effect measures the level of production increase in other sectors caused by production increase in one sector

2. Based on the initial budget of JFY2010; Excluding discretionary grant to local government

3. Average of HC service, medicines and medical devices

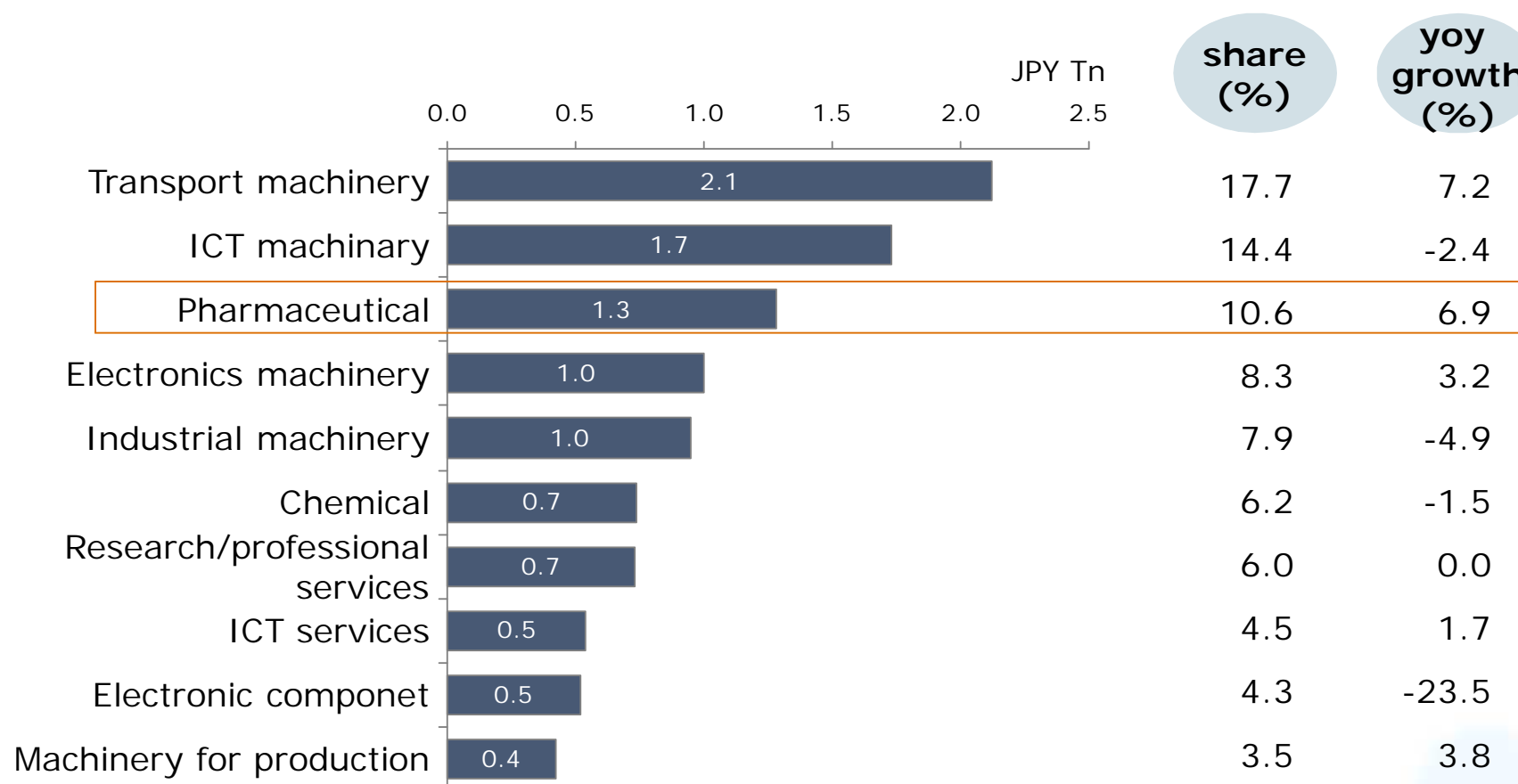
Source: Analytical research on inter-industry relations by healthcare, nursery care and social welfare by IHEP

Sizeable amount of R&D in healthcare contributes to economic growth

R&D investment by pharmaceutical industry in Japan



Top 10 industries for R&D investment in Japan (2010)



Source: Ministry of Internal Affairs and Communications

Summary – Impact of Innovative Pharmaceuticals



- **High Life Expectancy and Health Outcomes**
- **Improved Quality of Medical Care and Quality of Life**
- **Positive Economic Impact:**
 - *Healthcare system-wide savings*
 - *Improved productivity*
 - *An engine for economic growth, including Job creation*

Driver of R&D Investments = Pharmaceuticals



The world's top companies by their total R&D investment

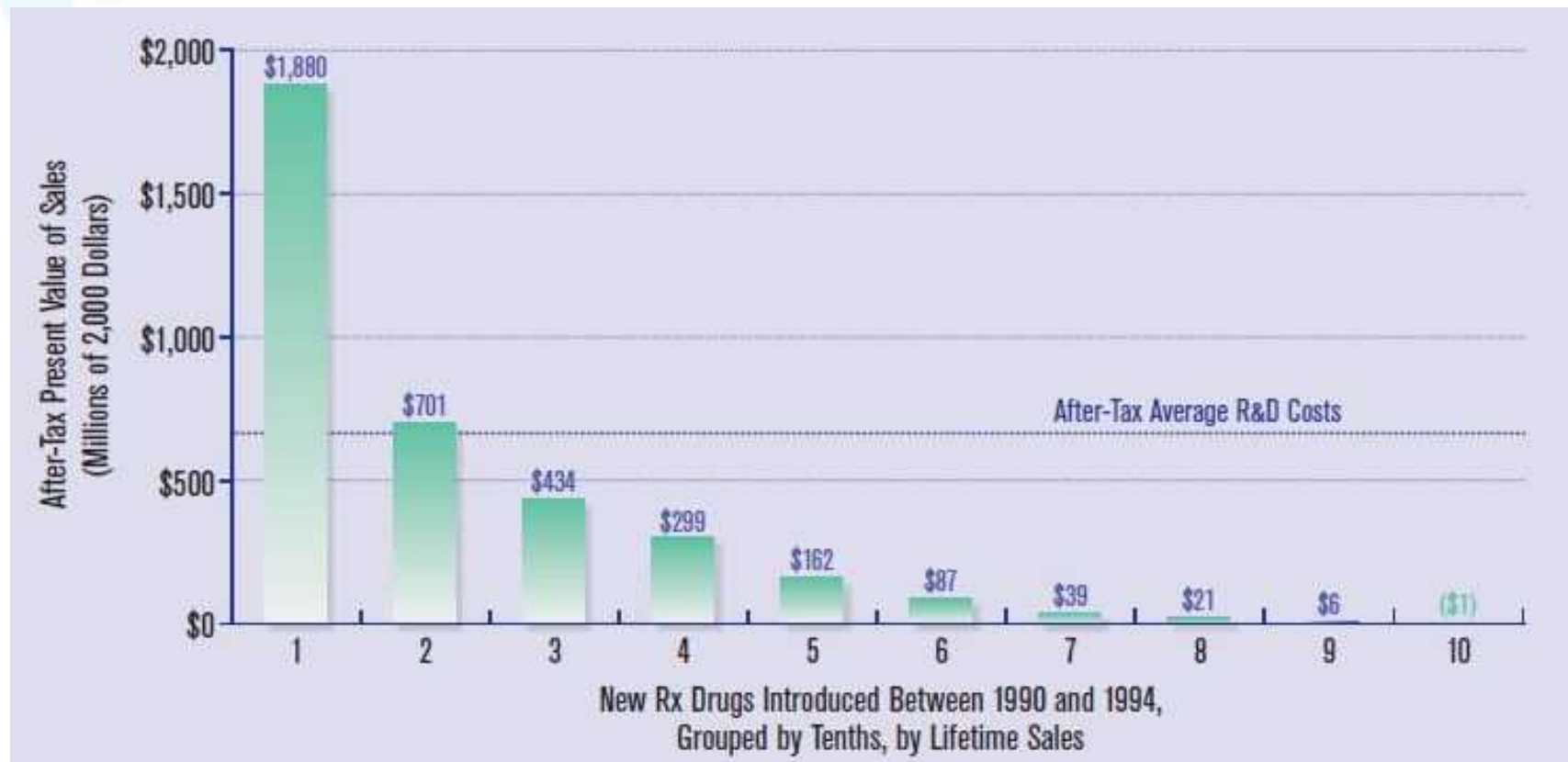
Rank	Company name	R&D investment (€ Millions)
1	Roche (Switzerland)	7,181
2	Pfizer (USA)	7,016
3	Microsoft (USA)	6,740
4	Toyota Motor (Japan)	6,666
5	Merck US (USA)	6,403
6	Volkswagen (Germany)	6,258
7	Samsung (South Korea)	6,181

8	Novartis (Switzerland)	6,022
9	General Motors (USA)	5,189
10	Johnson & Johnson (USA)	5,101
11	Nokia (Finland)	4,938
12	Intel (USA)	4,901
13	Daimler (Germany)	4,852
14	Sanofi-Aventis (France)	4,390
15	Panasonic (Japan)	4,383

Source: http://iri.jrc.ec.europa.eu/research/scoreboard_2011.htm

Just 2 in 10 Approved Medicines Recoup R&D Costs

P/RMA



Industry is responding to Japanese society's needs



Current status of requests for development of unmet medical needs and indications

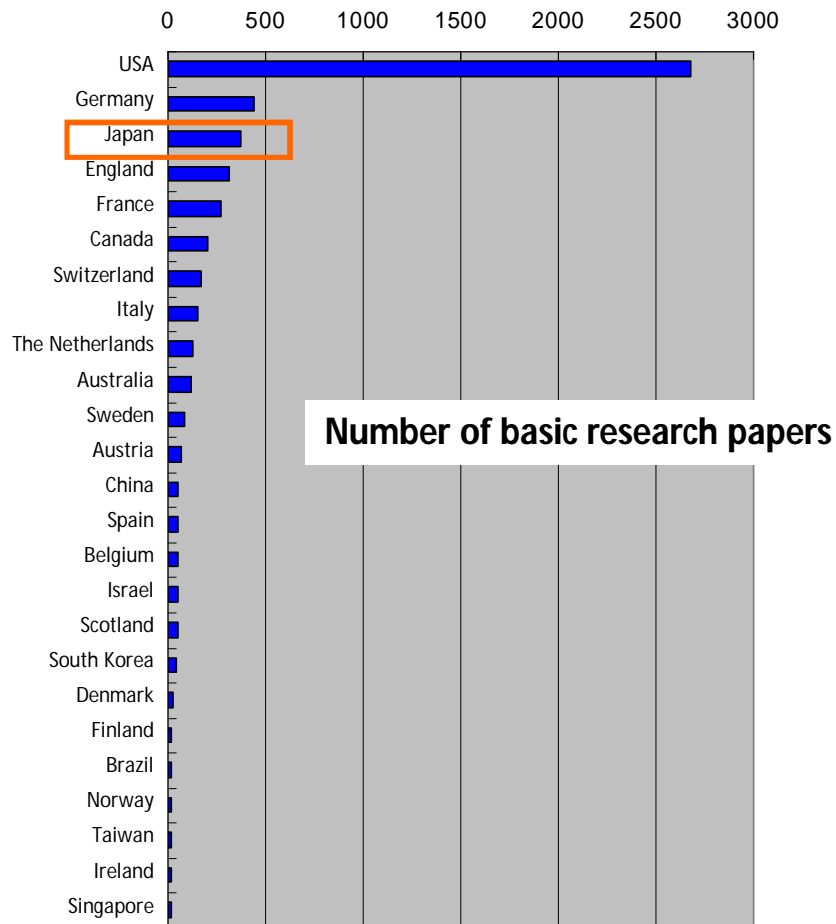
Total requested:	188	(PhRMA 37)
Approved	68	(12)
Applications submitted	34	(9)
Clinical trial plan submitted	62	(9)
Paper NDA planned	7	(2)
Others	17	(5)

(From: Document presented at Review Committee for Unmet Medical Needs and Indications on March 23, 2012)

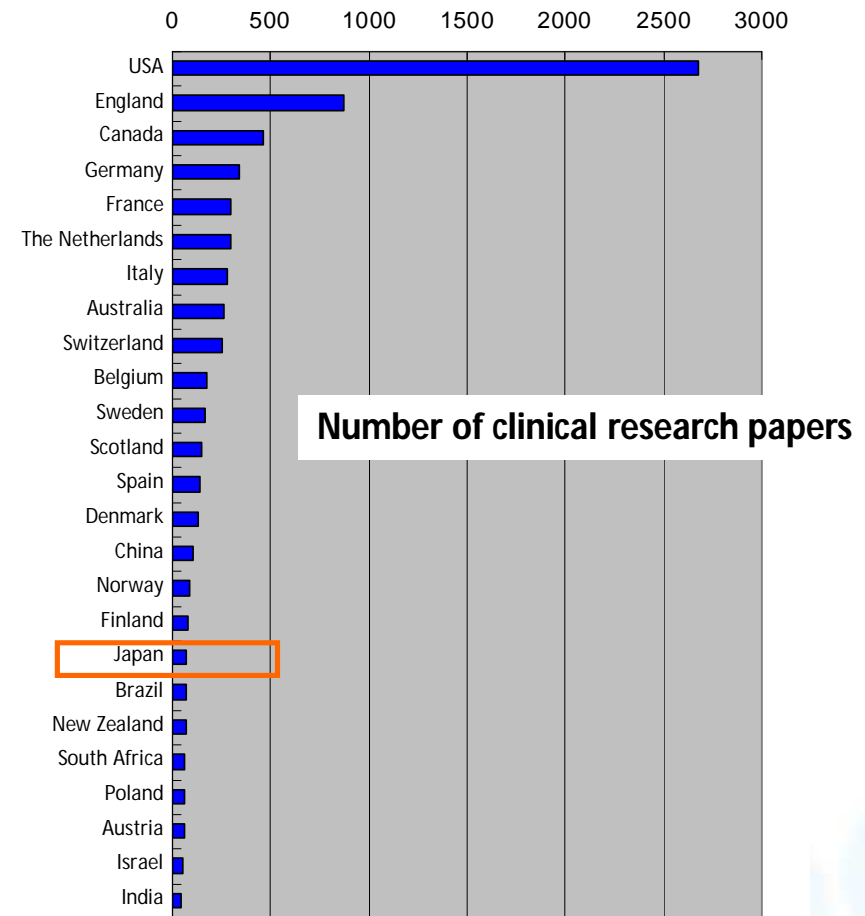
Japan's Strength/Weakness in R&D



Strong in basic research



Weak in clinical research



Source: Office of Pharmaceutical Industry Research News No. 25. August 2008

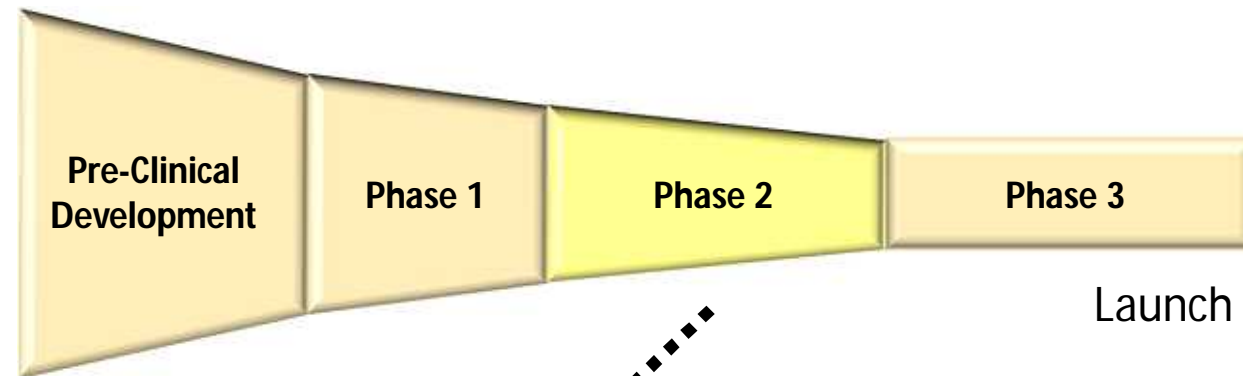
Change in the clinical development model



Earlier Go/No Go decision making from the PoC stage

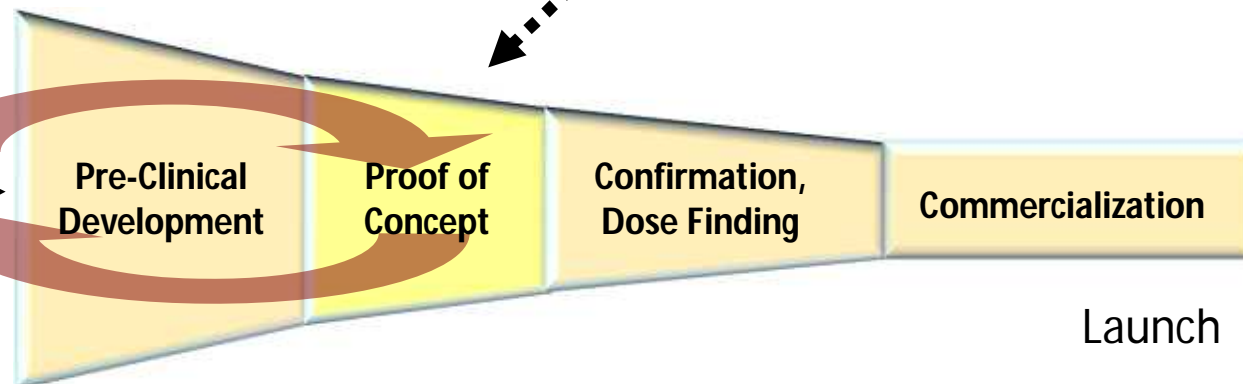
Traditional Model

Few Targets
"black box"
mechanism



Contemporary Model

Many Targets
with Known
Pharmacology



CREATING

LEARNING

CONFIRMING

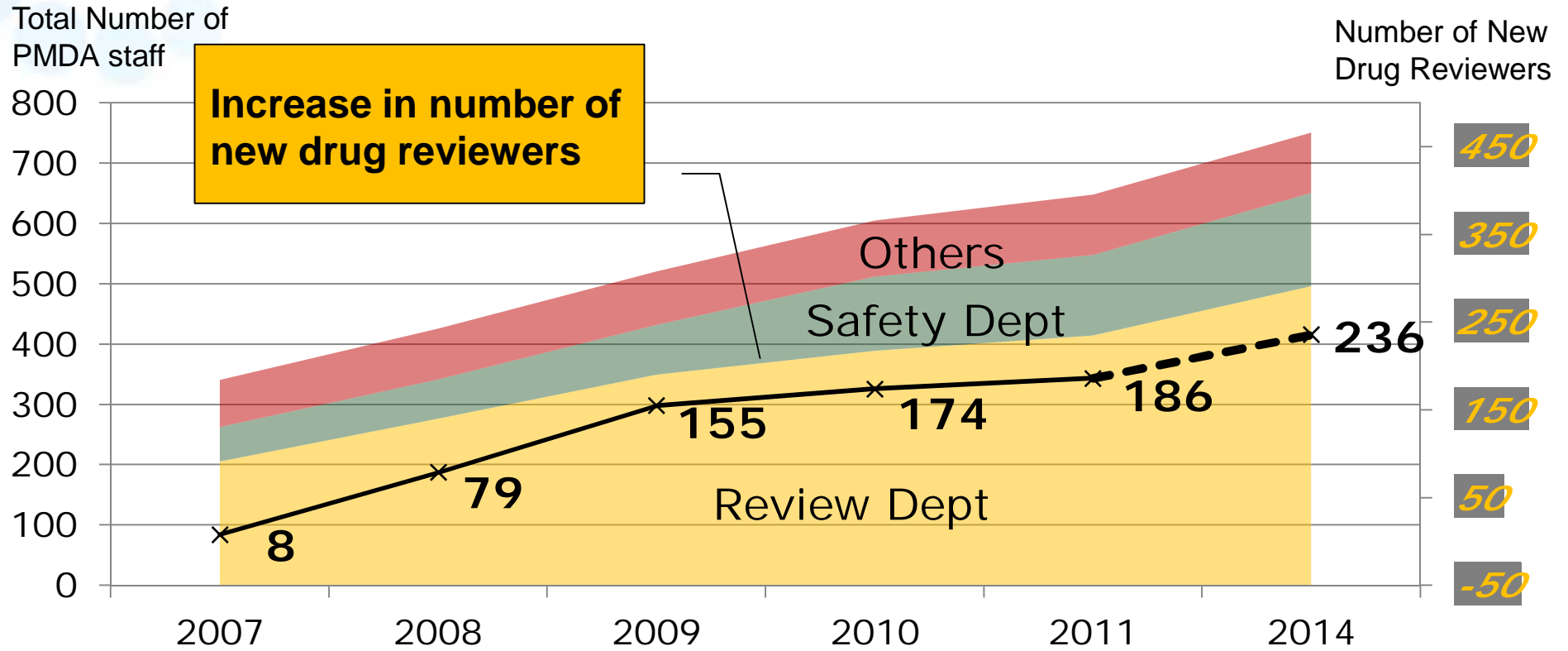
PoC: Proof of concept refers to the first trial in humans to demonstrate the feasibility of an experimental drug.

PMDA Reform



- **PMDA's five-year plan sets the following goals**
 - **Increase in the number of staff**
 - 236 additional drug reviewers
 - **Target for review time for NDAs by FY2011**
 - Total review time for priority items: 9 months
 - Total review time for standard items: 12 months

PMDA: Increase in Number of Staff

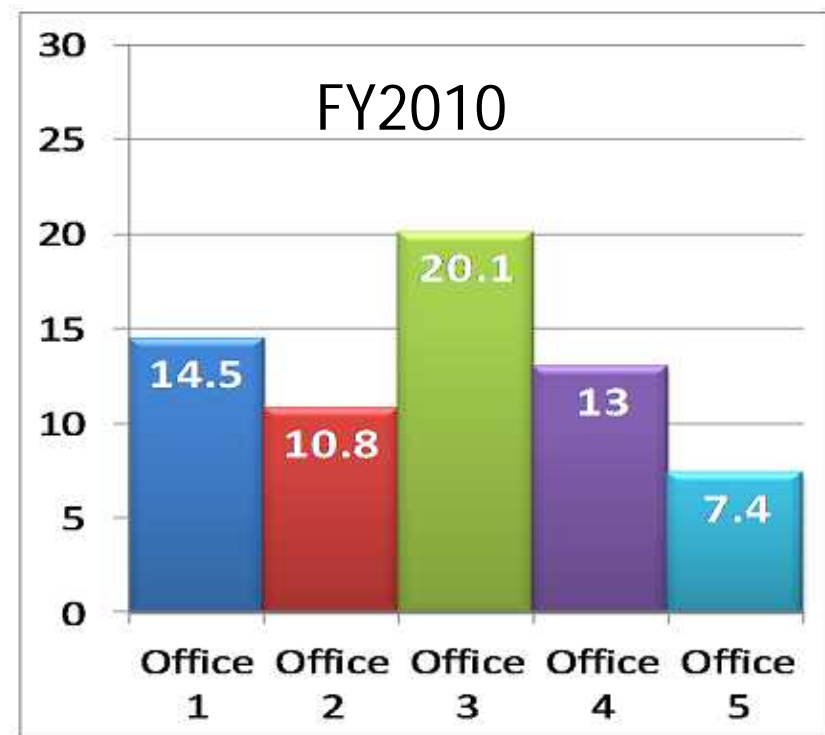
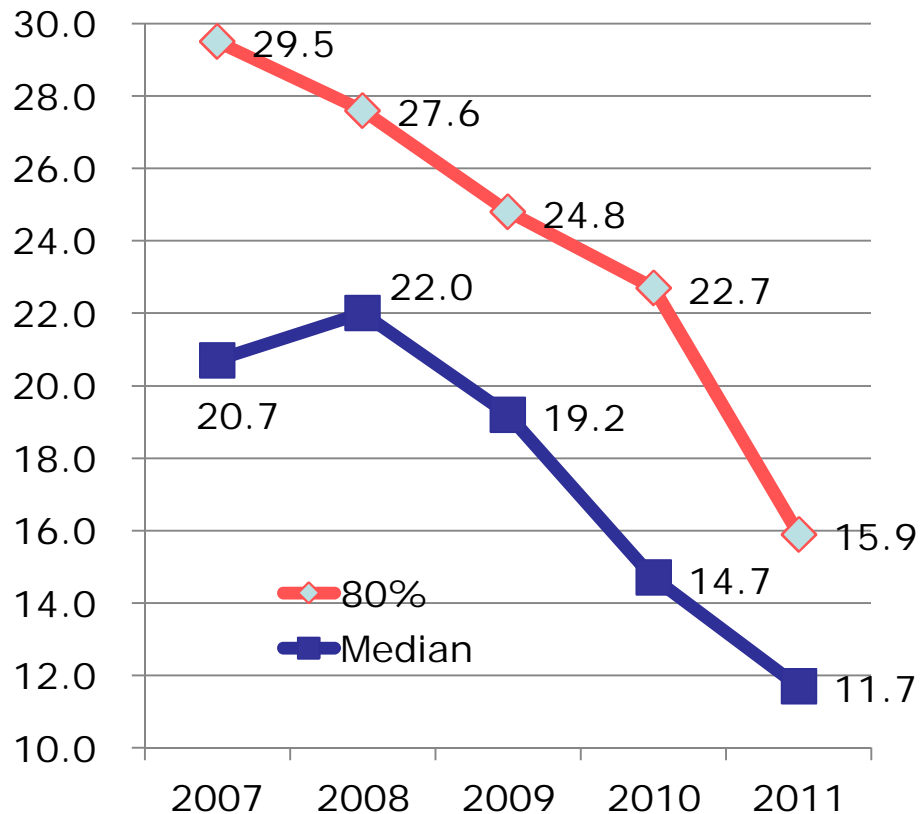


Source: PMDA 5 year Plan

PMDA: Alternative Metrics for Performance Measurement



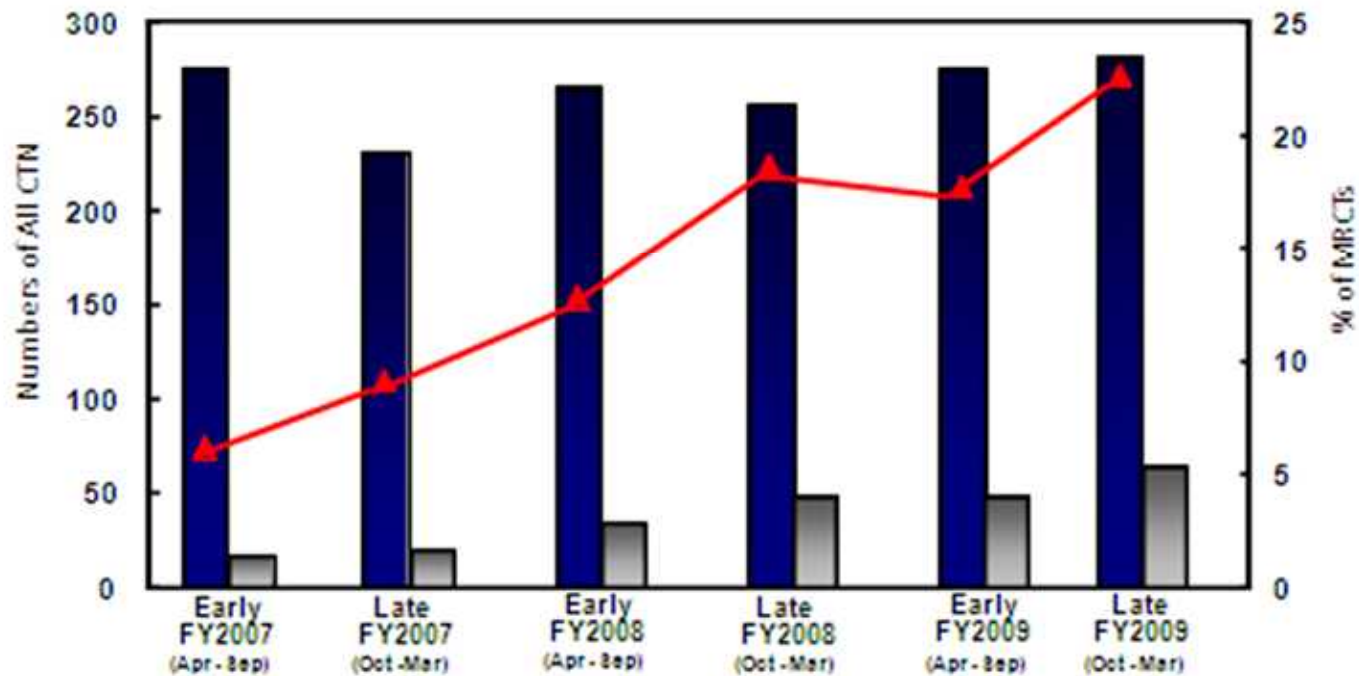
- As variations in review times among offices exist, we propose PMDA to additionally monitor the 80th percentile total review time as the performance metrics.



Trends of MRCTs including Japan % of MRCTs in Clinical Trial Notifications



Trends of MRCTs including Japan-1 -% of MRCTs in Clinical Trial Notifications-



Asia Regulatory Conference, April 2011: Seoul, Republic of Korea
Shinobu UZU, International Planning Director, Ministers' Secretariat, MHQV

PhRMA's Recommendations (1/2)



What Japan needs to do in regulatory science in order to be a globally competitive pharmaceutical center of excellence are:

- Establishment of a drug discovery support organization that would mediate between Japan's "seeds" and global industry or between global "seeds" and Japan's industry. There is no border in true innovation.
- Further harmonization with international standards in clinical development and regulatory science
- Further enhancement of the PMDA system by adding more pharmaceutical professionals and experts to the PMDA staff in order to support pharmaceutical R&D and to bolster approval reviewing.
- PMDA to agree to review time performance metrics at the 80th percentile

PhRMA's Recommendations (2/2)



- Relax the requirement that phase I studies be conducted solely with Japanese patients, and accept data from phase I studies conducted in other East Asian countries

PhRMA companies are making serious efforts to reduce drug lag









- **Increasing use of simultaneous global development programs**
 - ~ 50 global studies that include Japan in 2011
- **Responding to request for unapproved drugs and indications**
 - ~ Actively engaging in 37 requests with 12 approvals to date
- **Earlier entry of new development candidates into Japan**
 - ~ Encouraged by the innovative premium pricing policy

Vaccine Gap



Recommended Routine Immunization Status

						
Hepatitis B		●		●	●	★
Hib		●	●	●	●	★
Pneumococcal (children)		●	●	●	●	★
HPV		●	●	●	●	★
Varicella		●			●	
Mumps		●	●	●	●	

Recommended immunization

WHO recommendation for all regions

Vaccine Fact Book

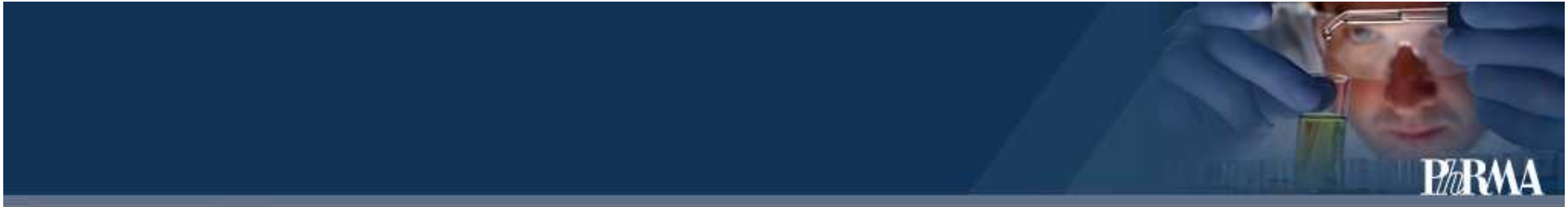


PhRMA Vaccine Committee issued "Vaccine Fact Book" in March, 2012. "Vaccine Fact Book" seeks to explain to non-specialists what vaccines do, how they are developed, how they are given and what results have been obtained when they are routinely used.

PhRMA distributes Vaccine Fact Book to vaccine stakeholders including MHLW, PMDA, Diet members, academia and media.

Contents

- 1 BASIC CONCEPT OF VACCINATION
- 2 VACCINE DEVELOPMENT AND IMPLEMENTATION
- 3 PUBLIC HEALTH EFFECTIVENESS OF VACCINE IMPLEMENTATION
- 4 VACCINES IN USE
- 5 VACCINES IN DEVELOPMENT



Thank you for your attention.