

欧州製薬団体連合会

加藤会長記者会見

efpia\*

European Federation of Pharmaceutical  
Industries and Associations



European Federation of Pharmaceutical  
Industries and Associations

Chairman  
Press Conference  
4 March 2010

# EFPIA Japan EFPIA Press Conference

4 March 2010

EFPIA Japan

## Board Members

<b>Chairman:</b>	<b>Masuhiko Kato</b>	<i>(AstraZeneca K.K.)</i>
<b>Vice Chairman:</b>	<b>Marc Dunoyer</b>	<i>(GlaxoSmithKline K.K.)</i>
<b>Vice Chairman:</b>	<b>Patrick Chocat</b>	<i>(sanofi-aventis K.K.)</i>
<b>Board of Director:</b>	<b>Hiroyuki Mitani</b>	<i>(Novartis Pharma K.K.)</i>
<b>Board of Director:</b>	<b>Jean-Luc Lowinski</b>	<i>(Bayer Yakuhin, Ltd.)</i>
<b>Board of Director:</b>	<b>Claus Eilersen</b>	<i>(Novo Nordisk Pharma Ltd. )</i>
<b>Board of Director:</b>	<b>Wayne Paterson</b>	<i>(Merck Serono Co., Ltd.)</i>
<b>Director General:</b>	<b>Takahiro Maehama</b>	<i>(EFPIA Japan)</i>

**Controller**

**Mitsuru Kikuchi**

*CHUGAI PHARMACEUTICAL CO., LTD.*

**Pricing &  
Economics  
Committee**

**Technical  
Committee**

**Public  
Relations  
Committee**

**Intellectual Property,  
Legal & Corporate Ethics  
Committee**

**Vaccine  
Committee**

**Chairman**  
**Kuniyuki Hara**  
*sanofi-aventis K.K.*

**Chairman**  
**Mizuho Inazu**  
*Novartis Pharma K.K.*

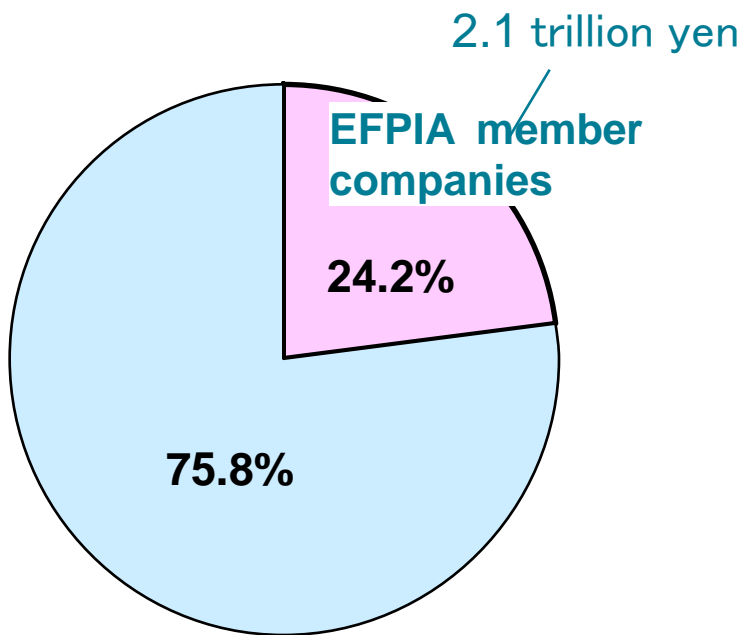
**Chairman**  
**Hideto Kita**  
*Novartis Pharma K.K.*

**Chairman**  
**Muneki Natani**  
*Sanofi-aventis K.K.*

**Chairman**  
**Shunjiro Sugimoto**  
*GlaxoSmithKline K.K.*

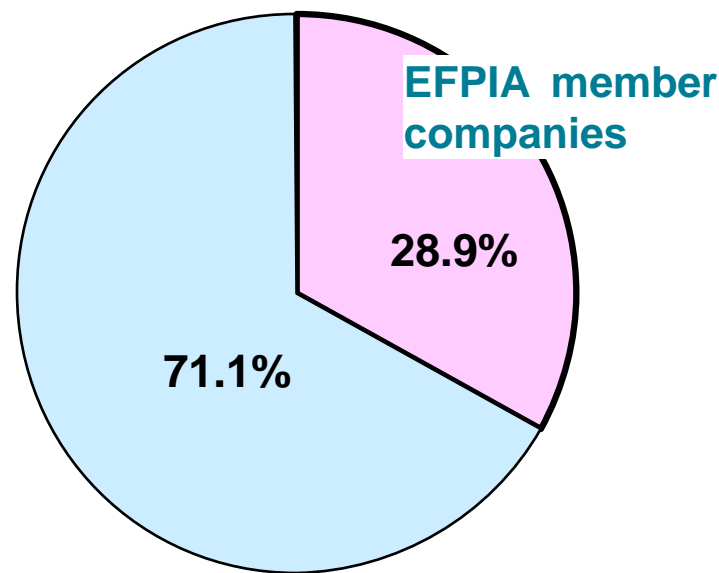
- Actelion Pharmaceuticals Japan Ltd.
- Amersham K.K.
- AstraZeneca K.K.
- Bayer Yakuhin, Ltd.
- Bracco-Eisai Co., Ltd.
- CHUGAI PHARMACEUTICAL CO., LTD.
- CSL Behring K.K.
- Ferring Pharmaceuticals Co., Ltd.
- GALDERMA K.K.
- GlaxoSmithKline K.K.
- Guerbet Japan KK
- JANSSEN PHARMACEUTICAL K.K.
- Lundbeck Japan K.K.
- Merck Serono Co., Ltd.
- NIHON SERVIER COMPANY LIMITED
- Nippon Boehringer Ingelheim Co., Ltd.
- Novartis Pharma K.K.
- Novo Nordisk Pharma Ltd.
- Pierre Fabre Japon Co., LTD
- sanofi-aventis K.K.
- SOLVAY SEIYAKU K.K.
- UCB Japan Co., Ltd.

## Sales (2009)



Market total: 8.9 trillion yen (IMS)

## New drug approvals (2007 - 2009)



Approvals total : 342(PMDA Homepage)

# of employees : ~28,000 people (EFPIA Japan companies)

**“2.1trillion yen (24.2%)”**

Our total ethical pharmaceutical sales were 2.1 trillion yen based on NHI price or 24% of the total market (8.9 trillion yen)

Source: JPM, Jan –Dec 2009  
Copyright : IMS Japan K.K.

**“4 & 3”**

4 EFPIA J member companies were included in the top 10 companies  
3 EFPIA J member companies in the top 11- 20 companies

Source: JPM, Jan –Dec 2009  
Copyright : IMS Japan K.K.

**“7 (50%)\*”**

In terms of growth, 7 EFPIA Japan member companies (50% of the relevant members) showed a higher growth rate than the market growth rate of

7.2%

※14 EFPIA member companies are included in the IMS Data.

Source: JPM, Jan –Dec 2009  
Copyright : IMS Japan K.K.

**“ 30% ”**

Our member companies obtained 30% of the new drug approvals in the past three years (2007-2009)

Source: PMDA Homepage

**“Contribute to healthcare and patients  
in Japan by early introduction of  
innovative medicines and vaccines”**

- **Realize the best access to innovative medicines and vaccines for patients in Japan by contributing to the establishment of systems to promote their development and delivery**
- **Build strong credibility with society with our member companies united**

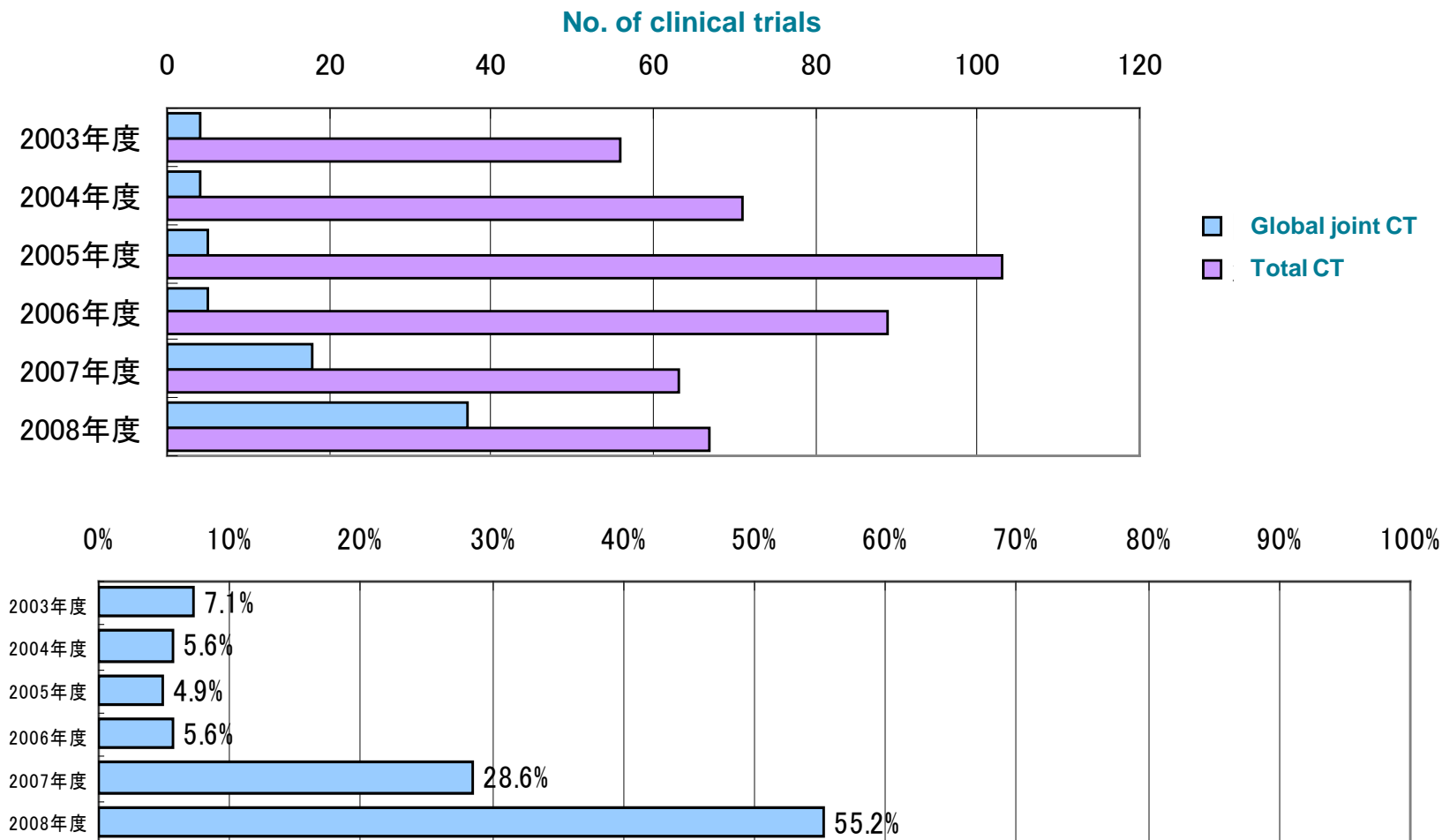


- 1. Expedite the access of Japanese patients to innovations**
- 2. Acquire reward for innovation with the new pricing system**
- 3. Pursue better balance between prevention and treatment**
- 4. Make Japan a dynamic and attractive place to invest in for pharmaceutical companies**
- 5. Increase credibility of the pharmaceutical industry further**

## 1. Expedite access for Japanese patients to innovations

- Promote further efficiency improvement of Japanese clinical trials
- Realize a more efficient review process by PMDA.
- Expand the scope of MRA for GMP beyond oral solid preparations

The ratio of global joint clinical trials was 55% in 2008



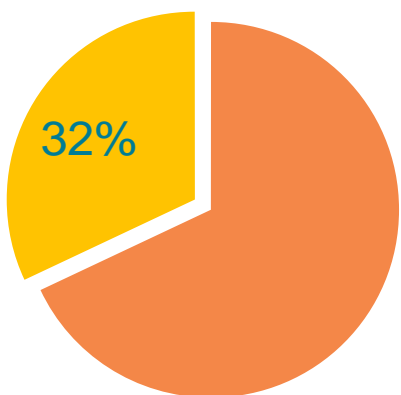
## 2. Acquire reward for innovation with the new pricing system

- Sustain the new pricing system with no price decrease for new products until generic entry
- Obtain price premium for innovation
- Eliminate systems and rules to hinder innovation
- Enlarge price premium by additional scientific data obtained during re-examination

In respect of premium obtaining drugs for acceleration and requests for development, EFPIA member companies' products account for about 30% of the total obtaining drugs

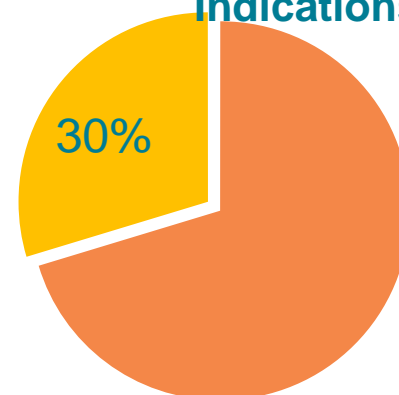
**Premium obtaining Drugs**

**EFPIA  
Member  
companies**



**Requests for development of Unapproved Drugs and Unapproved Indications**

**EFPIA  
Member  
companies**



## 3. Pursue better balance between prevention and treatment

- Promote disease prevention by vaccines
  - Insist on global harmonization of Biological standards
  - Recommend the introduction of Epidemiology
  - Expand the scope of public funding for vaccination.

MMR and polio vaccines have not been approved yet

Vaccine	US	EU	Launched in Japan (ranking)
Hib	✓1987	✓	Dec. 2008 (132 <sup>nd</sup> )
Human papillomavirus (HPV)	✓2006	✓	Dec. 2009 (99 <sup>th</sup> )
PCV-7	✓2000	✓	Feb. 24, 2010 (98 <sup>th</sup> )
MMR*	✓1971	✓	Not launched
Inactivated polio	✓1987	✓	Not launched
Rotavirus	✓2006	✓	Not launched

\* Vaccination of combination of 3 vaccines, namely, measles (M), mumps (M) and rubella (R)

As of February 2010

## Rubella, measles and mumps have almost vanished in the West

### Incidence by year (no. of people)

	Voluntary Vaccination* (Low vaccination rate)				Periodic Vaccination* (High vaccination rate)			
	Mumps Epidemic parotitis		Chickenpox		Rubella		Measles	
Year	Japan	USA	Japan	USA	Japan	USA	Japan	USA
2000	132,877	338	275,036	27,382	3,123	176	22,552	86
2001	254,711	266	271,409	22,536	2,561	23	33,812	116
2002	180,827	270	263,308	22,841	2,971	18	12,473	44
2003	84,735	231	250,561	20,948	2,795	7	8,285	6
2004	127,592	258	245,941	32,931	4,239	10	1,547	37
2005	187,837	314	242,296	32,242	895	11	537	66
2006	200,639	6,584	265,453	48,445	509	11	516	55
2007	67,803	800	245,880	40,146	463	12	3,133	43

reference :

Population in Japan: 127 million

Population in USA: 280 million

\* Recommended in Japan

All but chickenpox required in USA  
when entering elementary school

Source:

Japan: (Infectious Disease Surveillance Center: Infectious Disease Data)

USA: (CDC: MMWR annual report)



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