

# Press Conference for New JBEC Chairman

March 11, 2014

Tony Alvarez, Chairman of the Japan-Based  
Executive Committee of PhRMA

# Promotion of Innovation in the healthcare area and the activities of PhRMA

# Survey on “Value of Innovative New Drugs in Japan” to verify the contribution that innovation makes to society

(April, 2013)

日本における  
革新的新薬の  
価値

**P/RMA**  
RESEARCH × PROGRESS × HOPE

2013年4月12日



Published a Booklet on “Development of New Drugs”,  
which demonstrated, from the perspective of patients and healthcare  
providers, how these newly approved drugs helped save and improve  
lives over the past six years  
(October, 2013)



# In 2013...

Changes in Japan's healthcare policies had positive impact on the following:

- Speed of new drug approval
- Reform in FY2014 drug pricing
- Expanded vaccine policy
- Pharmaceutical industry's role in Japan's economic growth strategy

# Regulatory Issues

# Review Time (Median) for Approved New Drugs

Regular review		FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	Apr.-Oct. 2013
Total Review Time (m)		22.0	19.2	14.7	11.5	10.3	11.0
	Regulatory Review Time	11.3	10.5	7.6	6.3	5.7	6.5
	Applicant-elapsed Time	7.4	6.7	6.4	5.1	4.2	4.4
No. of approvals		53	92	92	80	81	53

Priority review		FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	Apr.-Oct. 2013
Total Review Time (m)		15.4	11.9	12.0 (9.2)	9.2 (6.5)	9.0 (6.1)	8.2 (7.3)
	Regulatory Review Time	7.3	3.6	5.3 (4.9)	4.1 (4.2)	3.4 (3.8)	3.4 (3.6)
	Applicant-elapsed Time	6.8	6.4	6.0 (3.4)	5.0 (2.0)	4.6 (1.5)	4.5 (2.8)
No. of approvals		24	15	20	50	53	16

# Pricing Issues



# Impact of the new pricing scheme on new drug development Follow-up Study

Impacts of the new scheme towards domestic R&D activity were surveyed on 21 companies, of which 13 were further interviewed

## Survey

### ➤ Survey period

- 01/2013 - 02/2013

### ➤ Companies

- Japan based: 9 companies

- |                  |            |
|------------------|------------|
| • Astellas       | • Kissei   |
| • Daiichi-Sankyo | • Otsuka   |
| • DSP            | • Shionogi |
| • Eisai          | • Takeda   |
| • KHK            |            |

- Foreign based: 12 companies

- |               |                  |
|---------------|------------------|
| • Abbvie      | • Janssen        |
| • AstraZeneca | • MSD            |
| • Biogen      | • Novartis       |
| • BMS         | • Pfizer         |
| • Eli Lilly   | • Roche (Chugai) |
| • GSK         | • Sanofi         |

## Interview

### ➤ Interview period

- 04/2013

### ➤ Companies

- Japan based: 4 companies

- Daiichi-Sankyo
- DSP
- Eisai
- Shionogi

- Foreign based: 9 companies

- |               |            |
|---------------|------------|
| • AstraZeneca | • MSD      |
| • BMS         | • Novartis |
| • Eli Lilly   | • Pfizer   |
| • GSK         | • Sanofi   |
| • Janssen     |            |

### ➤ Interviewees

- Executives, heads of R&D

# Survey results: Solving the drug lag

Time to NDA submission was shortened after introduction of premium pricing for innovative new drugs.

-2011-2012 : “30 months” → “17 months”

- In 5 years after 2013: “17 months” → “4 months”

# Survey results: Positive impact on new drug development decision

More companies decided to start various drug development initiatives since introduction of premium pricing in 2010

Companies which experienced positive impacts (%)

2010 survey 2012 survey

Initiation of development of drugs with high unmet needs

27%

71%

Initiation of development of dosage/forms for the Japanese

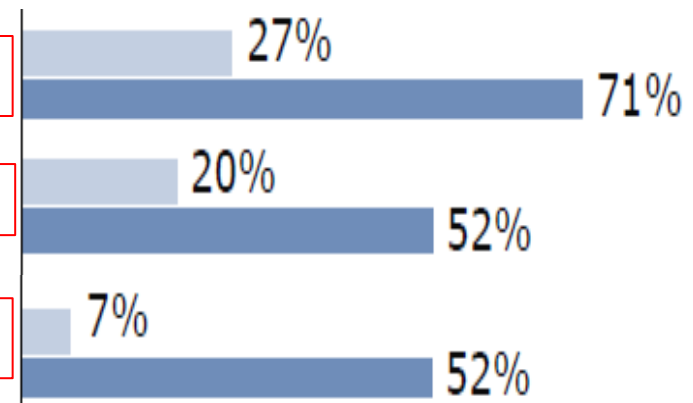
20%

52%

Initiation of development of drugs with low success rate

7%

52%



# The Role of Vaccines

Published “Vaccine Fact Book”  
to educate Japanese public on the importance of vaccine  
(April, 2012)



# Role of Pharmaceutical Industry in driving Japanese economy

Held a symposium  
to make younger researchers in Japan aware of  
the importance of translational research  
(August, 2013)

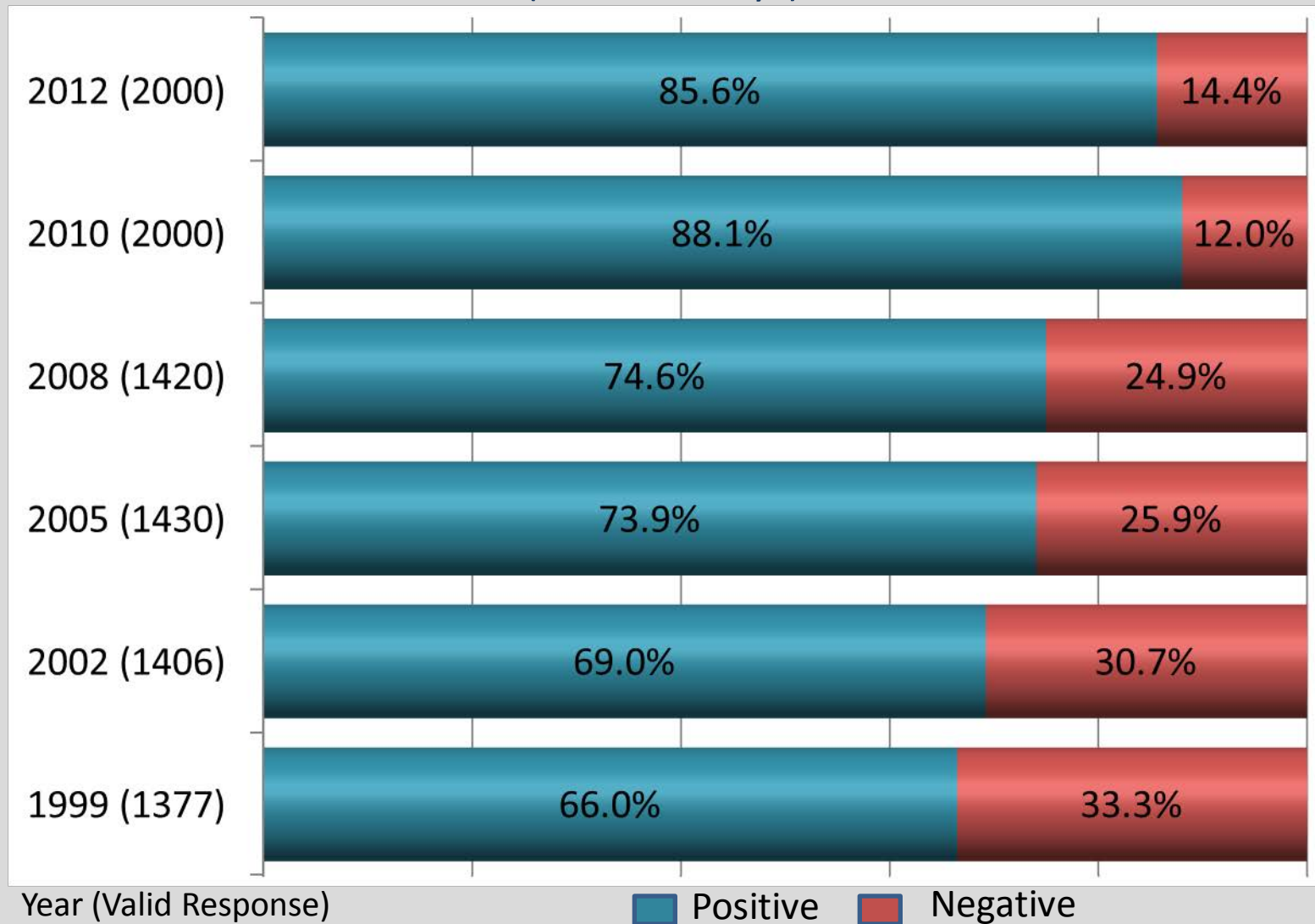


# The issue of ethics in the pharmaceutical industry



# Reliability of the pharmaceutical industry

85.6% of Japanese public replied “The pharmaceutical industry is reliable”  
(JPMA surveys)



## In summary, PhRMA (JBEC) will:

- Support Abe Administration's promotion of innovation in healthcare and PMDA's commitment to further acceleration of drug review time;
- Do everything necessary to make premium pricing for innovative new drugs a law;
- Work with all parties to revise "market expansion re-pricing" and "14-day Rx limit" on new drugs;
- Continue activities for increasing awareness of vaccines' importance; and
- Promote drug discovery innovation in Japan