



# **Japan and Emerging Markets Business Briefing**

**10<sup>th</sup> December 2009**

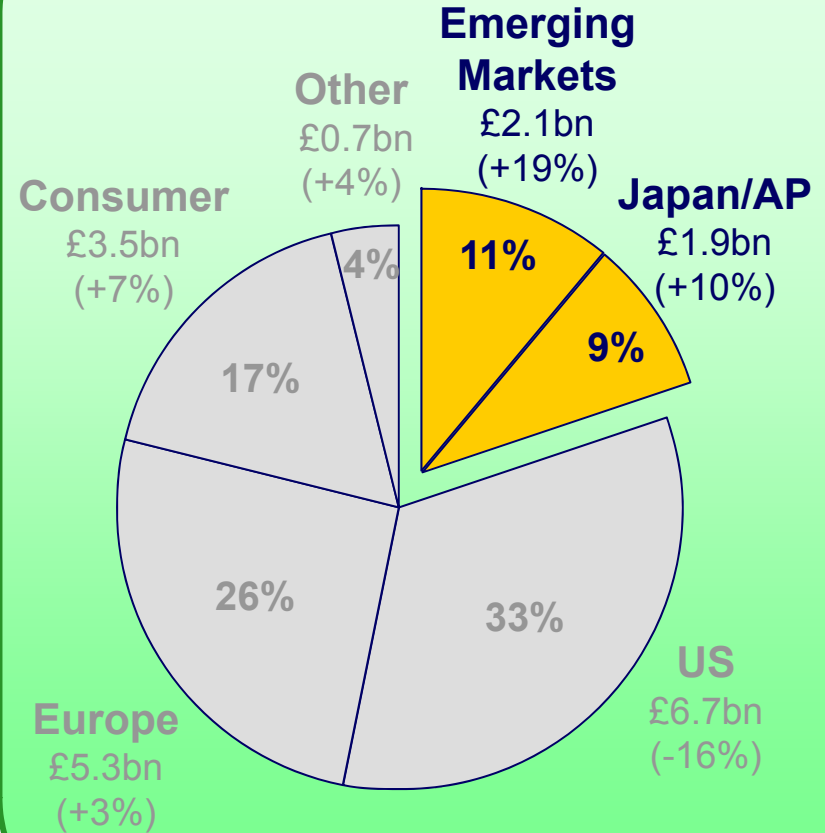
# Key pillar of GSK strategy

Grow a Diversified  
Global Business

Deliver More Products  
of Value

Simplify the Operating  
Model

## Turnover Q309 YTD



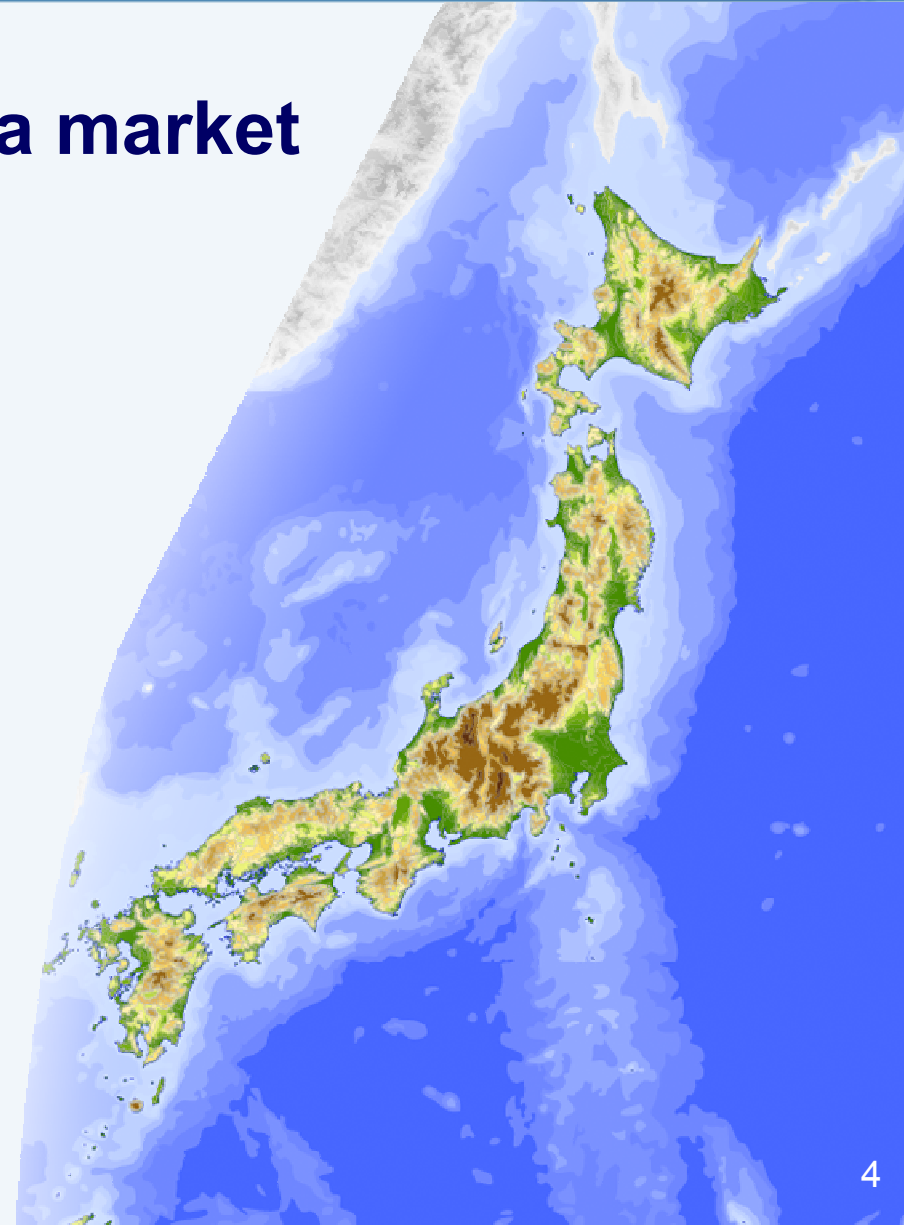


# **Japan Business Briefing**

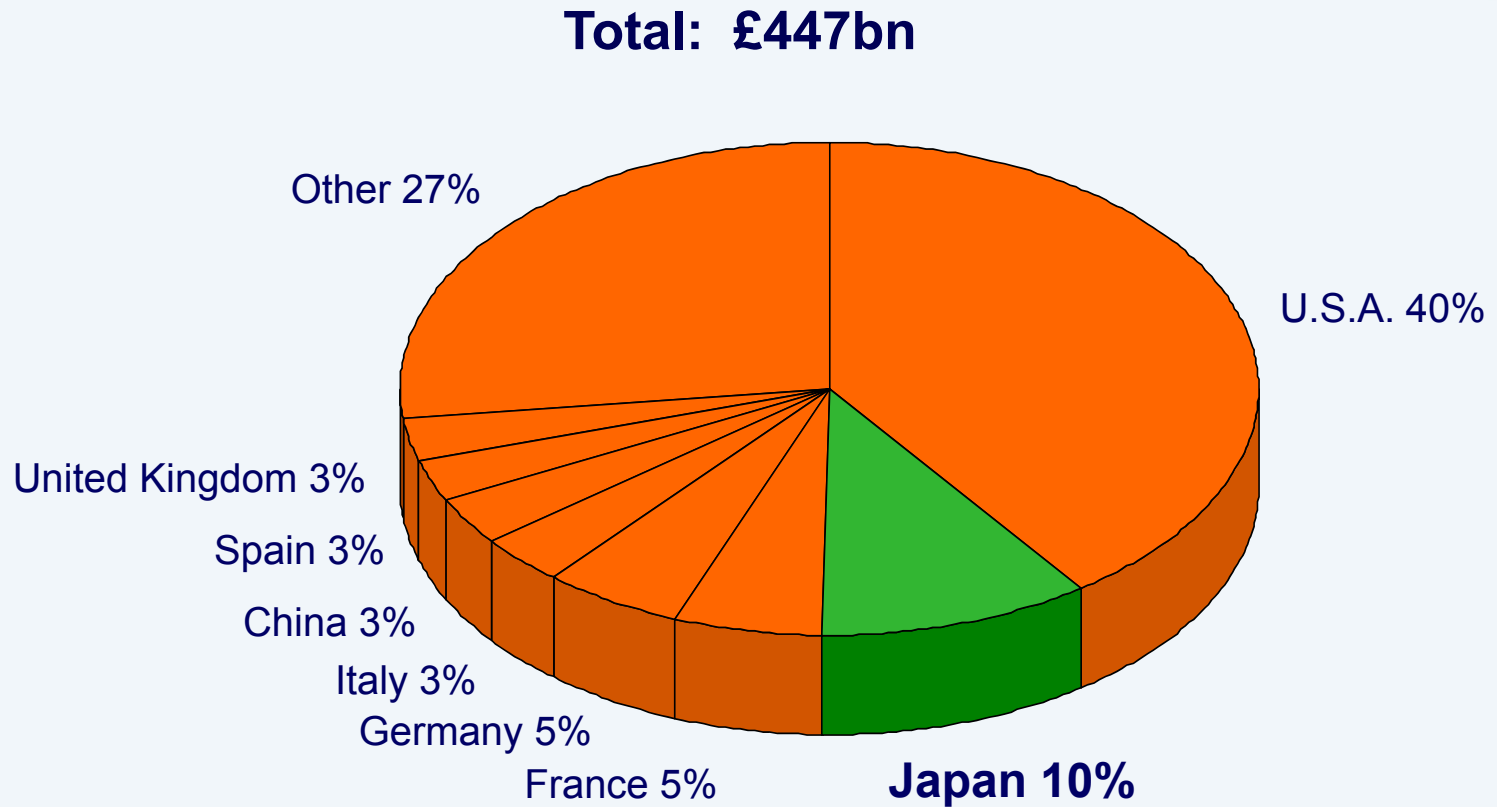
**Marc Dunoyer**  
**President**  
**Asia Pacific/Japan**  
**10<sup>th</sup> December 2009**

# Agenda

- **Japan's evolving pharma market**
- **GSK in Japan**
- **Strategy for growth**



# Japan is the second largest pharma market

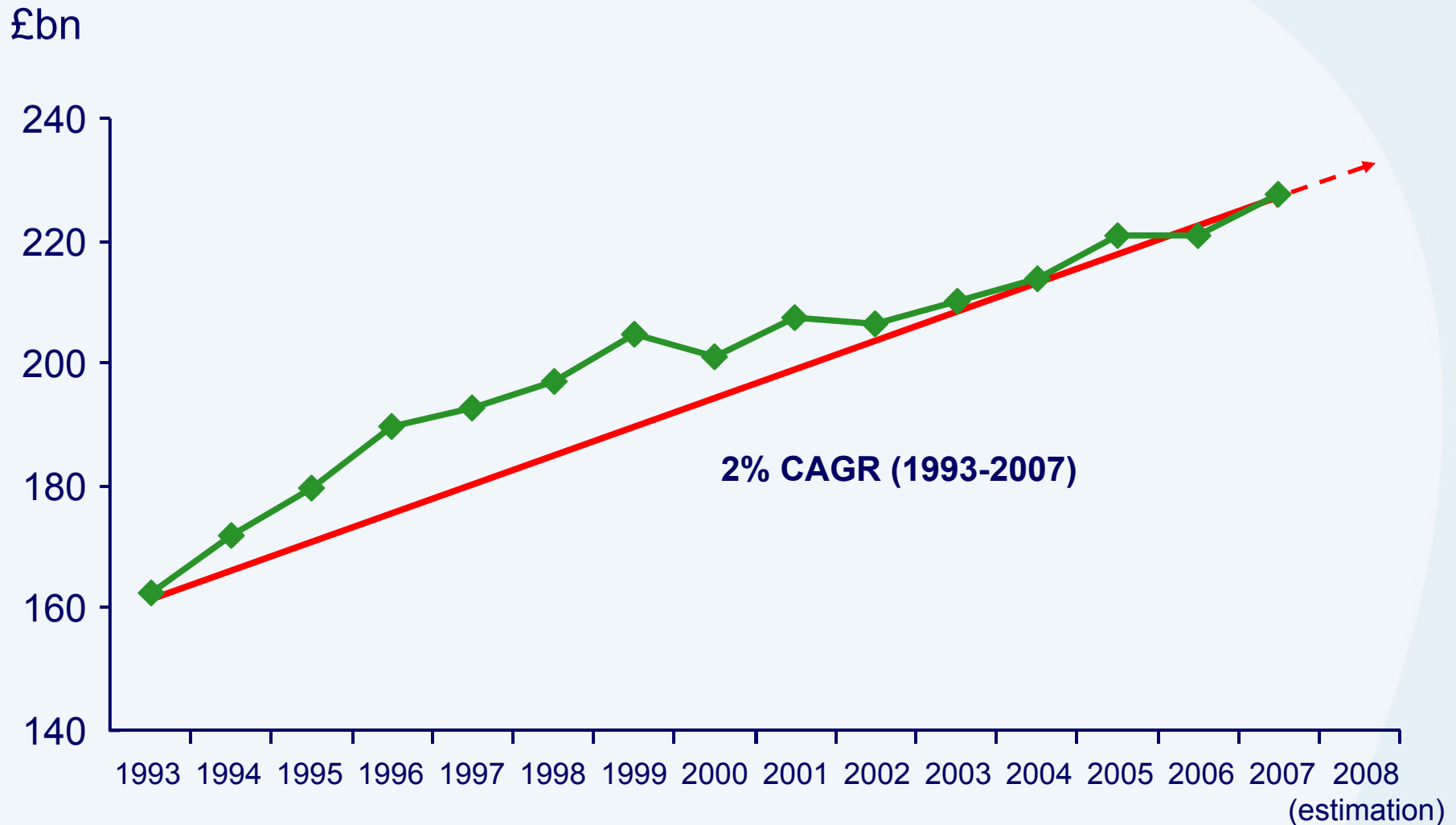


# Per capita healthcare and Rx expenditure

## Per Capita Expenditure

Market	Rx	Healthcare	Rx as % of Healthcare	Rx as % of GDP
1. U.S.A	£594	£4,627	13%	2.1%
2. France	£370	£2,913	13%	1.5%
3. Japan	£350	£1,723	21%	1.5%
4. Spain	£318	£1,502	21%	1.5%
5. Germany	£274	£2,421	12%	1.2%

# Evolution of healthcare expenditure in Japan....

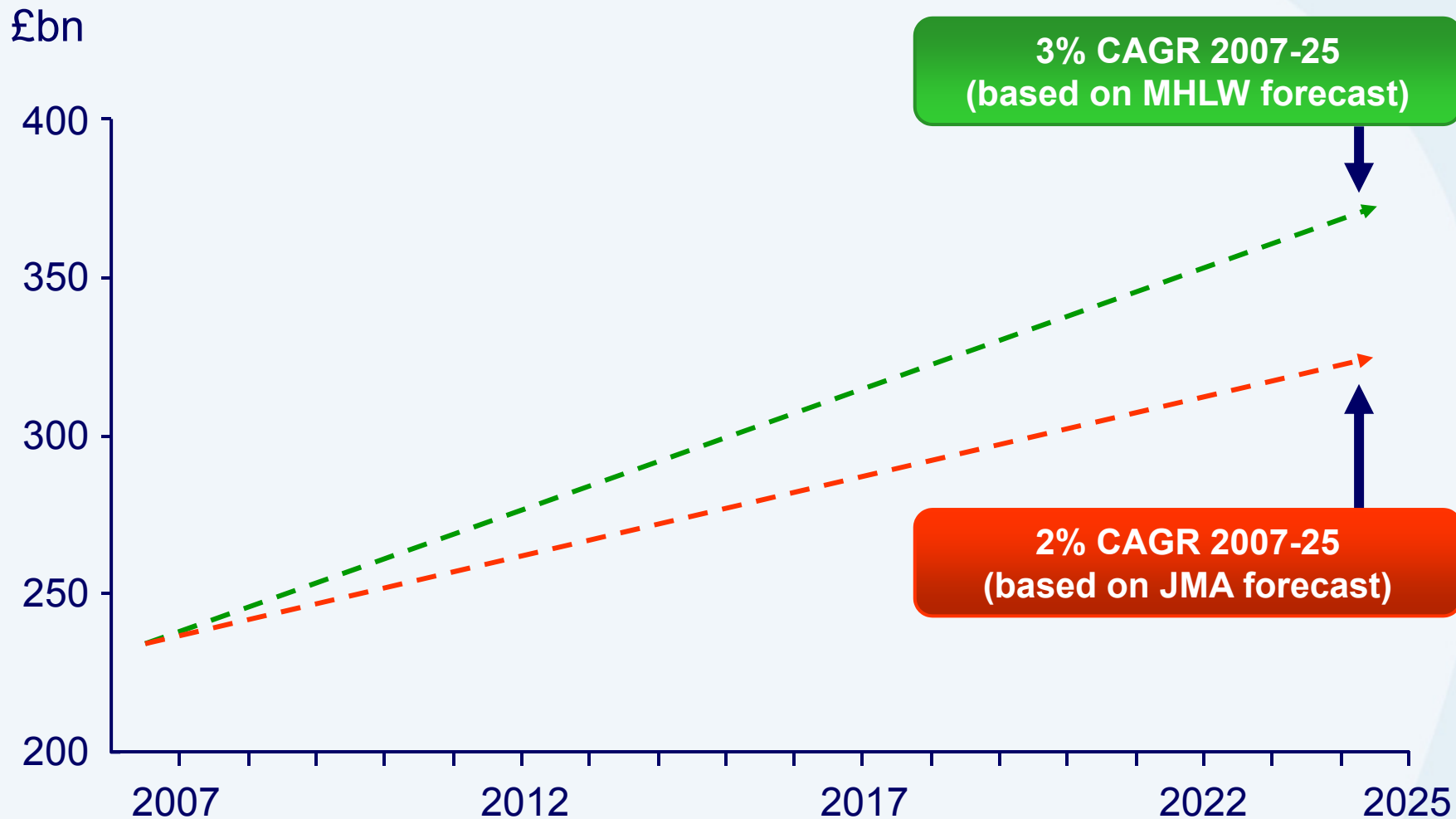


Source: MHLW (Ministry of Health, Labor, and Welfare)

Note: National Medical Expenditure

(1GBP=150JPY)

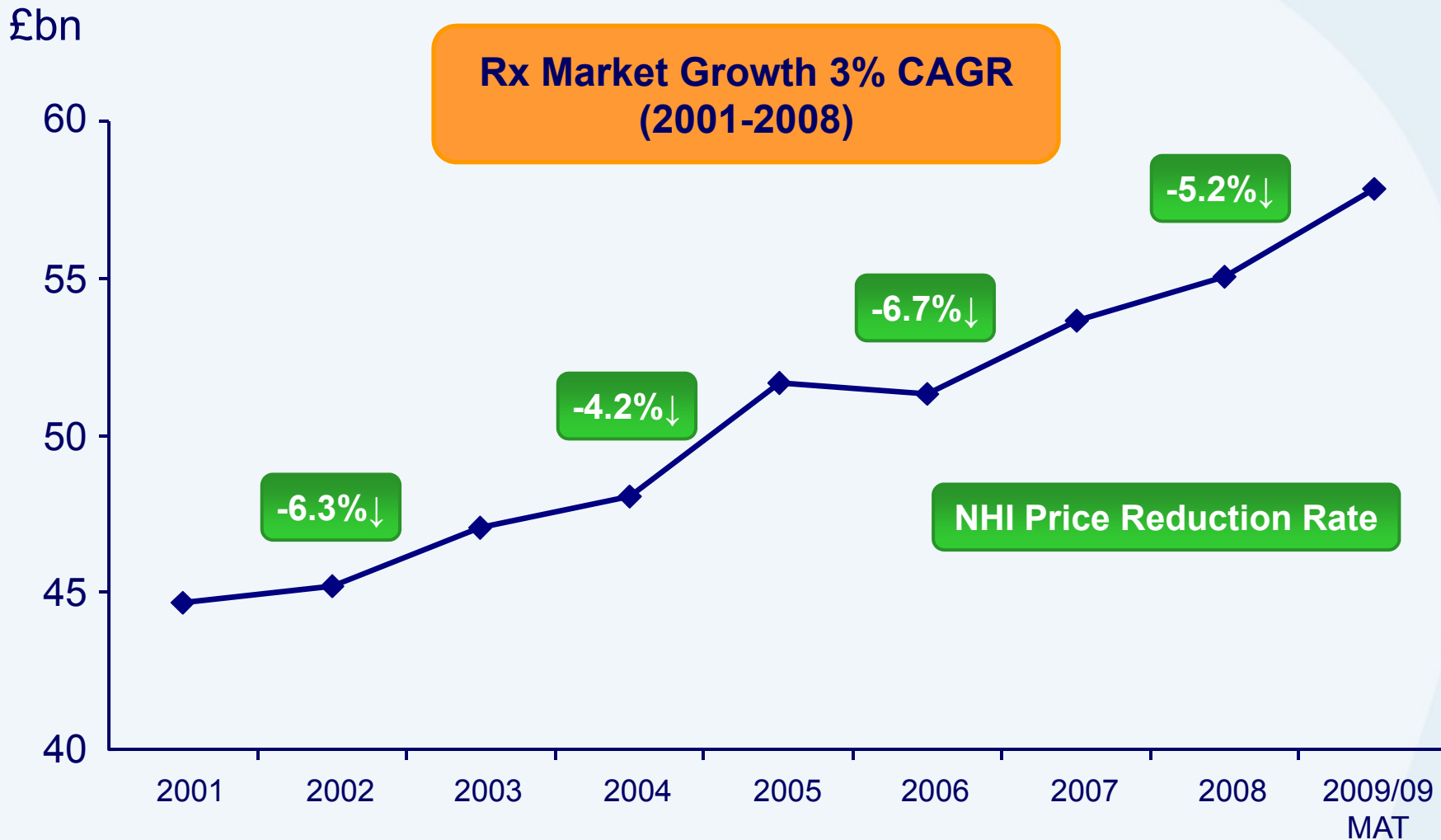
# .... and forecast to grow



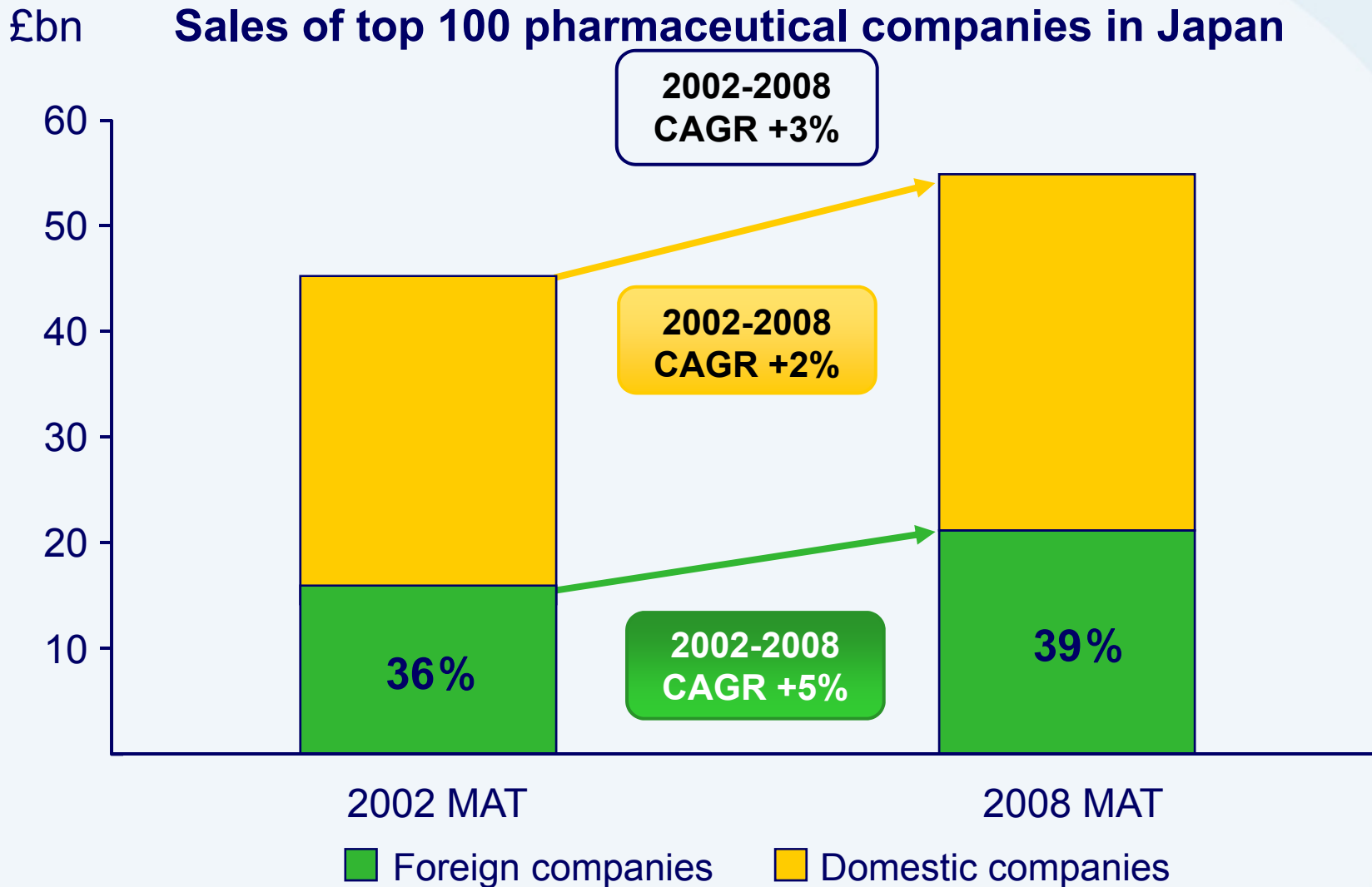
Source: MHLW (Ministry of Health, Labor, and Welfare)  
JMA (Japan Medical Association)

(1GBP=150JPY)

# Rx market growth despite biannual price reductions



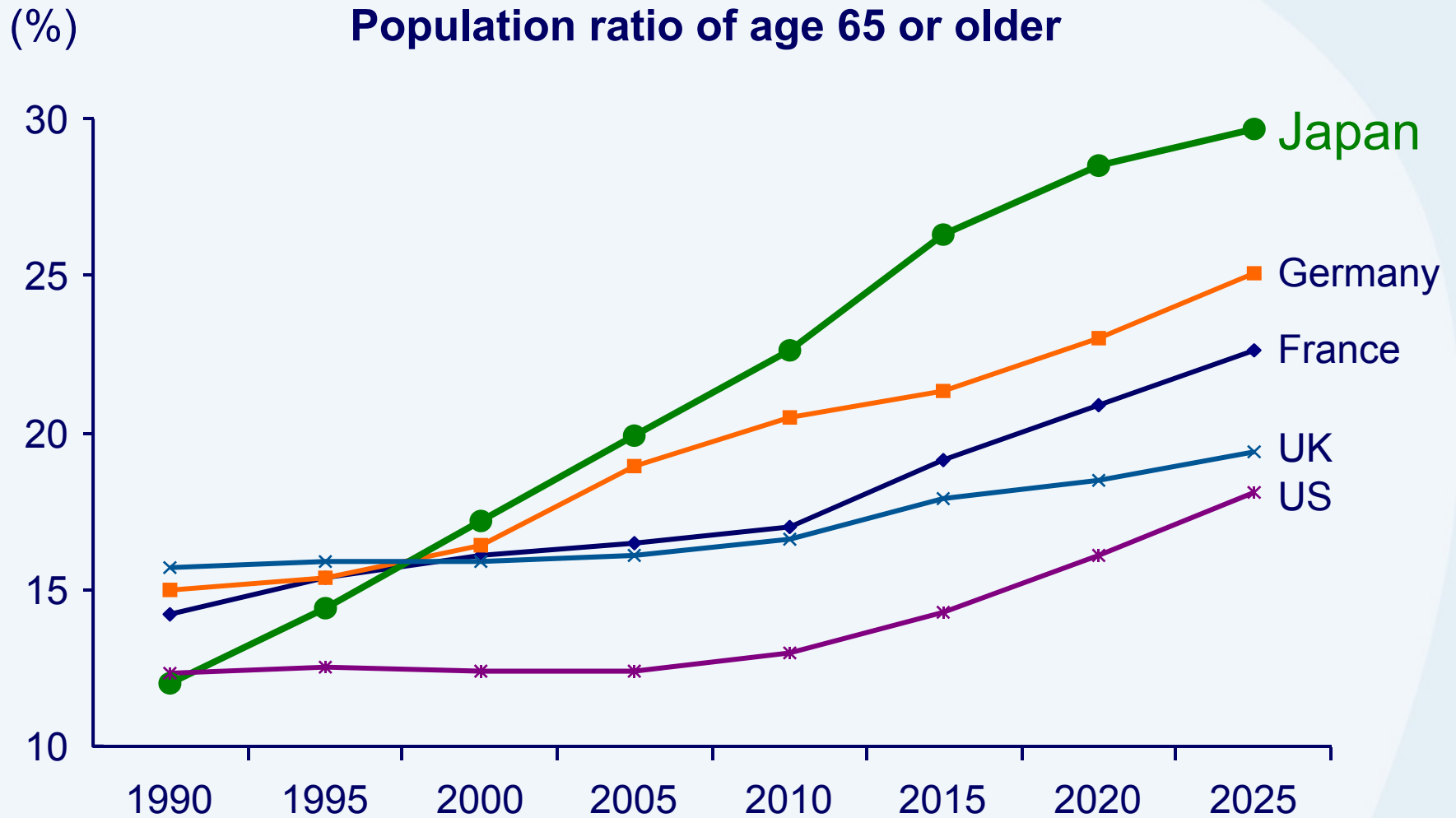
# Foreign companies outpace domestic companies



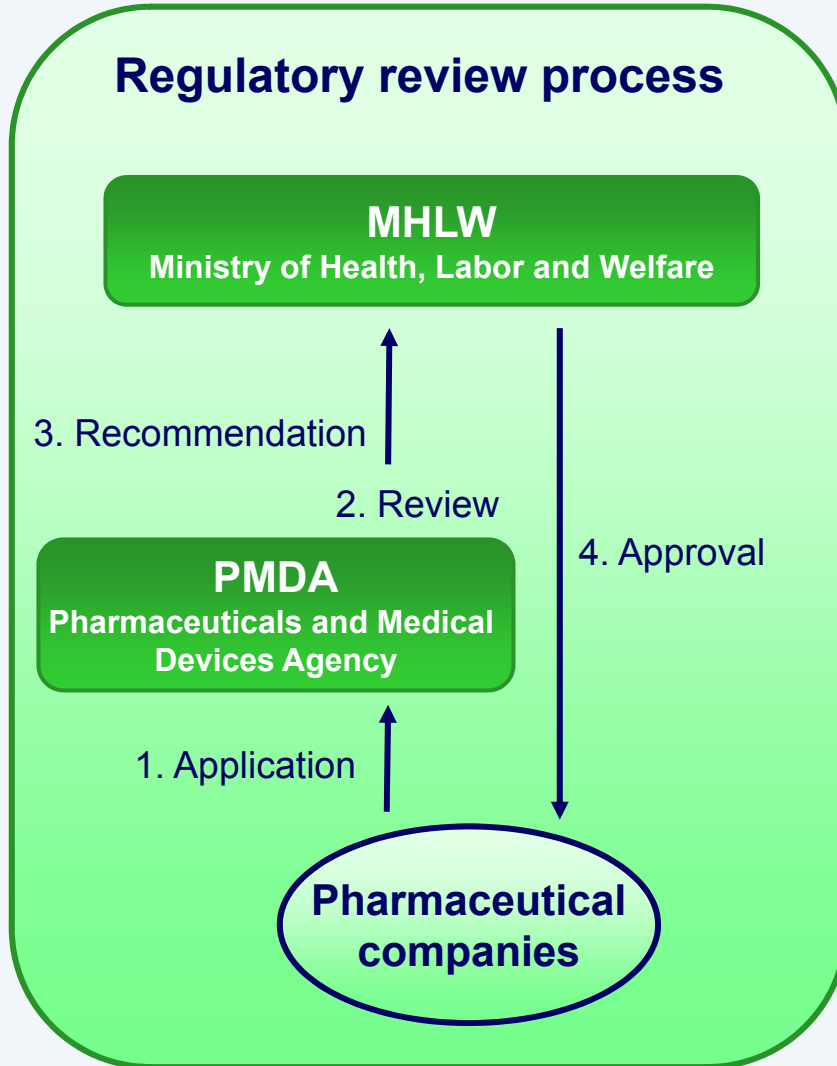
# Japanese pharma market dynamics

- **Demographics**
- **Changing regulatory environment**
- **Price regulation**
- **Generics**
- **Underdeveloped vaccines market**

# Demographics - ageing population

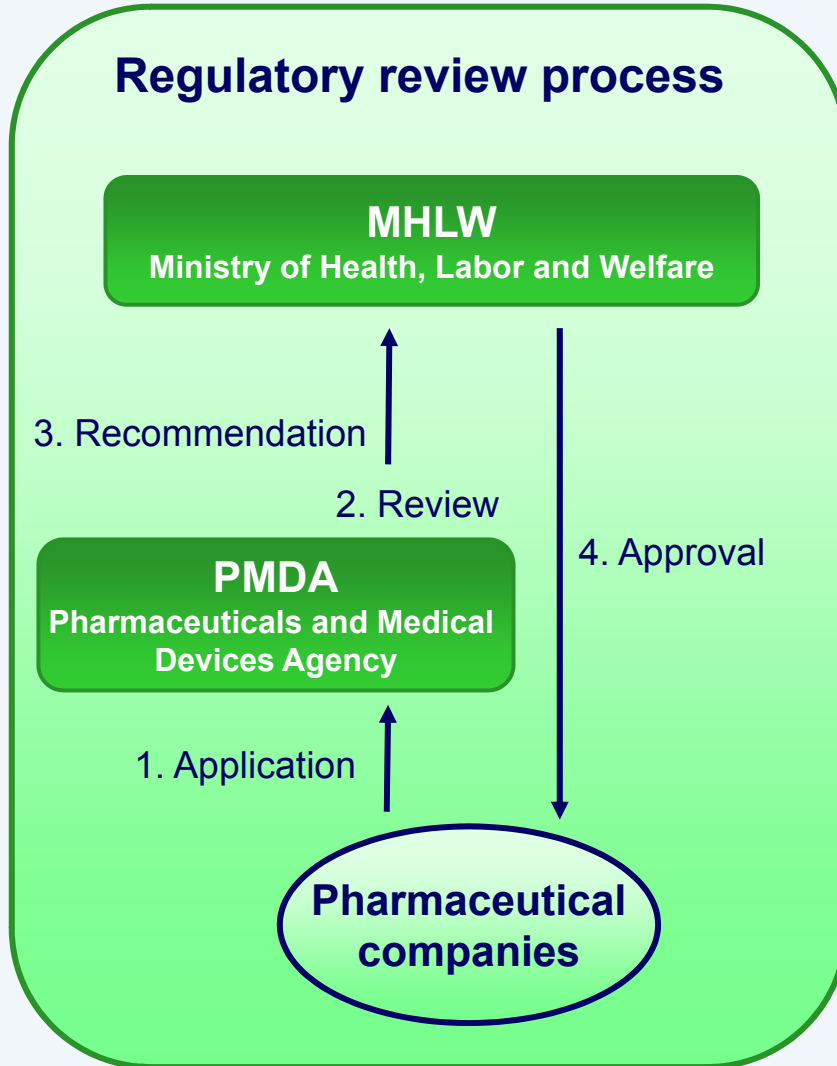


# Regulatory review and reimbursement

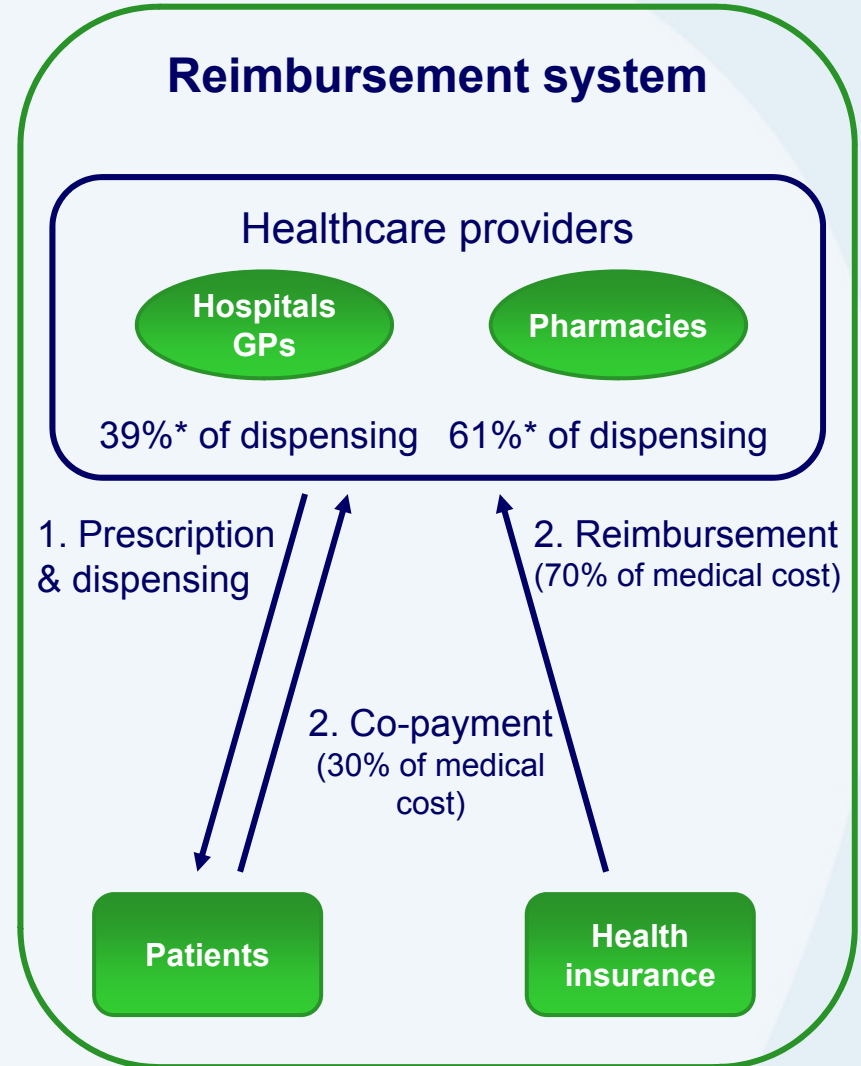


# Regulatory review and reimbursement

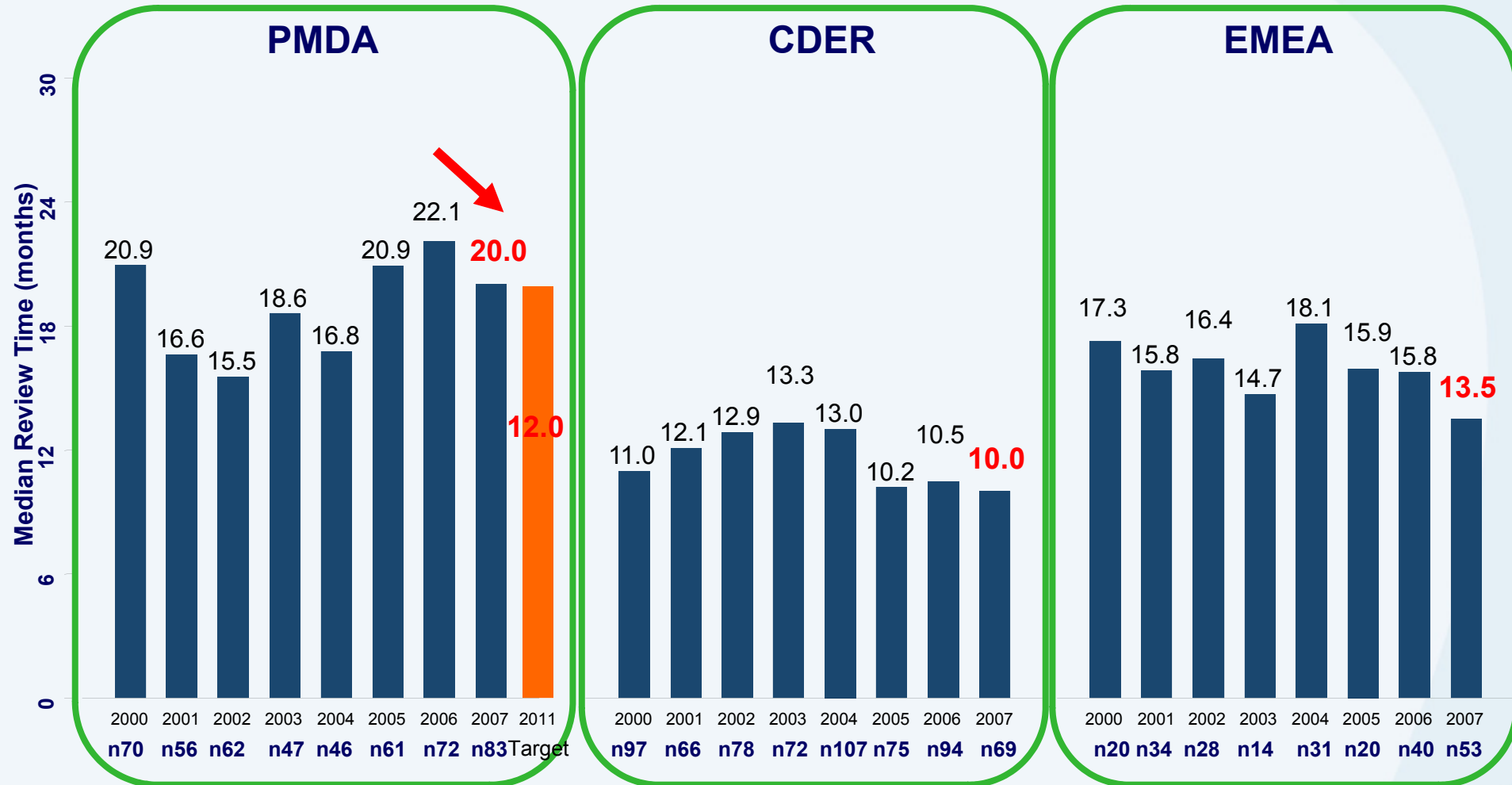
## Regulatory review process



## Reimbursement system

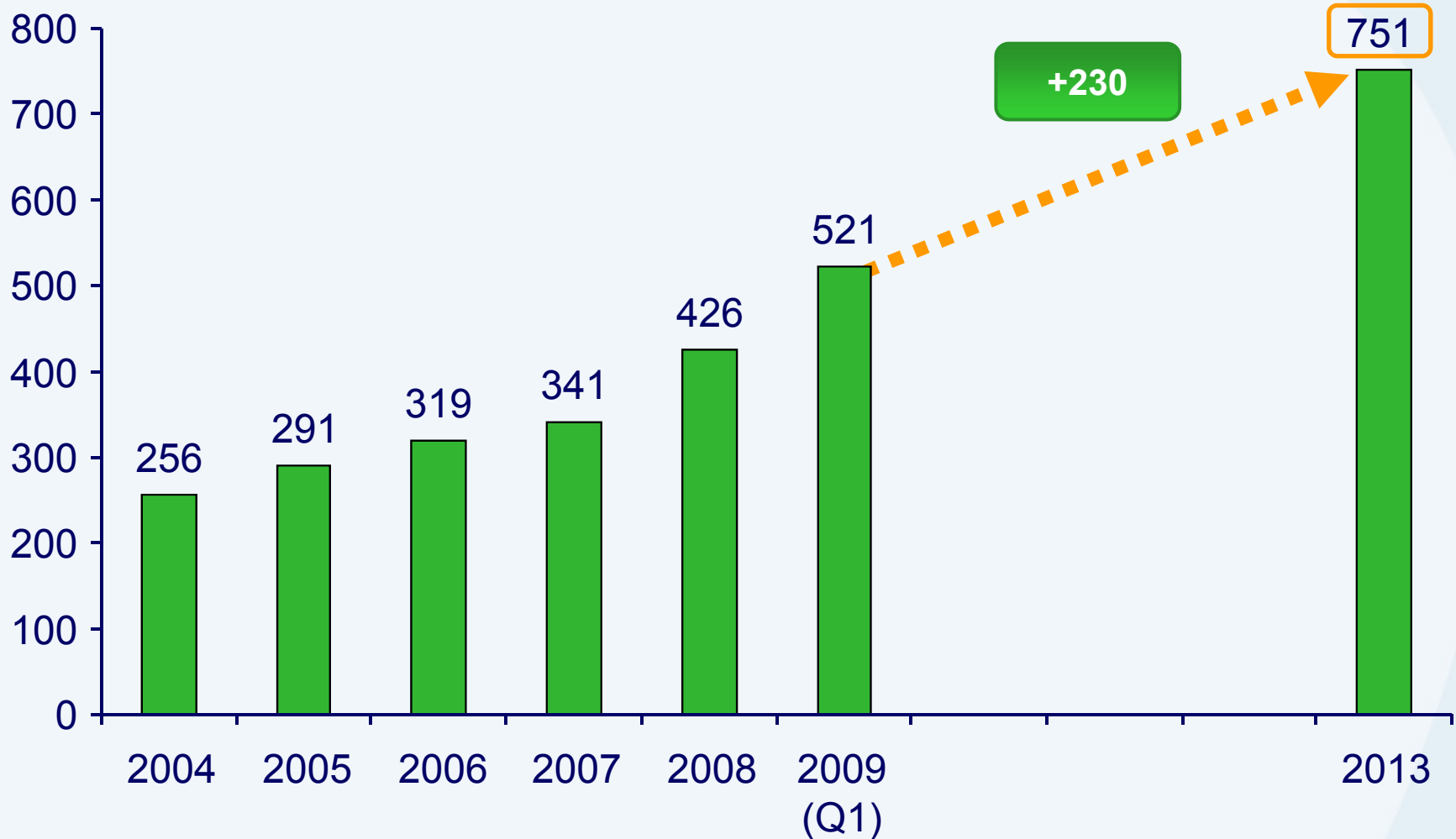


# Longer regulatory timelines... but improving



# Improving resource levels in reviewing body

## Number of reviewers in PMDA



# Initial pricing based on differentiation

- Higher evaluation for innovative drugs
- Higher evaluation for paediatric and orphan/small market drugs since April 2008

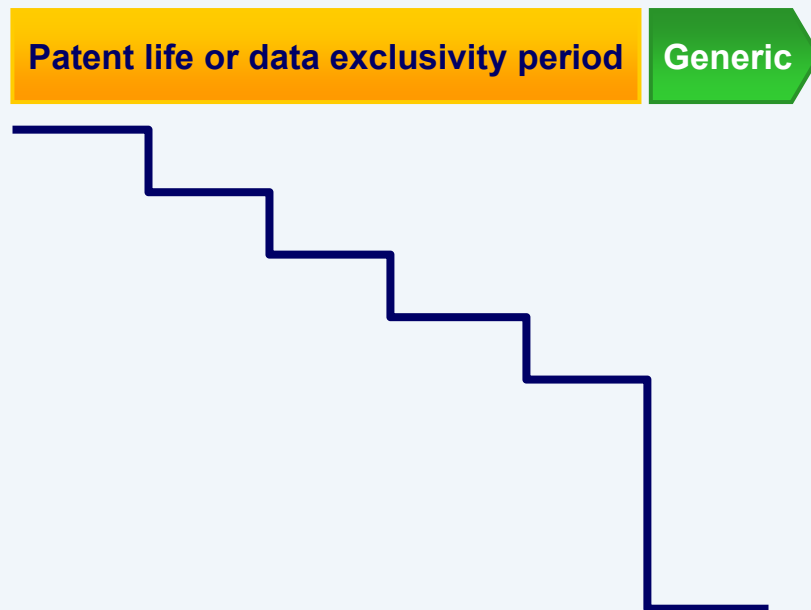
	Prior to April 08	Post April 08
Breakthrough premium	50-100%	70-120%
Paediatric premium	3-10%	5-20%
Kit premium	3-10%	5-20%
Orphan/small market premium	10%	10-20%

# Proposed new pricing system

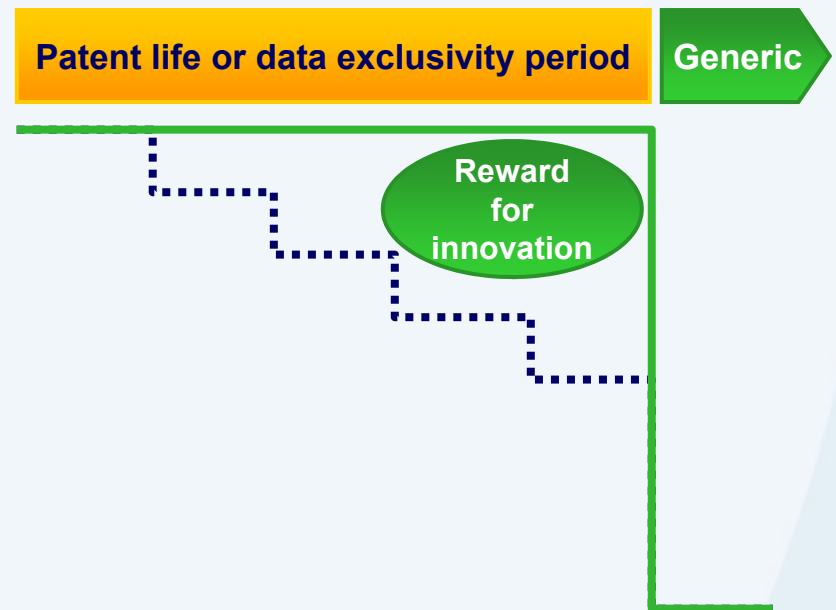
- Proposed new drug pricing rule to reward innovative products and promote greater use of generics

## Current pricing trend

(Price reduction: 4 to 7% every 2 years)



## Proposed pricing concept



# Will generic erosion accelerate?

	Volume Share	Value Share
US	77%	22%
UK	59%	22%
Germany	47%	20%
France	24%	12%
Japan	20%	8%
2012 Govt target	30%	

Source: US, UK & Ger based on IMS 2008 data; Fr based on IMS MAT10/09; Japan based on September 2009 MHLW survey.

# Underdeveloped vaccine market

## Pharmaceuticals

Worldwide sales ca. £447 bn

Japan sales ca. £46 bn  
i.e. 10% of worldwide Rx sales

Foreign companies make up  
**40%** of Japanese Rx sales  
(29 companies among top 100)

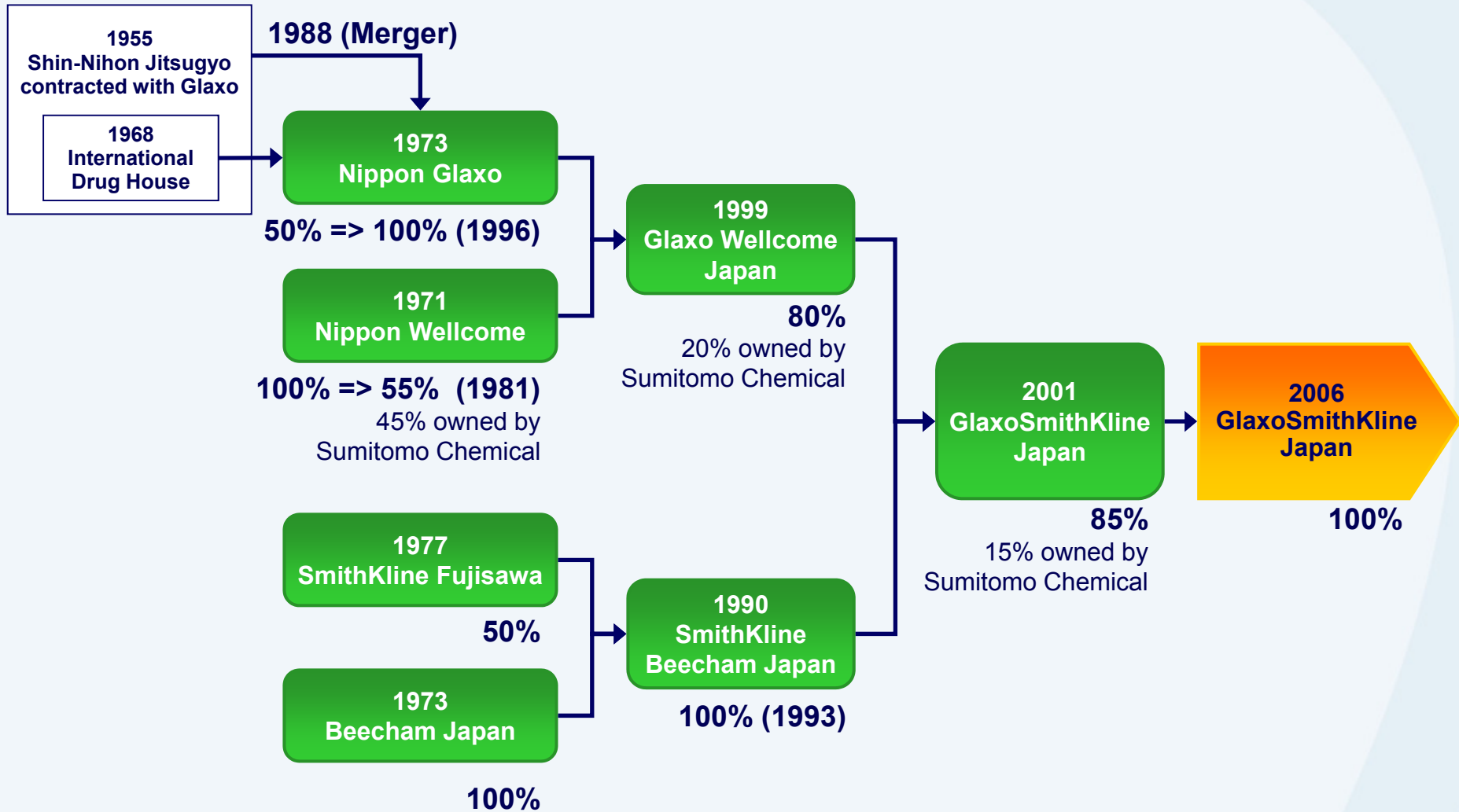
## Vaccines

Worldwide sales ca. £12 bn

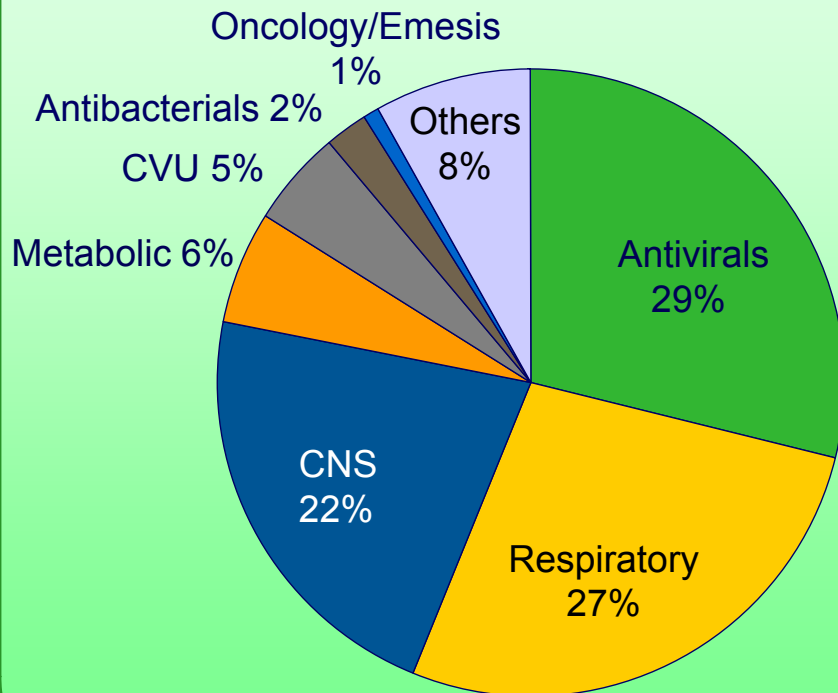
Japan sales ca. £0.5 bn  
i.e. 4% of worldwide Vx sales

Foreign companies makes up ca.  
**4%** of Japanese Vx sales  
(2 companies)

# History of GSK Japan



**Sales £1.1 bn (+19%\*)  
9mths to Sept 2009**

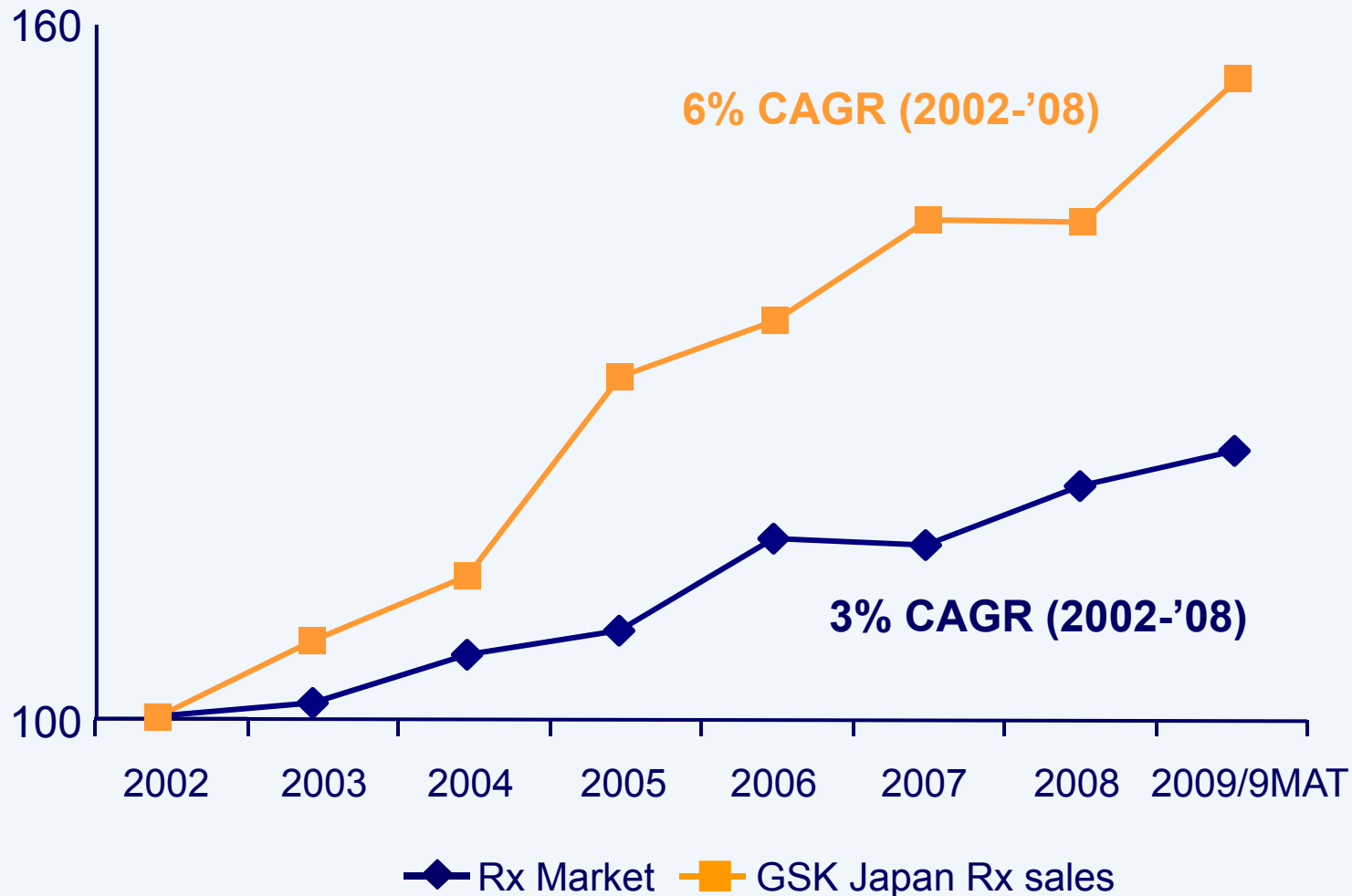


## ● GSK in Japan

- 3,700 employees (including Cx)
- 1,800 sales reps
- 14 sales branches (HQ in Tokyo)
- Major manufacturing site at Imaichi
- 32 clinical trials ongoing across 481 sites with 3,944 patients recruited

# GSK Japan vs Japan pharma market growth

Growth index based on NHIP sales value in 2002



# Sales ranking (& market share) of GSK Japan

## 2002

1	Takeda
2	Sankyo
3	<i>Pfizer</i>
4	<i>Chugai (Roche)</i>
5	Daiichi
6	Yamanouchi
7	<i>Novartis</i>
8	Eisai
9	Banyu
10	Shionogi
11	Mitsubishi
12	Otsuka
13	<b>GSK (2.5%)</b>
14	Tanabe
15	Ono

## 2005

1	<i>Pfizer</i>
2	Takeda
3	<i>Chugai (Roche)</i>
4	Astellas
5	<i>Novartis</i>
6	Daiichi
7	Eisai
8	Sankyo
9	Dainippon Sumitomo
10	<b>GSK (2.8%)</b>
11	<i>Banyu (Merck)</i>
12	Otsuka
13	Mitsubishi
14	<i>Astrazeneca</i>
15	Shionogi

## 2009

1	Takeda
2	Daiichi Sankyo
3	<i>Pfizer</i>
4	<i>Chugai (Roche)</i>
5	Mitsubishi-Tanabe
6	<i>Novartis</i>
7	Astellas
8	Eisai
9	<b>GSK (3.0%)</b>
10	<i>Sanofi-Aventis</i>
11	Otsuka
12	<i>Astrazeneca</i>
13	<i>Banyu (Merck)</i>
14	Dainippon Sumitomo
15	Kyowa Hakko Kirin

# GSK's strategy in Japan

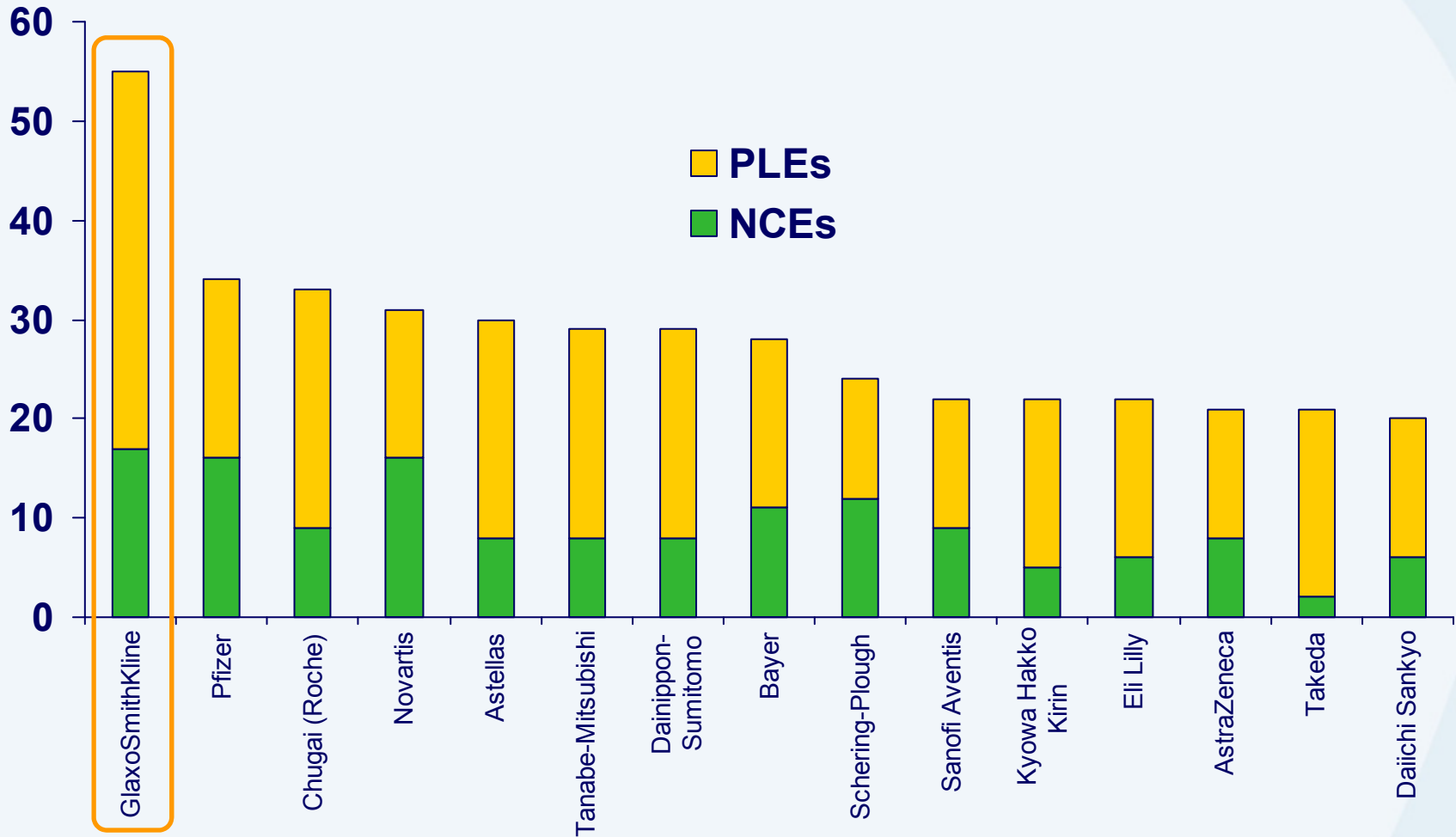
- **Create the portfolio**
- **Maximise current product opportunities**
- **Expand portfolio/deliver new product approvals**
- **Build vaccines business**
- **Achieve leadership position in pandemic flu**
- **Partner with domestic companies**

# Creation of the portfolio

- **Accelerated legacy compounds & eliminated backlog**
  - e.g. Requip, Arixtra, Lamictal, Avolve
- **Development of selected new assets**
  - Bridging studies wherever possible
  - Mix of local & foreign studies  
e.g. Allermist, Tykerb, Cervarix
  - Synchronous participation in global outcome studies or Asian studies, e.g. Tykerb gastric cancer

# Creation of the portfolio

## Number of approvals 2000-'09



Source: based on PMDA announcements

# Creation of the portfolio

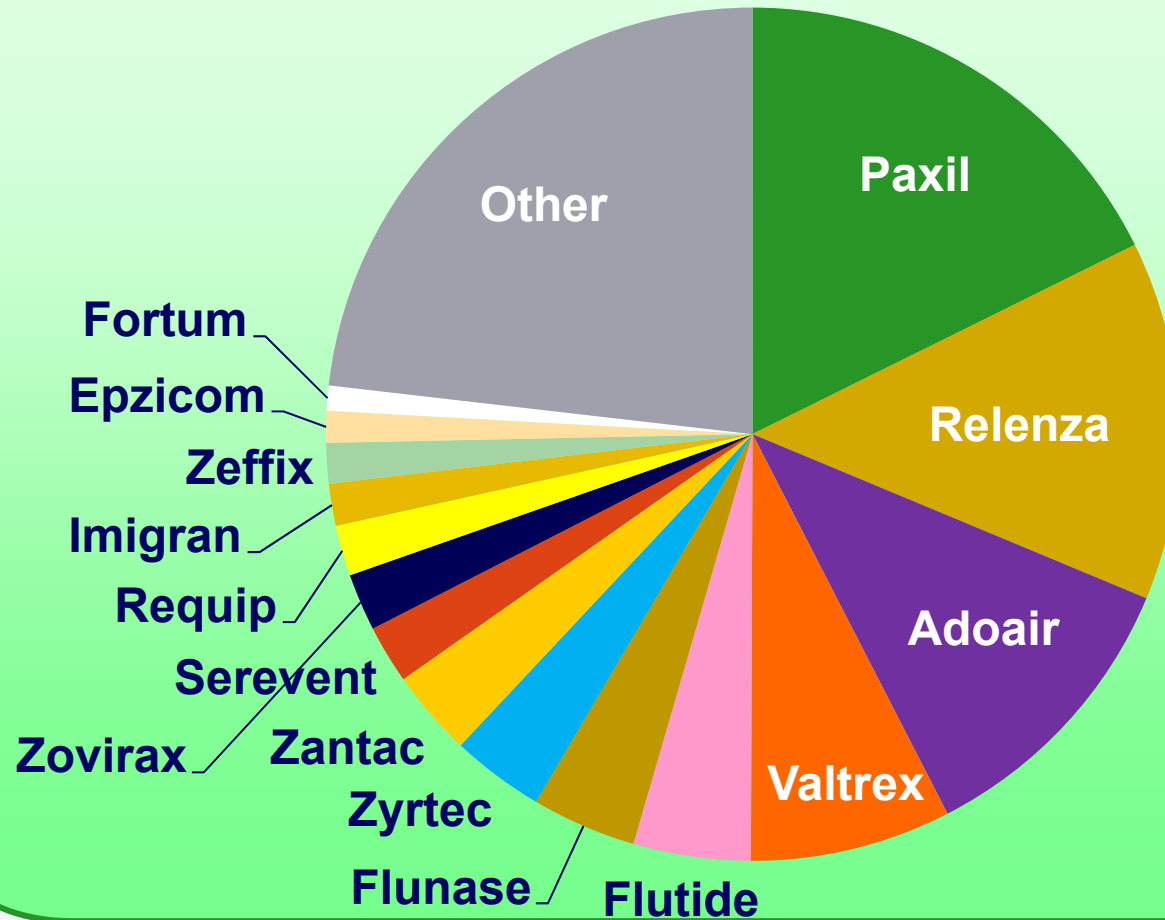
## NCE s

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
<b>Paxil</b>										
<b>Zefix</b>										
<b>Valtrex</b>										
<b>Imigran</b>										
			<b>Serevent</b> Rotadisk		<b>Hepsera</b>		<b>ReQuip</b>			
								<b>Arranon G</b>		<b>Cervarix</b>
								<b>Arixtra</b>	<b>Lamictal</b>	<b>Avolve</b>
								<b>Adoair</b>	<b>Amerge</b>	<b>Tykerb</b>
										<b>Allermist</b>
<b>Zofran</b> Zydis	<b>Imuran</b> heart, liver	<b>Valtrex</b> HSV	<b>Epivir</b> QD	<b>Zefix</b> Cirrhosis comb.	<b>Zovirax</b> cream	<b>Paxil</b> OCD	<b>Relenza</b> Prophylaxis	<b>Arixtra</b> abdo. surgery	<b>Adoair MDI</b> Paeds. Asthma.	
	<b>Flutide</b> Diskus	<b>Flutide</b> Air	<b>Imigran</b> Intranasal	<b>Serevent</b> Diskus	<b>Zefix</b> liver cirrhosis	<b>Relenza</b> Paeds	<b>Valtrex</b> chickenpox	<b>Imigran</b> SC Inj.	<b>Adoair Diskus</b> COPD, Paeds	
	<b>Alkeran</b> Inj.		<b>Imuran</b> lung	<b>Ziagen</b> QD	<b>Zyrtec</b> DS	<b>Flunase 56</b>	<b>Clavamox</b> LE	<b>Hepsera</b> cirrhosis mono	<b>BOTOX</b> JCP	
	<b>Imigran</b> Tab.		<b>Flunase</b> Paeds	<b>Epzicom</b>	<b>Clavamox</b>	<b>Imuran</b> IBD			<b>Paxil</b> SAD	
	<b>Flutide</b> Paeds			<b>Flolan</b> PAH		<b>Valtrex</b> GH supression			<b>Zyrtec</b> AD AR Paeds	
									<b>Clavamox</b> sachet	

## PLE s

# Maximise current product opportunities

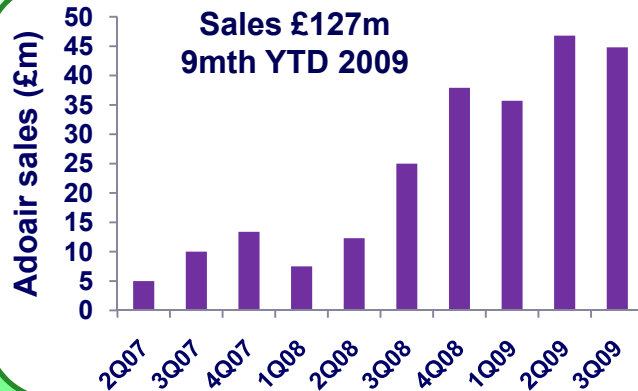
Sales £1.1 bn (+19%\*)  
9mths to Sept 2009



\* CER growth

# Adoair opportunity in Japan

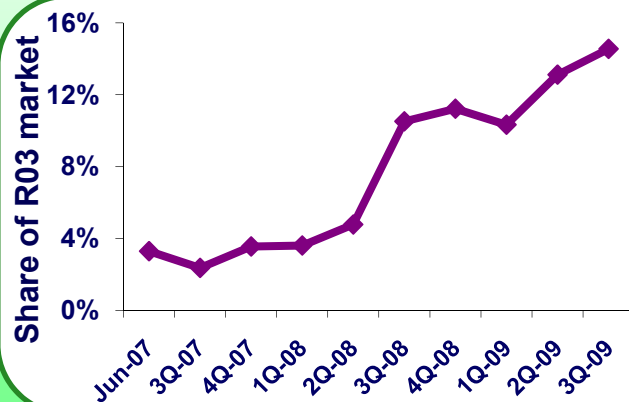
## Sales progression



## Progression of indication

- April 04: filed for asthma
- Nov 06: filed for COPD
- April 07: approved for asthma
- Jun 07: Adoair launched
- Jul 08: 60 blister Diskus launched
- Jan 09: approved for COPD

## Market share



Source: IMS-JPM

## Sales/promotion

- 1,300 GSK sales reps
- 1,000 Mitsubishi-Tanabe sales reps
- Significant promotional investment: 22% of GSKJ's total A&P spend

# Expand portfolio/deliver key new product approvals

## Recent approvals:

- Lamictal epilepsy
- Amerge
- Adoair COPD
- Allermist
- Tykerb BC
- Avolve BPH
- Cervarix

## Currently filed:

- Revolade ITP
- Volibris
- Xyzal
- Rotarix
- H1N1 vaccine

## Late stage pipeline:

- Synflorix
- MAGE A3
- pazopanib
- darapladib
- Wellbutrin SR
- Avolve prostate cancer
- Lamictal bipolar disorder
- Arzerra
- Syncria (Ph IIb)

# Expand portfolio/deliver new product approvals

## Penetrating into high potential therapeutic areas

**Now**

Anti-virals

CNS

Respiratory

Thrombosis

Other



**2015**

Anti-virals

CNS

CV

Diabetes

Oncology

Respiratory

Thrombosis

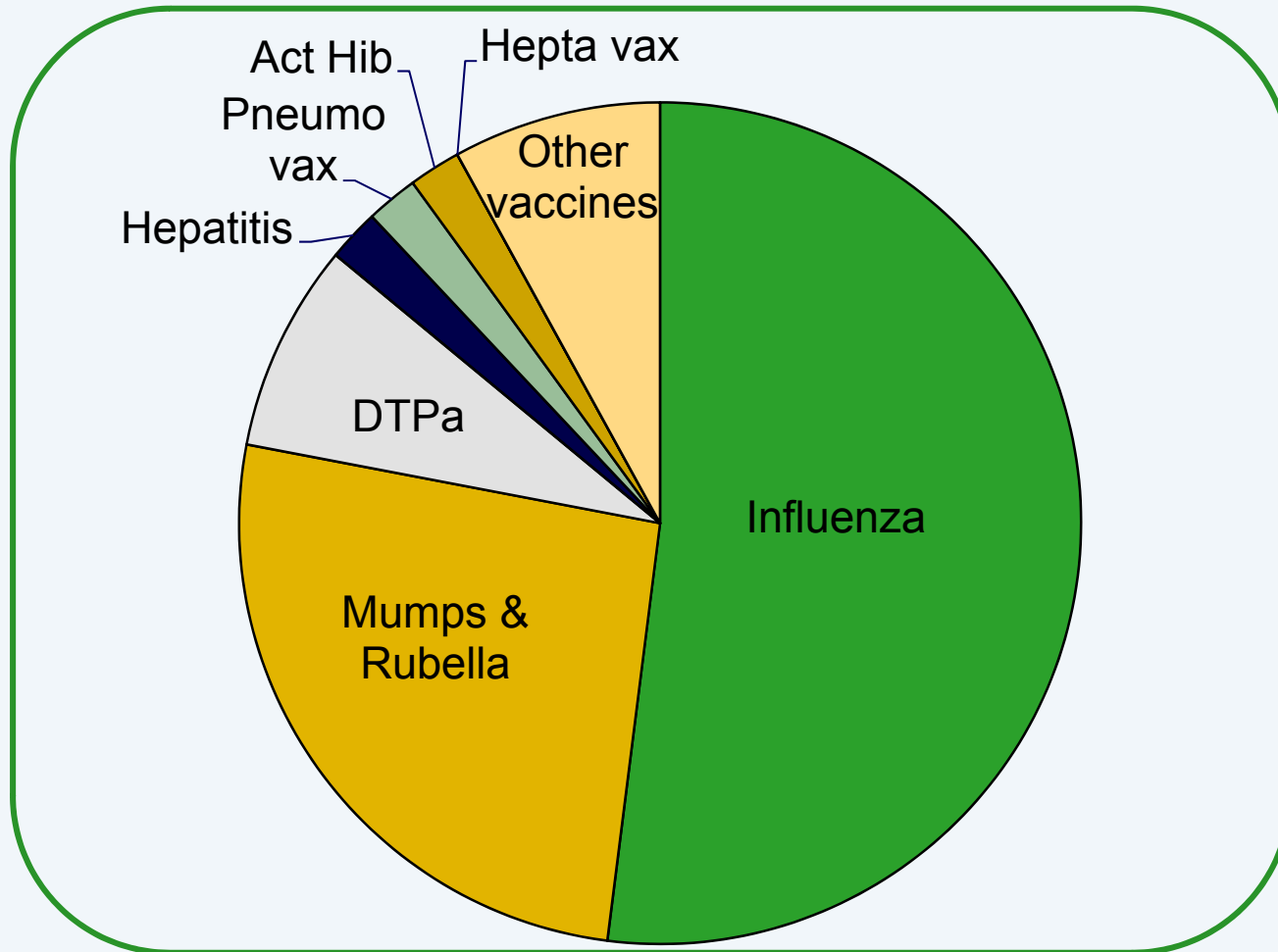
Urology

Vaccines

Other

# Build vaccines business

**Japan Vx market sales**  
**Total £639m (2009 Jun MAT)**

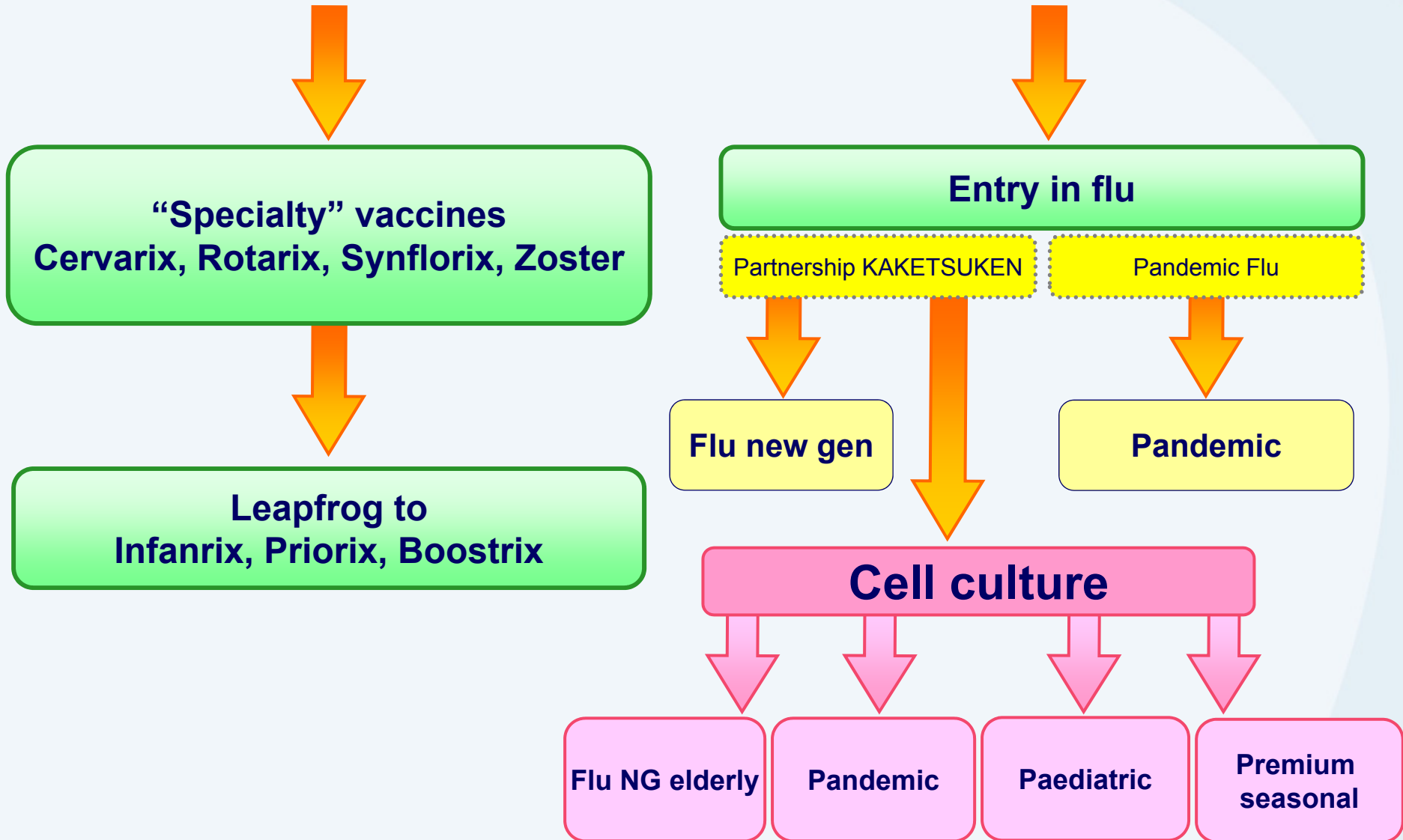


# Vaccine gap between EU/US and Japan

Vaccines	US	EU	Japan
MMR*	✓ 1971	✓	✗
Hib	✓ 1987	✓	✓ ActHIB 19 Dec 2008 (launched)
Inactivated polio vaccine	✓ 1987	✓	✗
Pneumococcus conjugate vaccine (7 valent)	✓ 2000	✓	✓ Prevenar 16 Oct 2009 (approved)
HPV vaccine	✓ 2006	✓	✓ CERVARIX 16 Oct 2009 (approved)
Rotavirus vaccine	✓ 2006	✓	✗

\*MMR = Combination of measles, mumps, rubella (used since 1971 but the current version is further improved )

# Build vaccines business



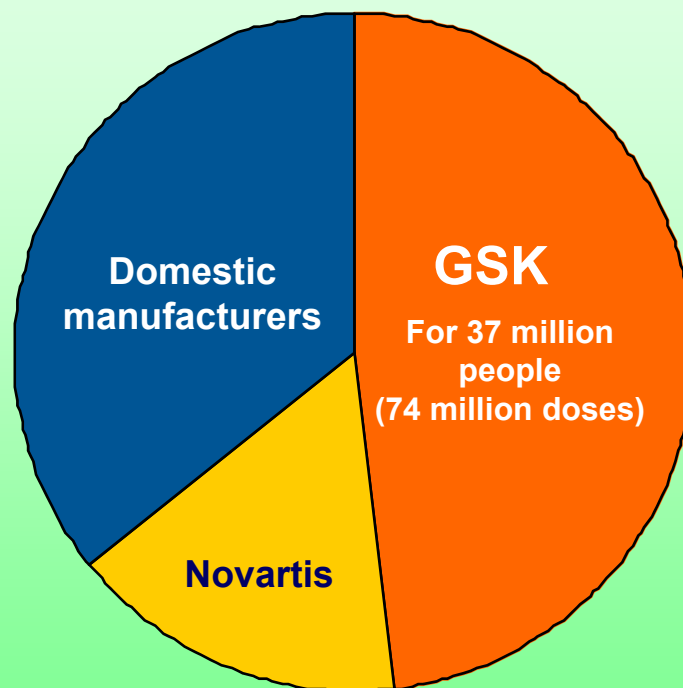
# Cervarix – bringing benefits to Japanese women

- **Approved for >10 yr olds in October - ahead of Gardasil**
- **Launching next week (17<sup>th</sup> December 2009), initially without reimbursement**
- **“Reasons to believe” in Japan:**
  - low screening rate: Japan 24%, lowest in OECD (US 79%)
  - relatively high mortality
- **Cervarix “firsts”:**
  - First HPV vaccine in Japan
  - First novel adjuvant approved in Japan
  - First GSK vaccine to be launched in Japan

# Achieve leadership position in pandemic flu - H1N1 vaccine

- Won Govt contract to supply 74m doses of H1N1 flu vaccine
- GSK largest supplier
- First ever imported flu vaccine in Japan
- First adjuvanted flu vaccine in Japan

H1N1 vaccine supply plan  
(covers 77 million people)



# Achieve leadership position in pandemic flu - Relenza

**Relenza**

**Retail  
(seasonal)**

ca.86,000 customers

**Corporate  
stockpile**

ca.180 customers

**Government  
stockpile**

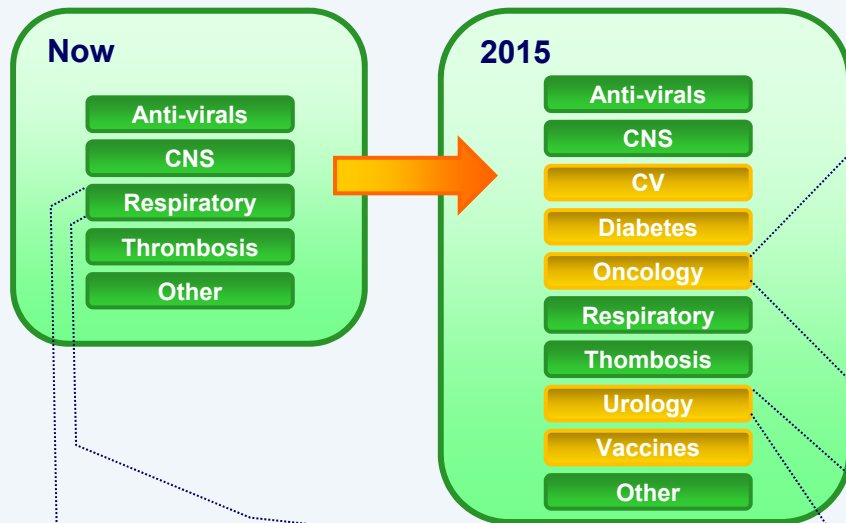
Government  
All local prefectures

**Relenza market share**



Source: Market share IMS-JPM; GSK reported sales

# Partner with domestic companies



## Partnering with Nippon Kayaku for Tykerb

- Expansion of account coverage with 400 reps specialised in Oncology



## Partnering with Mitsubishi Tanabe (MT) for Adoair COPD

- To accelerate COPD awareness with 1,000 reps with CV expertise
  - GSK reps: asthma & COPD
  - MT reps: COPD focus

## Partnering with Taiho for Avolve

- Urology expertise with 800 reps for faster penetration



# Operating profit margin

## Sep 09 YTD Operating Profit Margin<sup>1</sup> (%)

US	65.9
Europe	58.1
EM	34.9
<b>AP/J</b>	<b>52.7</b>

- Japan operating margin (OM) around 60%
- No major change in Japan's OM expected in the near term

<sup>1</sup> Note: operating margin excluding R&D, legal and other unallocated pharmaceuticals costs, as well as profit from asset sales

# Conclusion

- GSK Japan growth of 6% 2002-08 CAGR, significantly ahead of the market
- Objective to accelerate growth over the next 5 years, driven by:
  - maximisation of current business
  - delivery of new product portfolio
  - building of vaccines business

## 2015 therapy areas

Anti-virals

CNS

CV

Diabetes

Oncology

Respiratory

Thrombosis

Urology

Vaccines

Other



GlaxoSmithKline