El futuro de la Industria Farmacéutica en España

The future of Pharmaceutical Industry in Spain

Consejo General de Colegios Oficiales de Farmacéuticos

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The Future of Pharmaceutical Industry in Spain

- Environmental.
  - Economical crisis
  - Spanish Pharmaceutical Sector
  - Pharmaceutical Research & Development
  - Manufacturing & Exporting
  - Pharmaceutical Market
- Signals of changing
- The impact for future pharmaceutical industry

Crisis !

Environmental analysis

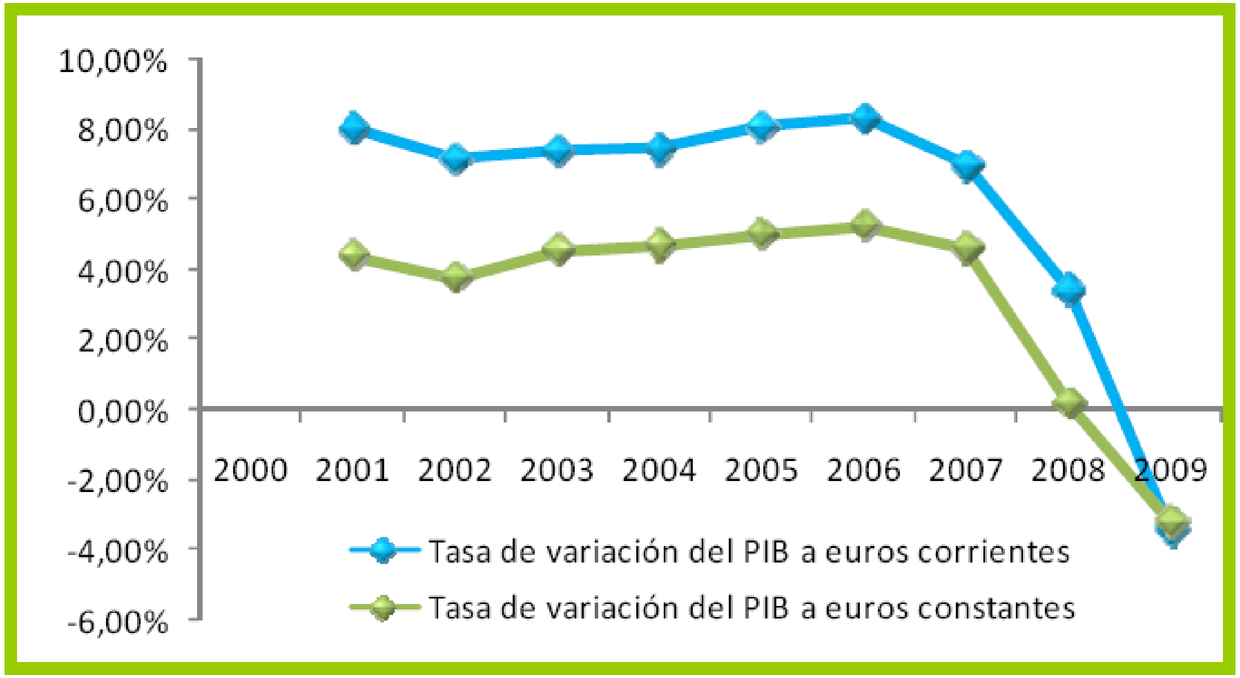
- Strong crisis environment in Spain & Europe
  - Strong recession
  - Double digit deficit in public gross budget
  - Much more unemployement rate than EU

	2008	2009	2010
Nominal GDP	+3,6%	-3,3%	+0,1%
Real GDP	+0,9%	-3,8%	-0,9%
Inflaction Rate	+4,1%	-0,1%	+3,0%
Industrial Productivity Index	-7,3%	-17,7%	-7,3%
Unmployment Rate (% of Active population)	11,4%	18,3%	20,3%
Public Deficit (% PIB)	-3,8%	-10,3%	-11,2%
Foreing Deficit (% PIB)	-9,6%	-5,8%	-5,2%

Source: Fundación de las Cajas de Ahorros (FUNCAS). Gabinete de Coyuntura y Estadística. (Actualizado a 11 de septiembre de 2009).

Evolution of GDP in Spain. Annual Variation

Periodo	Tasa de variación del PIB a euros corrientes	Tasa de variación del PIB a euros constantes
2000	----------	----------
2001	8,00%	4,37%
2002	7,13%	3,74%
2003	7,37%	4,53%
2004	7,42%	4,66%
2005	8,06%	4,99%
2006	8,31%	5,23%
2007	6,95%	4,58%
2008	3,40%	0,14%
2009	-3,43%	-3,21%

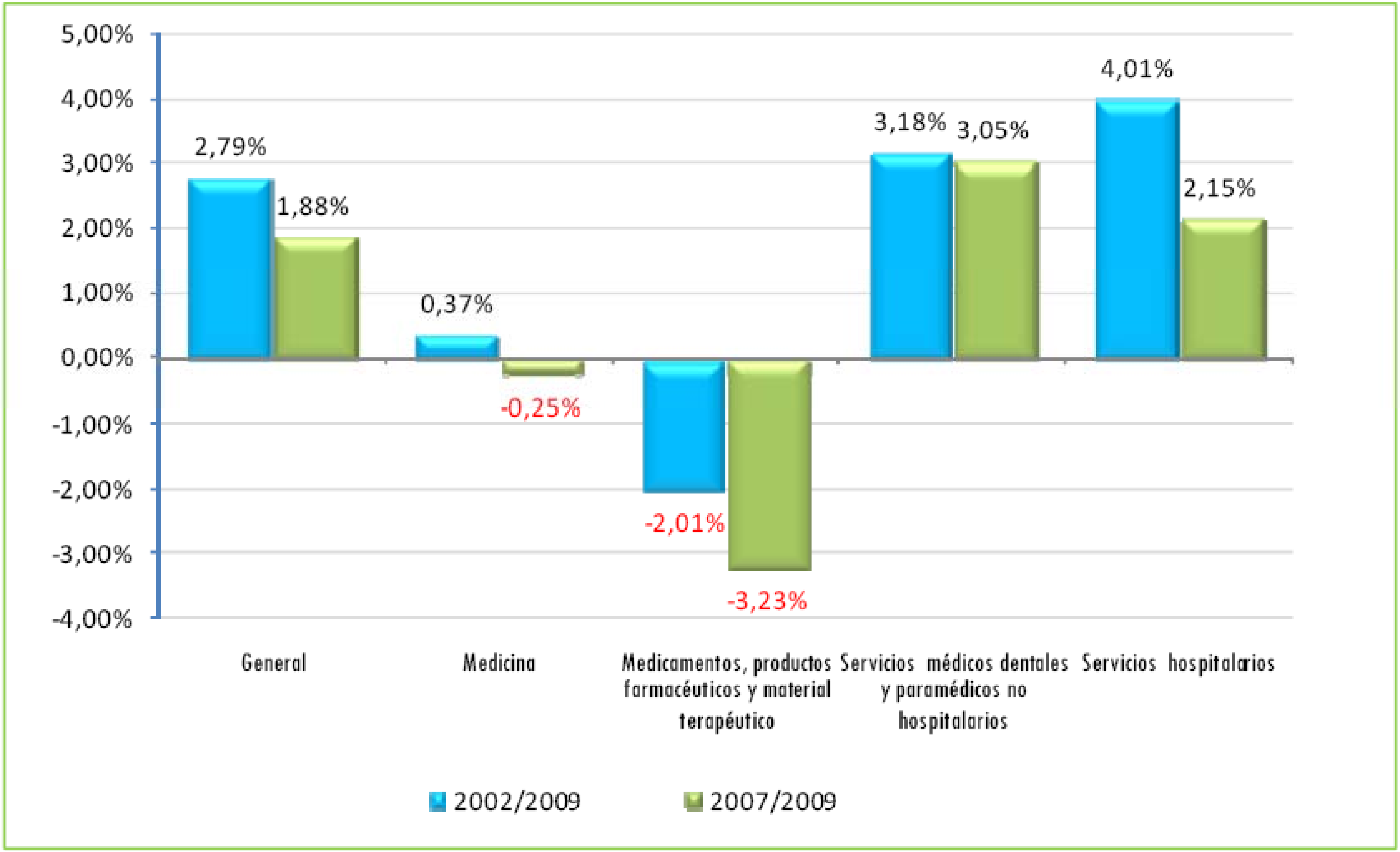


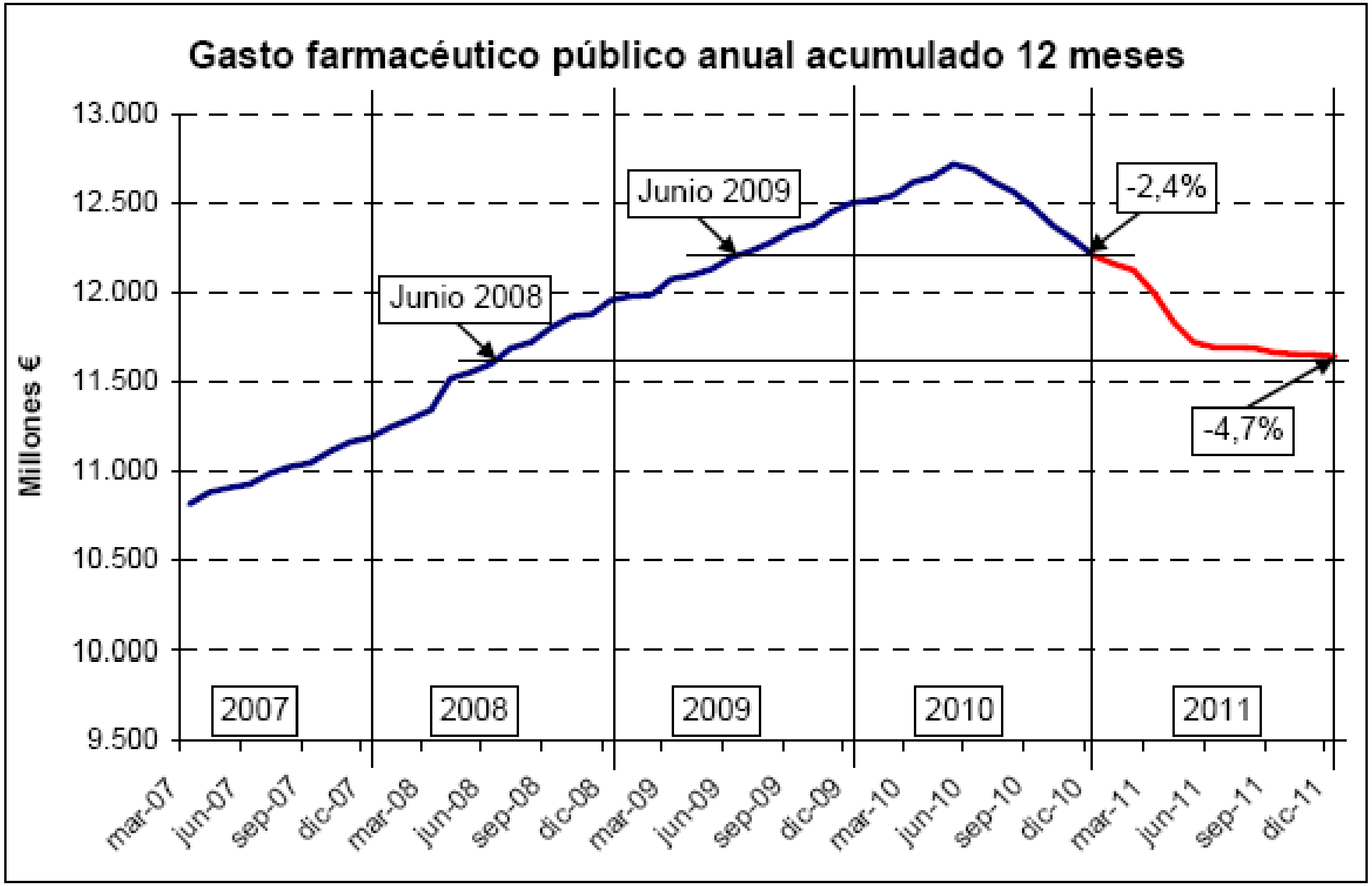
: Variación media del PIB

Periodo	Tasa de variación del PIB a euros corrientes	Tasa de variación del PIB a euros constantes
2000 / 2009	5,85%	3,19%
2007 / 2009	-0,08%	-1,55%

Inflaction Rate in Spain

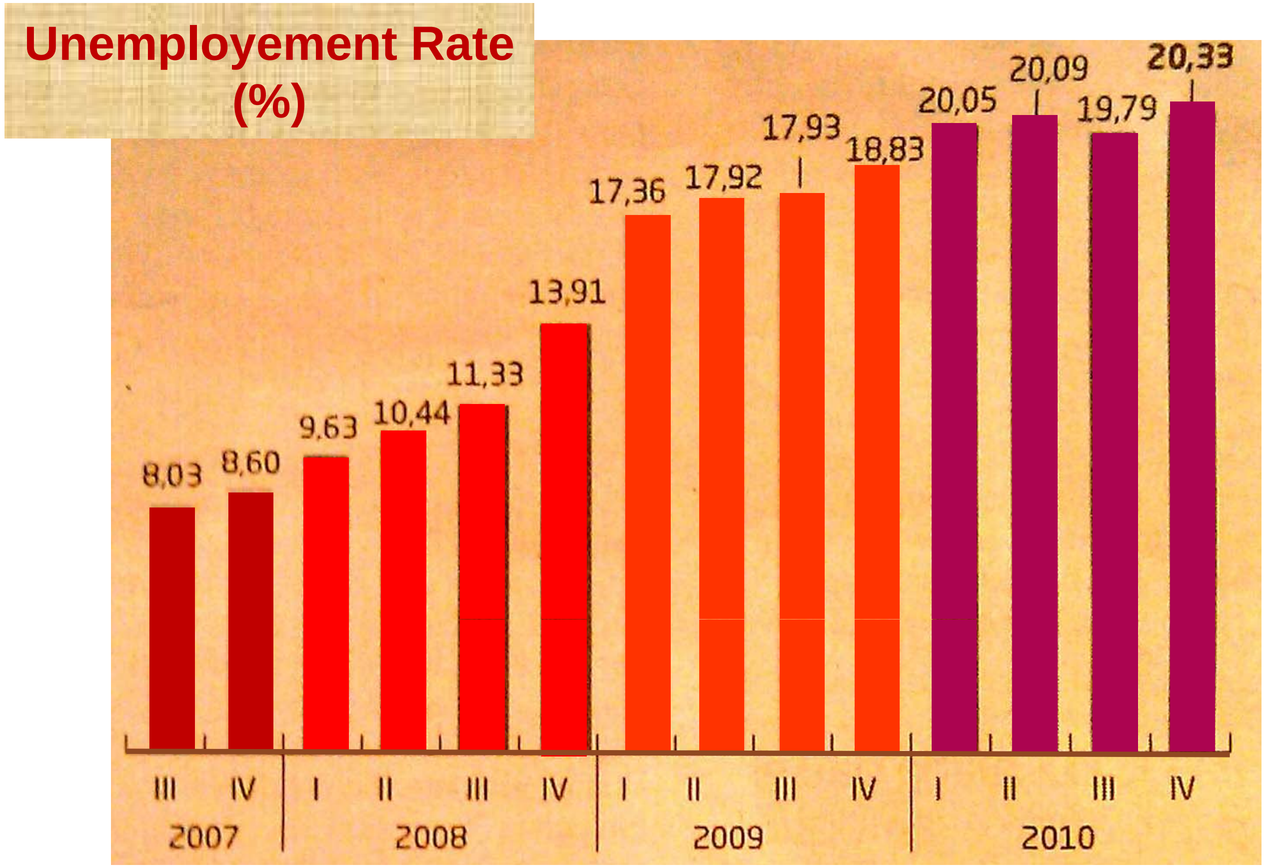
: Variación media del IPC general y subgrupos de medicina



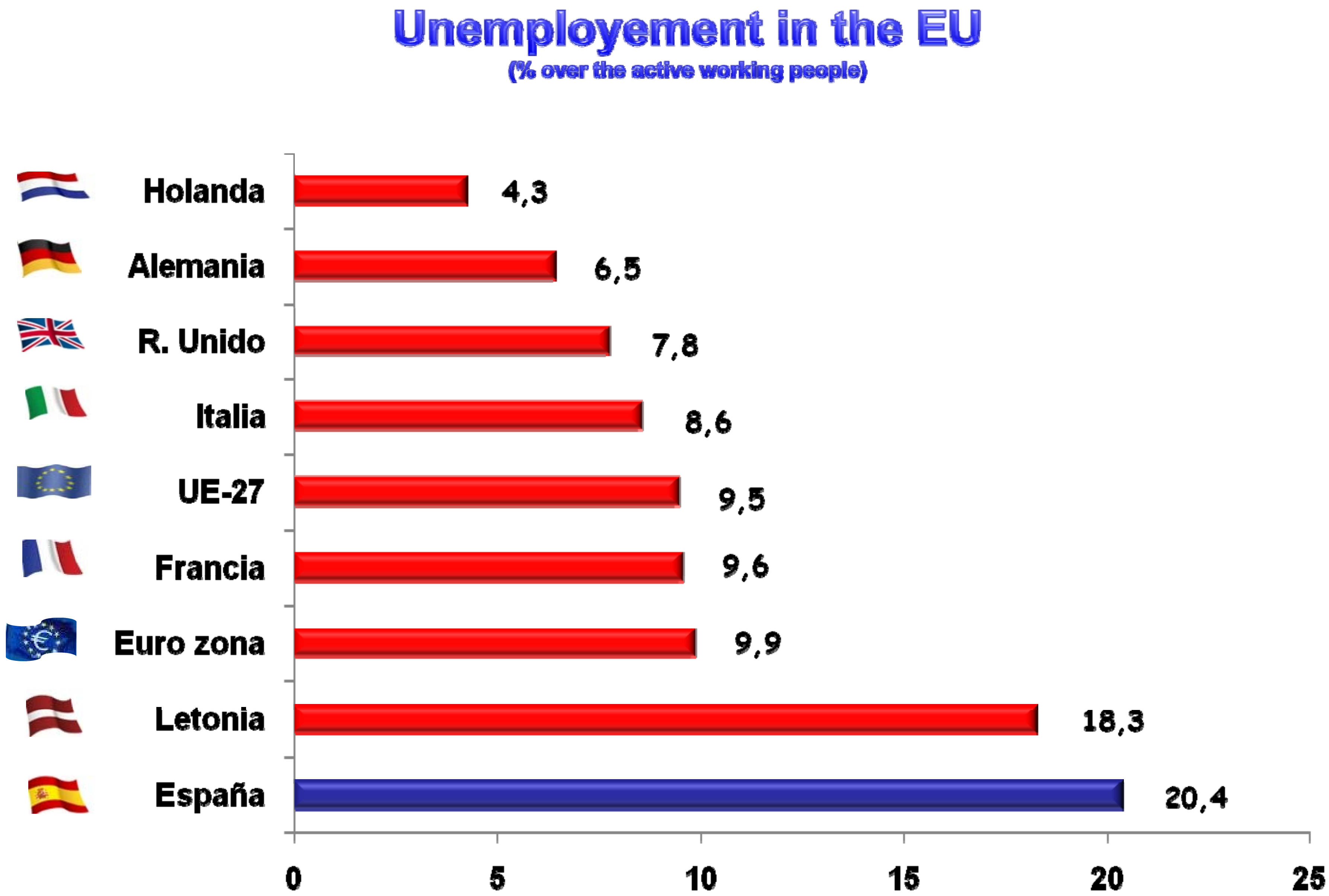


Fuente: MSPSI y estimaciones Farmaindustria

Economic Situation. Spain



Economic Situation. Spain



Pharmaceutical Sector

Spanish Pharmaceutical Sector

Strong economic engine for the national economy

Highest rate of R&D investment

Highest Industrial Production

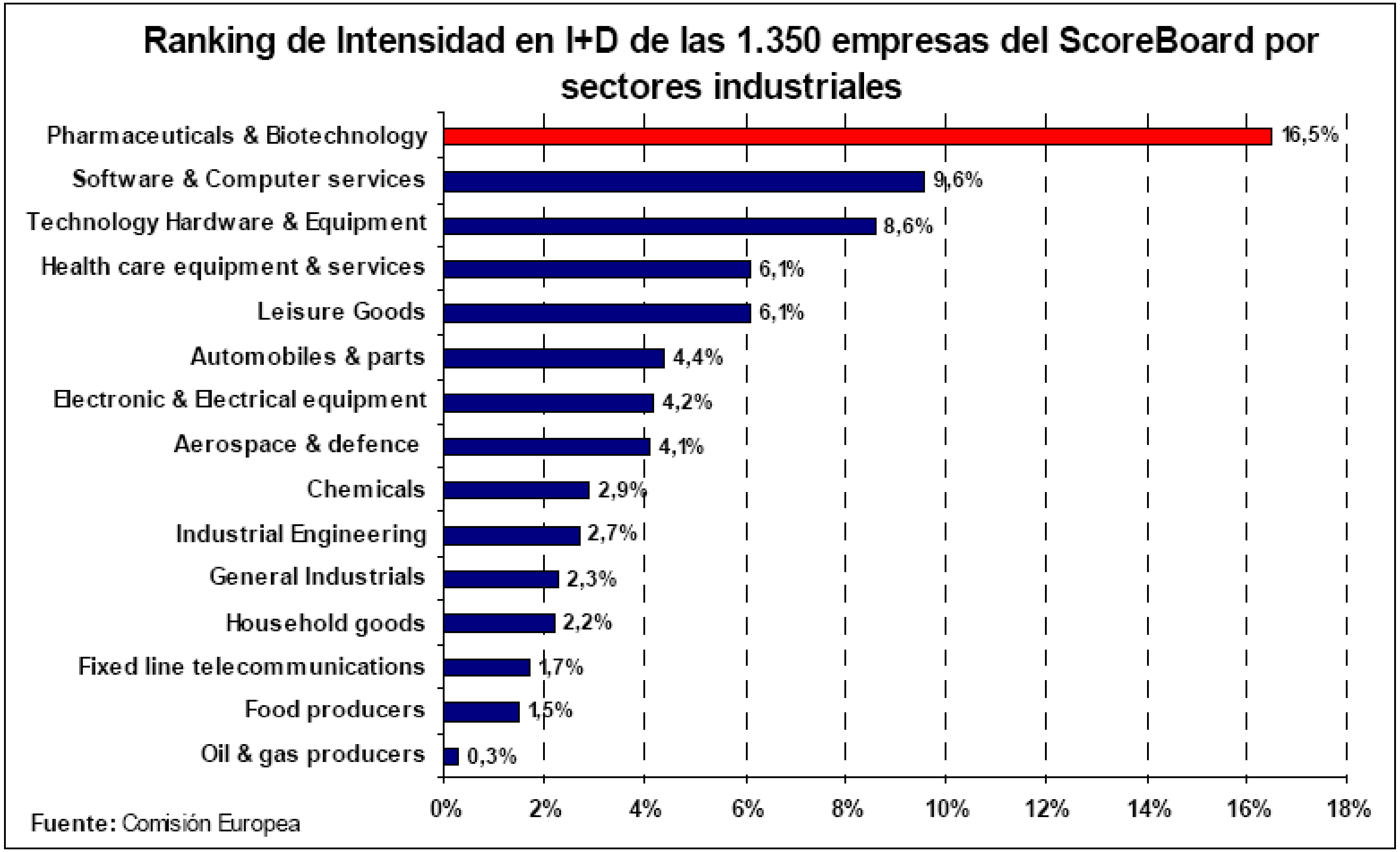
Highest productivity sector

High Qualified employement

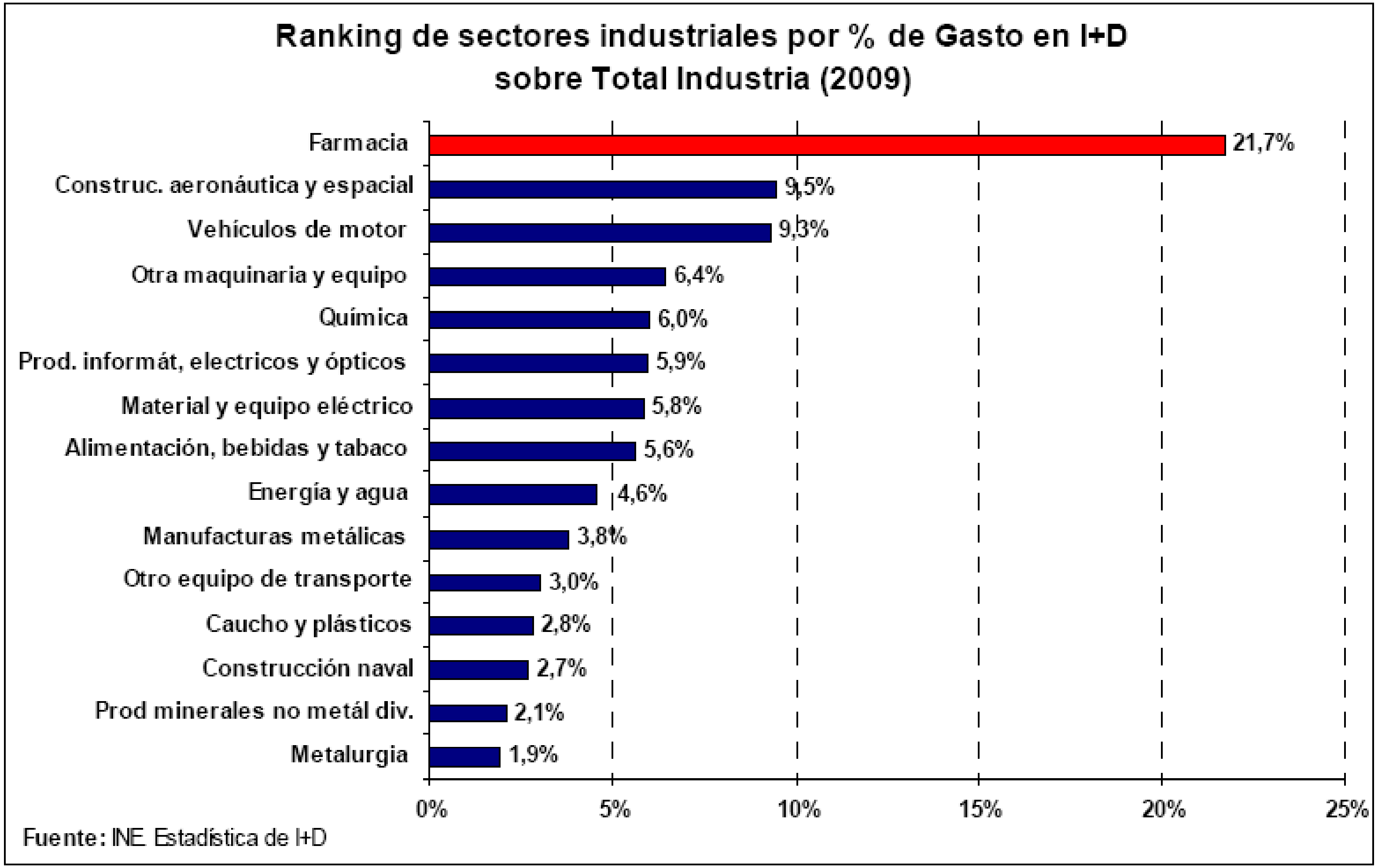
The reality of the Spanish Pharmaceutical Industry

- In the last 3 years (2007-2010) 15 R&D centers has been closed in USA and Europe. In this same period 20 new Centers were opened in Asia
- Spanish pharmaeutical industries are 20% of the total pharma market.
- The spanish pharmaceutical companies are 40% of the total R&D of the pharma sector
- Spanish Pharmaceutical Sector is the 20% of the total R&D made in Spain (400 mill€) and 50% of the total R&D employement (40.000 employees).

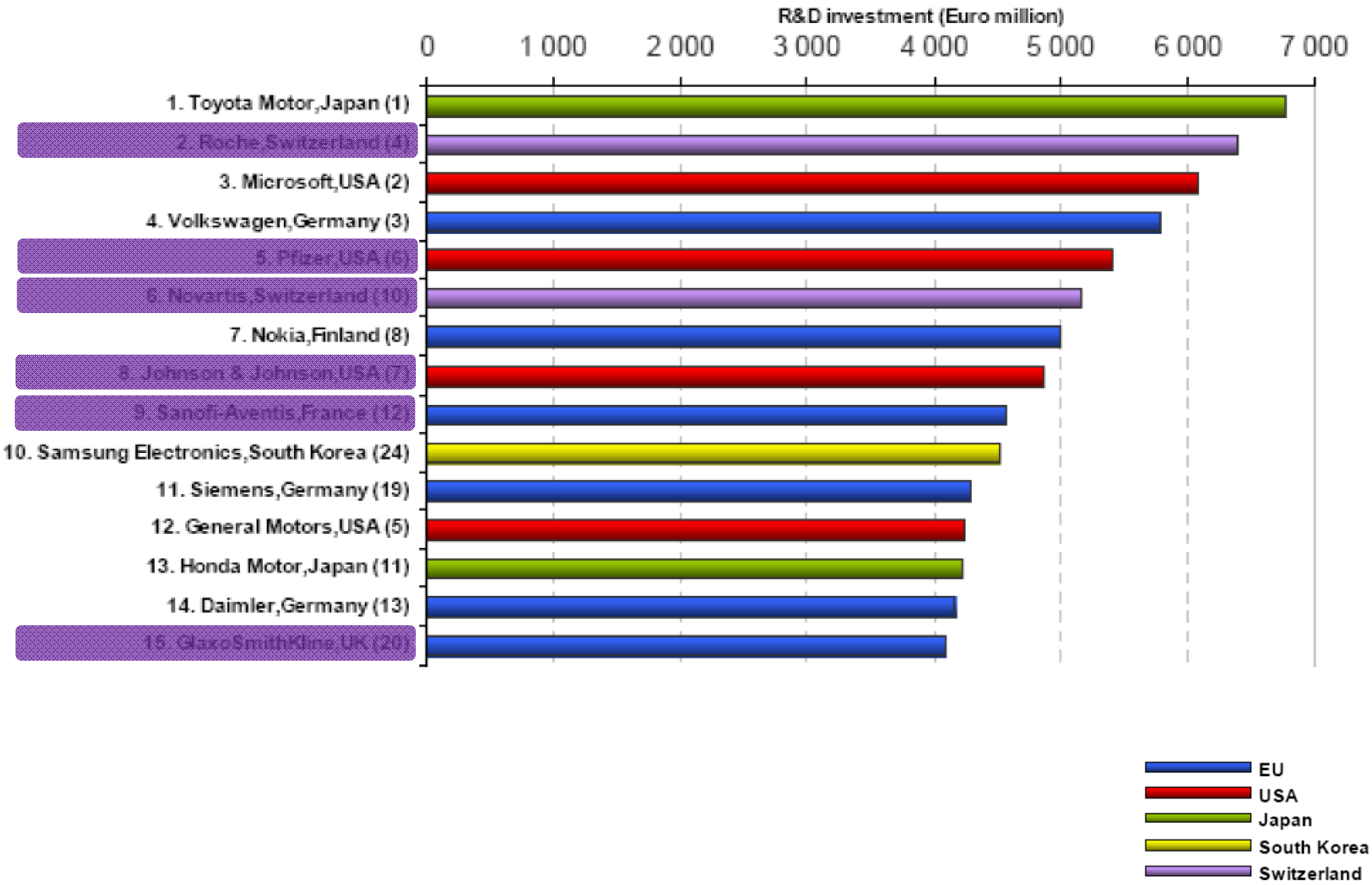
Worldwide. The pharmaceutical industry is the most R&D investment sector



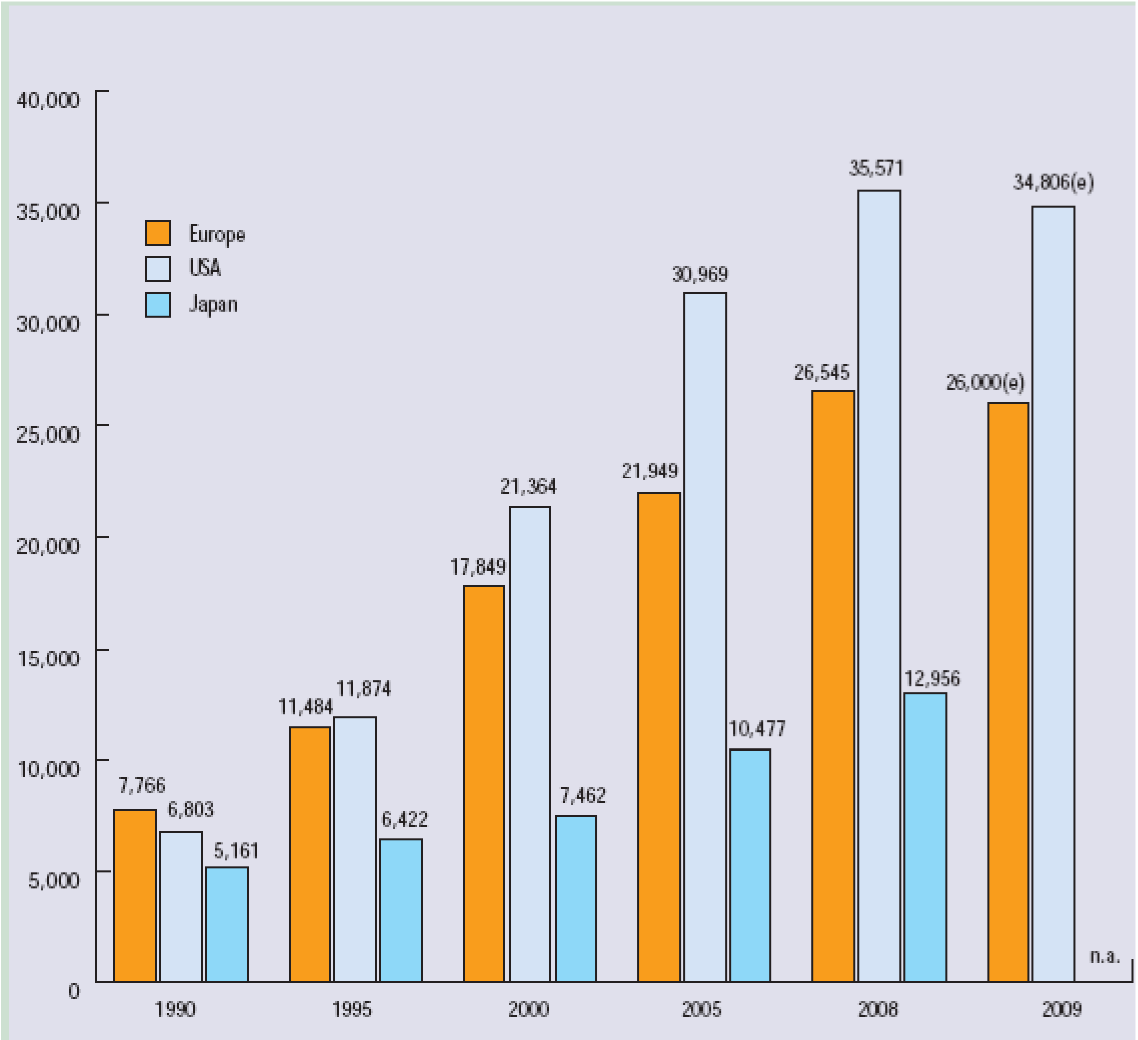
Spain. The pharmaceutical industry is the most R&D investment sector



Among the first worldwide 15 companies, 6 companies are Pharmas (2010)



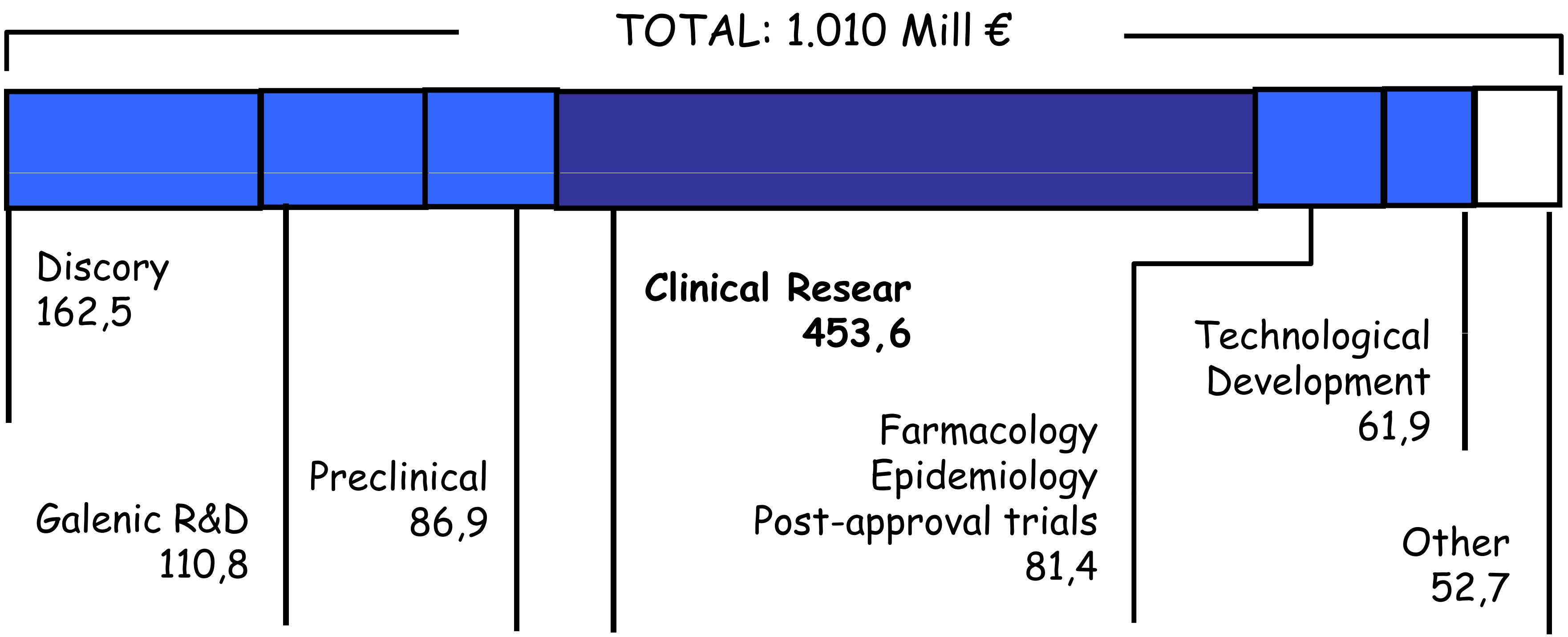
R&D investments in Europe, USA and Japan
(Mill €. Period 1990-2009)



Source: EFPIA Member Associations
(official figures) -
(e): EFPIA estimate

Spanish R&D Investment. 2008

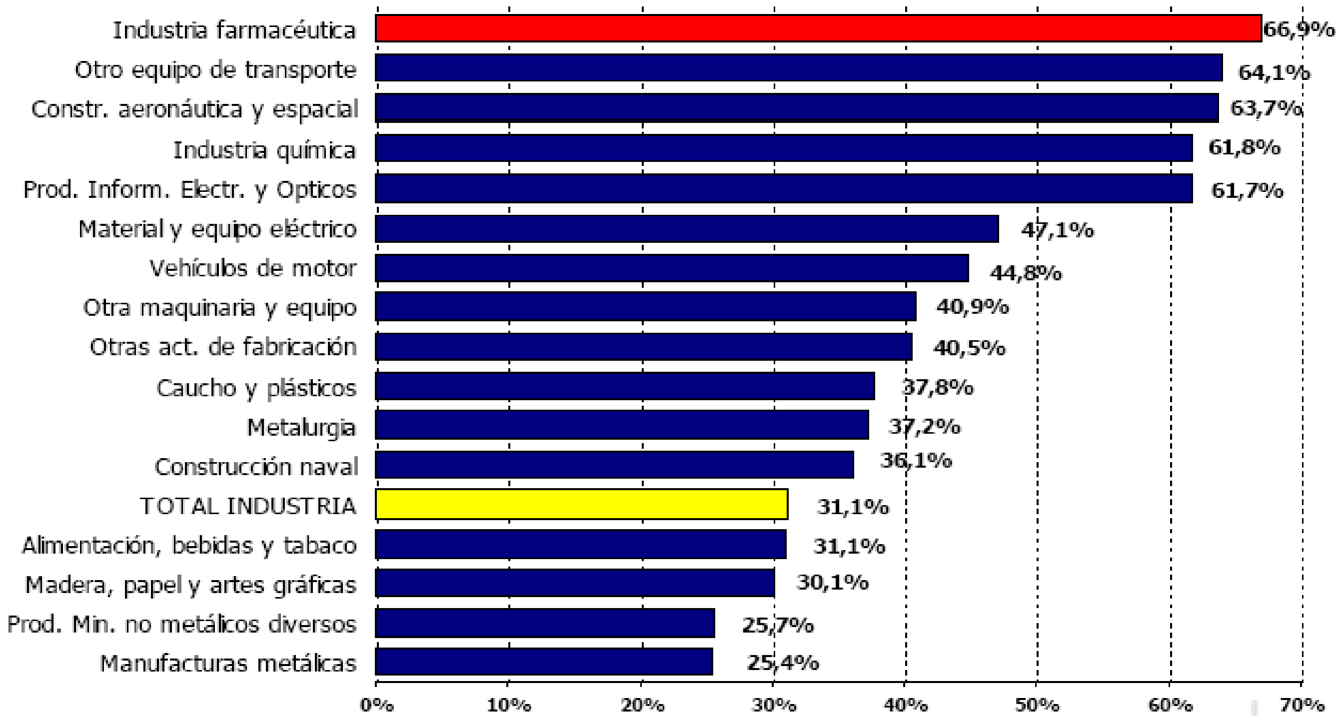
R&D investments by research phase (Mill€)



Spanish Pharmaceutical Industry: Strong qualified employement

2 of 3 companies have strong R&D activities

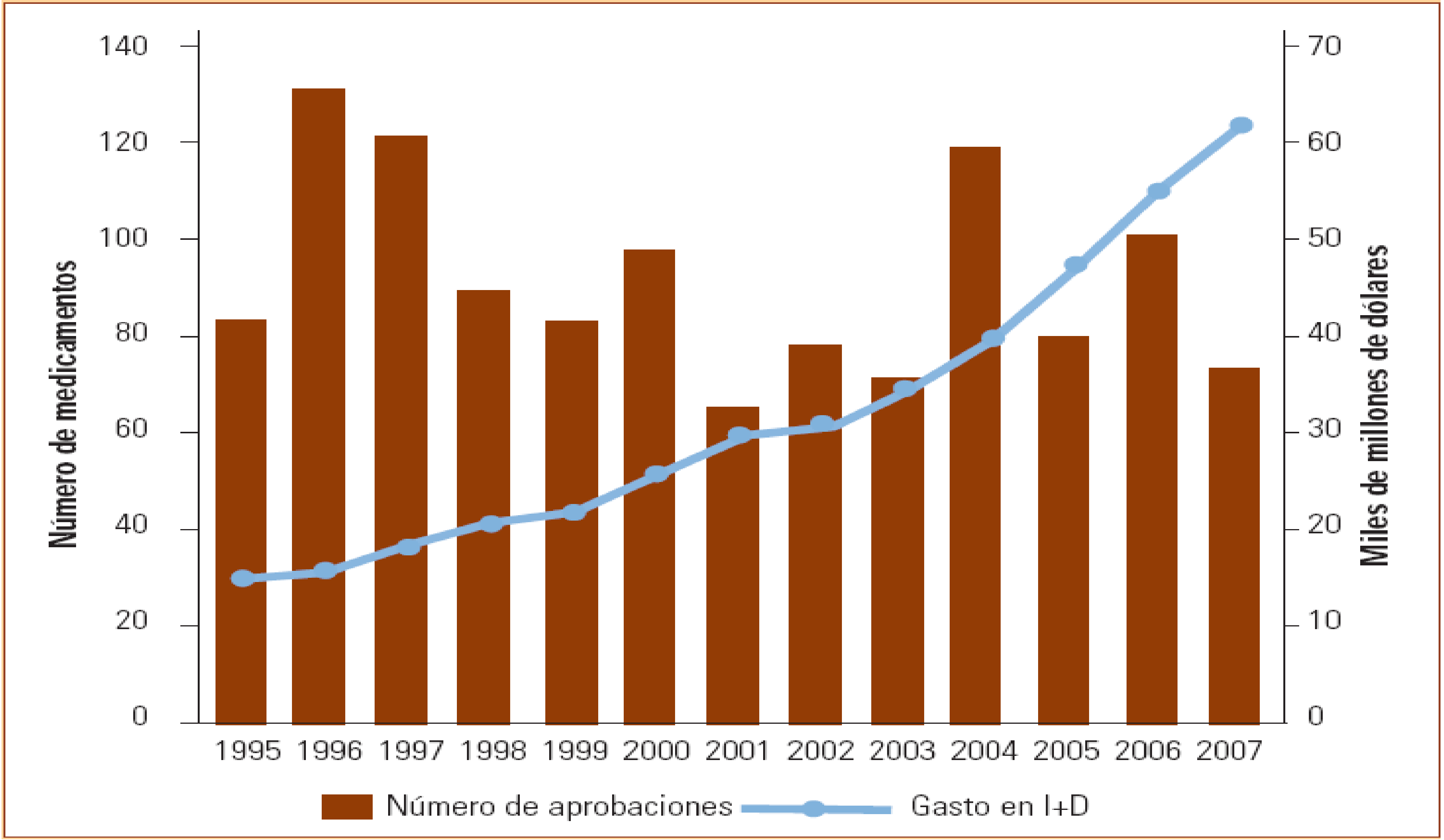
% Empresas que realizan I+D sobre el total de empresas. Principales sectores industriales (2008)



Fuente: INE. Encuesta sobre Innovación Tecnológica en las Empresas. 2008.

More R&D investment doesn’t warranty more NCE

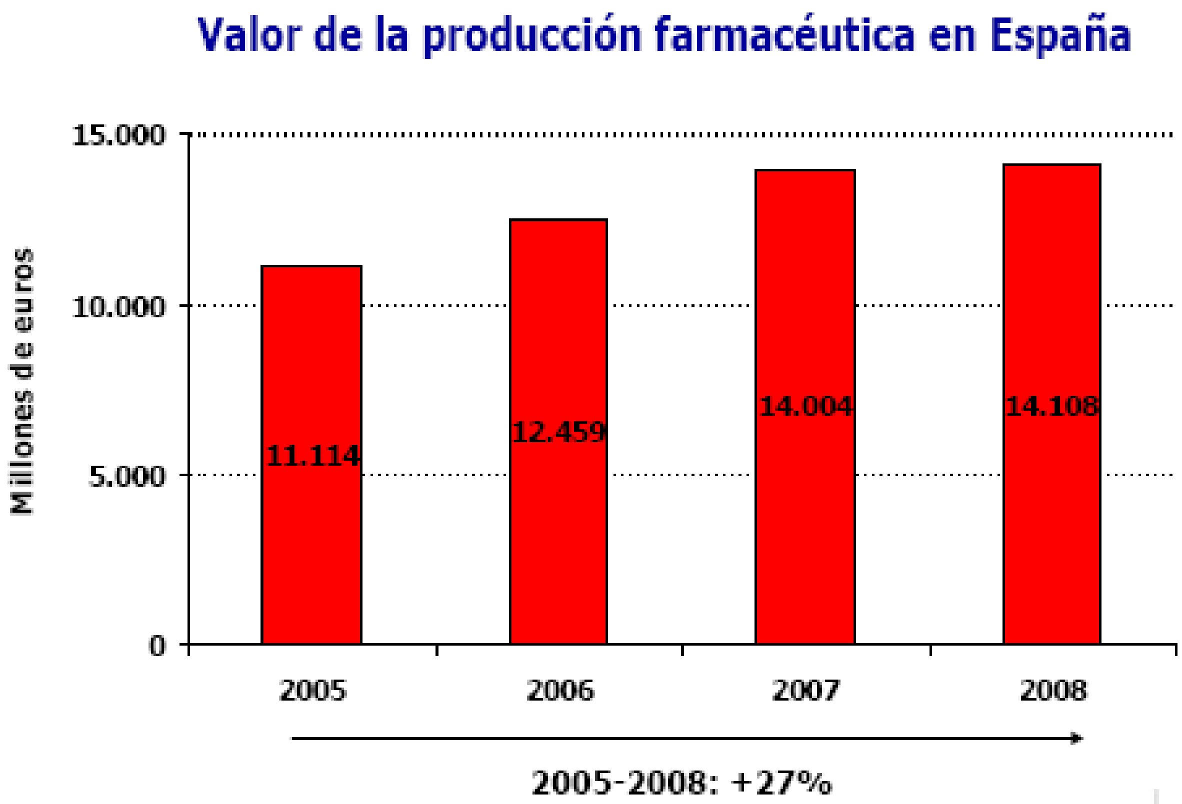
R&D investments and NCEs (USA 1995-2007)



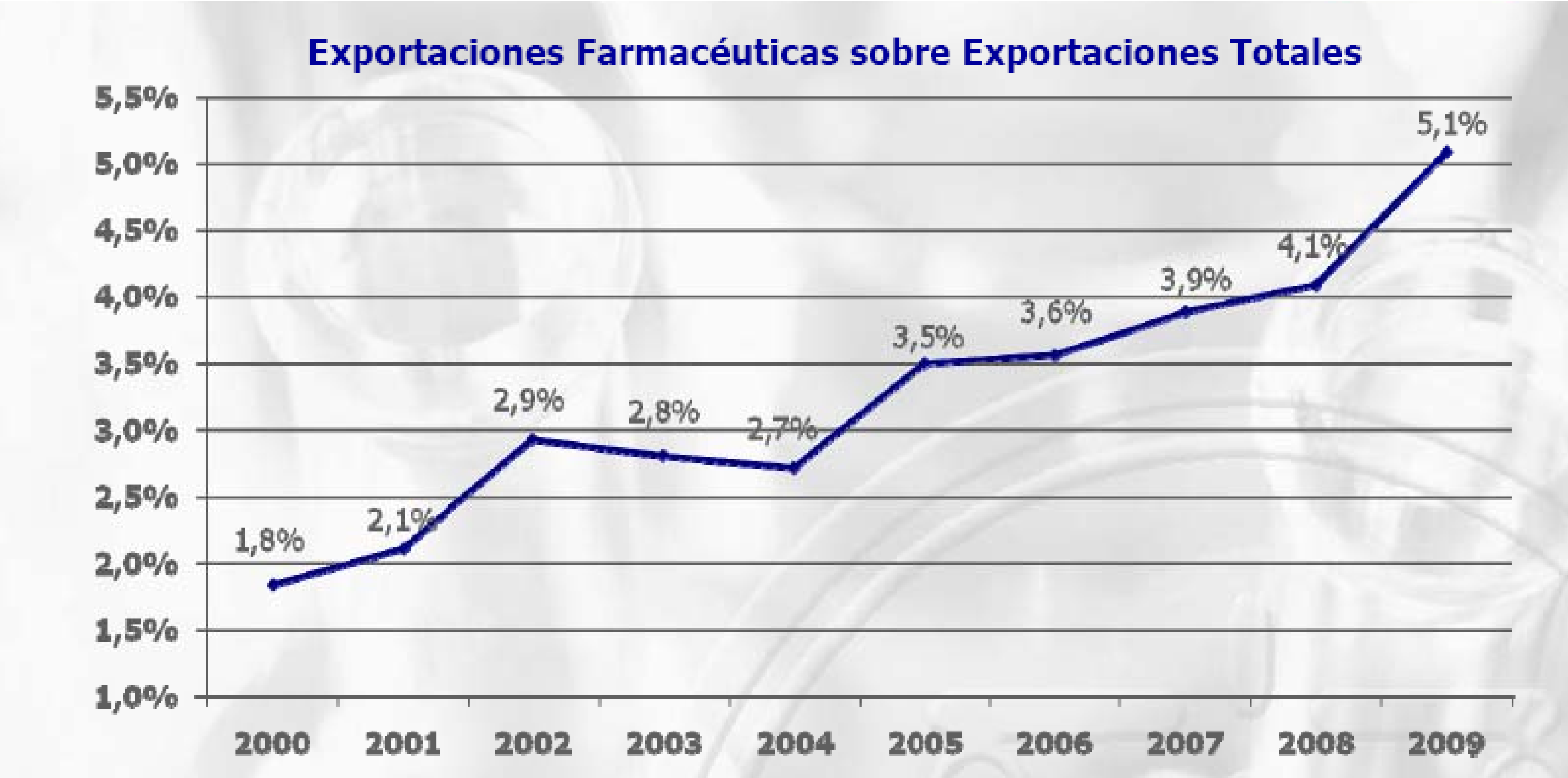
Source: FDA, PhRMA

Spanish Pharmaceutical Industry: High Productivity

The pharmaceutical manufacturing has been increased 27% in the las 3 years



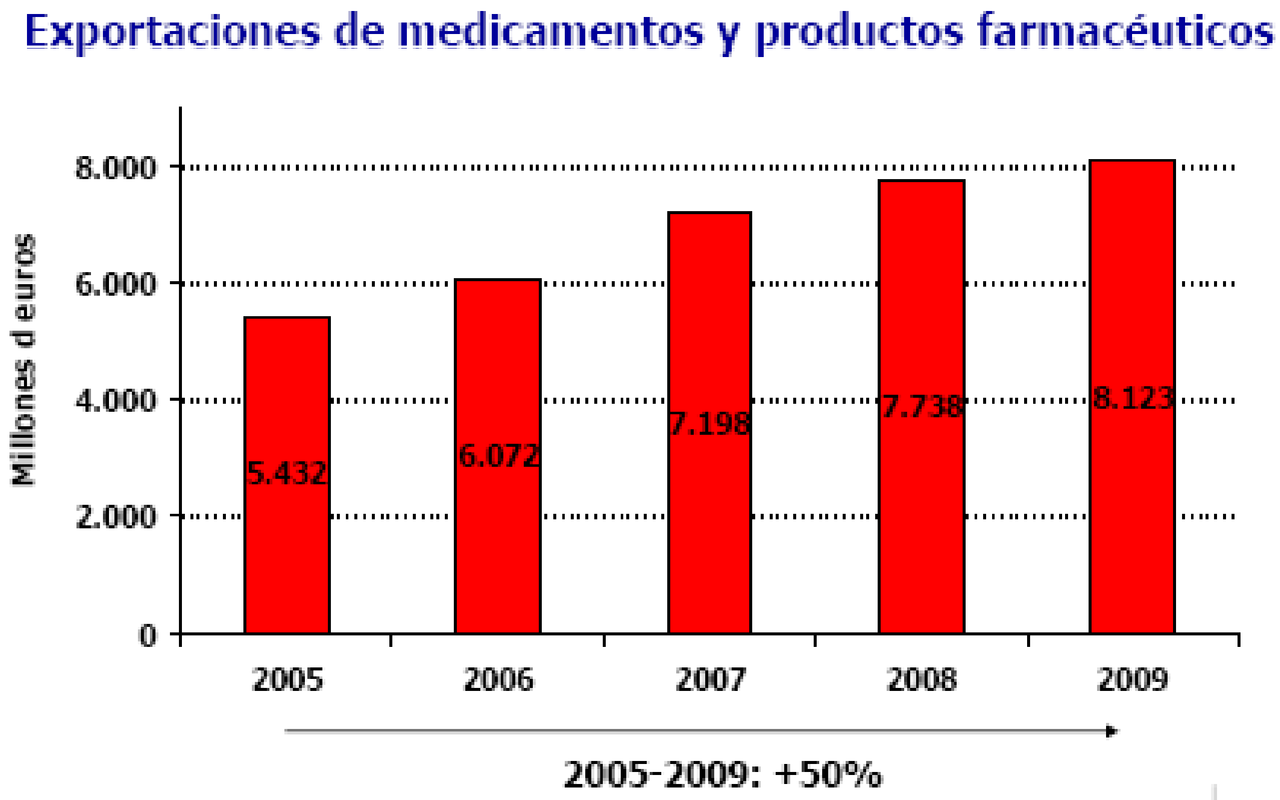
Spanish Pharmaceutical Industry: High Exporting Activities



Fuente: Secretaría de Estado de Comercio. Estadísticas del comercio exterior español

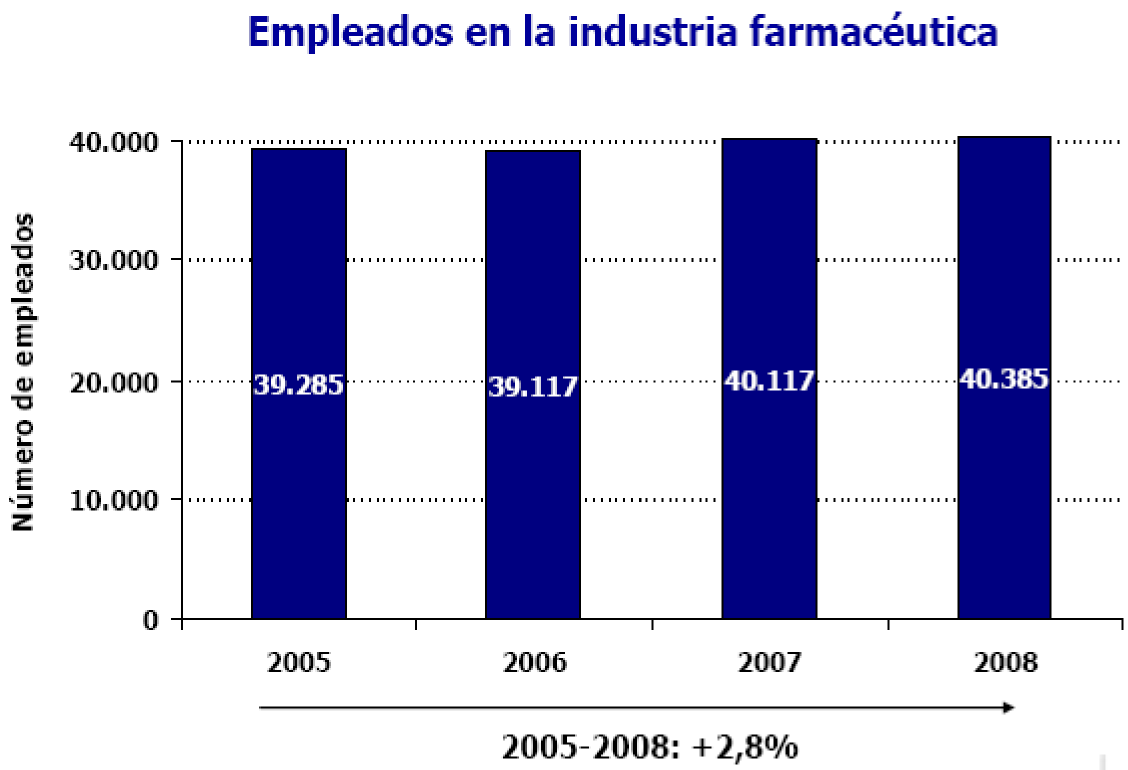
Spanish Pharmaceutical Industry: Strong Exportings

The pharmaceutical exporting has been increased 50% in 4 years



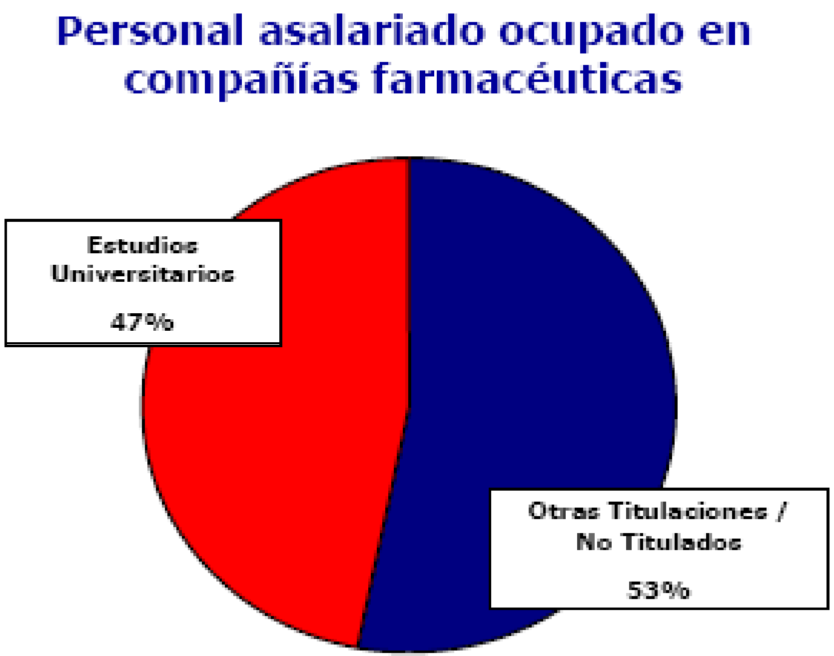
Spanish Pharmaceutical Industry: Highly qualified employement

Pharmaceutical industry generates a very stable employement



Spanish Pharmaceutical Industry: Highly qualified employement

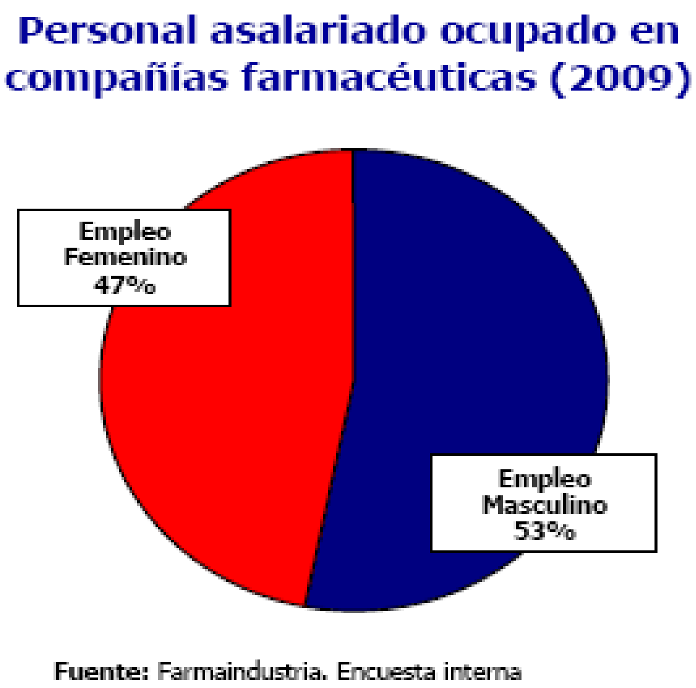
Half of the employement has University Degree



Fuente: Plan Profarma (Convocatoria 2008)

Spanish Pharmaceutical Industry: Strong qualified employement

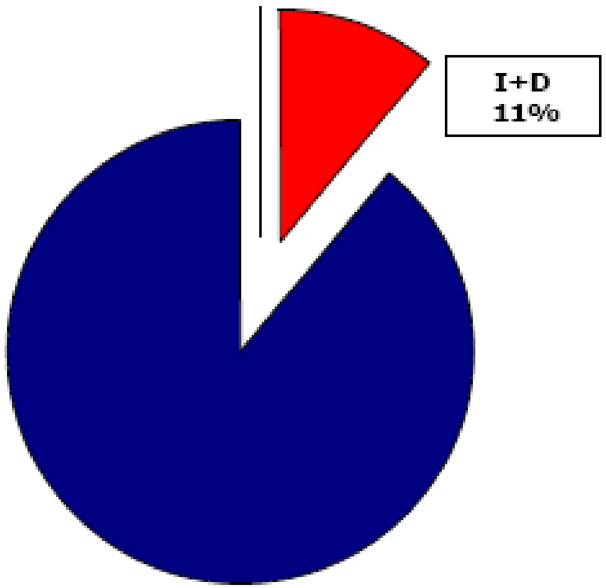
Half of the employement are women



Spanish Pharmaceutical Industry: Strong qualified employement

11% of the employees are devoted to R&D activities

Personal ocupado en el área de I+D (2008)



Fuente: INE. Estadística de I+D y Encuesta Industrial de Empresas

Top 10 Pharmaceutical Companies in Spain. 2010

Top 5 covers 25% of the total market

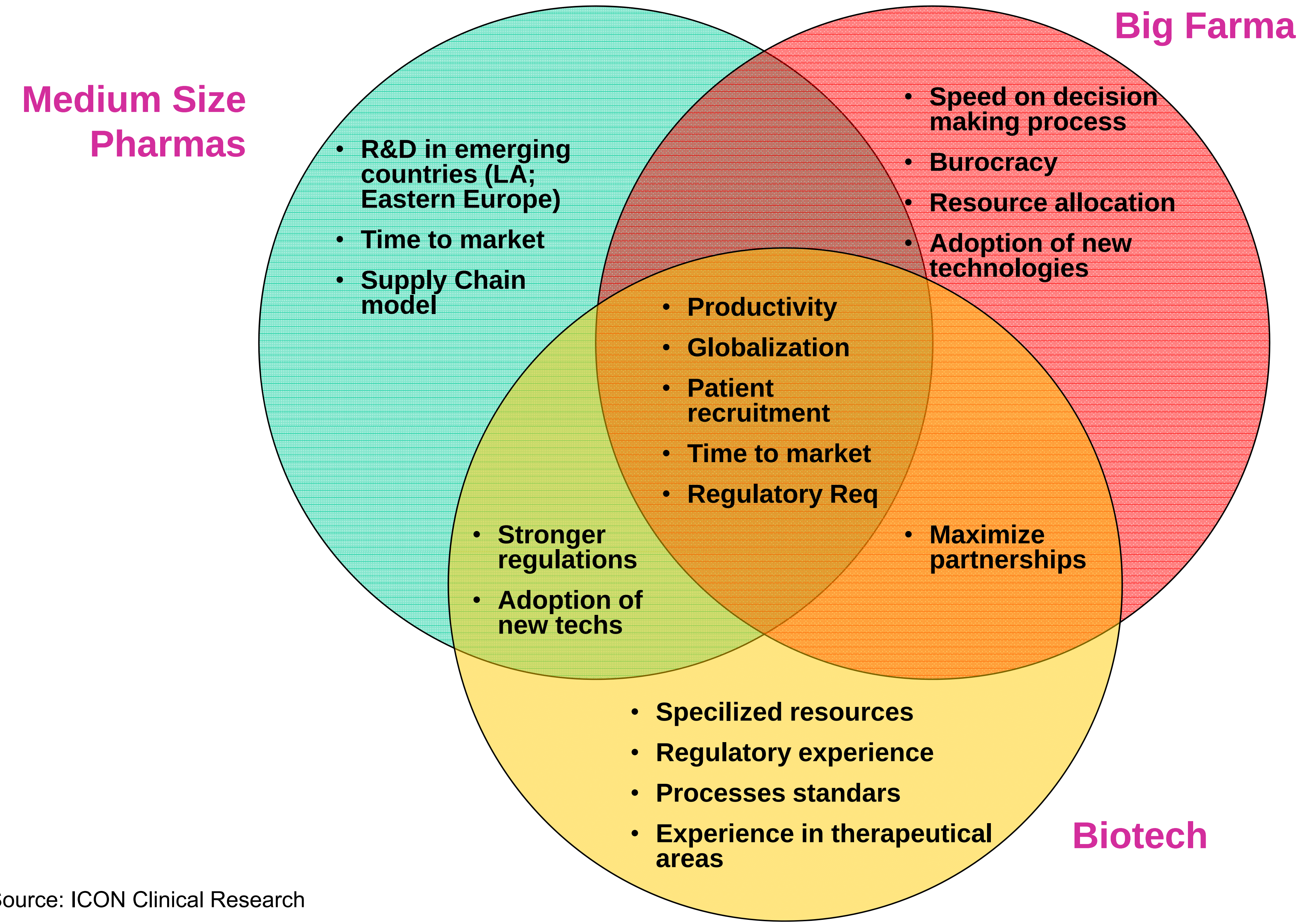
Actualmente en España existen en torno a **400 compañías farmacéuticas**.

El 90% de ellas se concentran en Cataluña y Madrid.

Cinco de los diez laboratorios más importantes en España han experimentado una evolución negativa en 2010.

PRINCIPALES LABORATORIOS (MARCAS)			
Compañía	**Ventas a PVL +000**	**% del Mercado**	**Crecimiento % +/-**
Sanofi-Aventis	566.391	5,40	-6,5
Novartis	562.018	5,36	4,5
Pfizer	539.683	5,14	-1,2
Almirall	525.104	5,01	-2,9
Glaxosmithkline	456.115	4,35	-2,1
AstraZeneca	450.743	4,30	8,5
Merck Sharp Dome	381.158	3,63	-0,8
Janssen Cilag	363.100	3,46	4,3
Boheringer Ing Esp	355.940	3,39	5,8
Esteve	355.872	3,39	4,4
Lilly SAE	338.074	3,22	10,8
Bayer	280.473	2,67	0,9
Ferrer Int. Grupo	242.310	2,31	15,15
Astellas Pharma	200.898	1,92	9,6
Roche	182.620	1,74	-8,3
Novo Nordisk	157.734	1,50	1,5
Menarini	149.385	1,42	1,5
Bristol Myer Squib	141.092	1,35	-20,5
Parke Davis	140.425	1,34	-25,5
Lundbeck	138.640	1,34	12,3
Totales	**6.527.775**	**62,24**	

Main Challenges of the Pharmaceutical Companies.

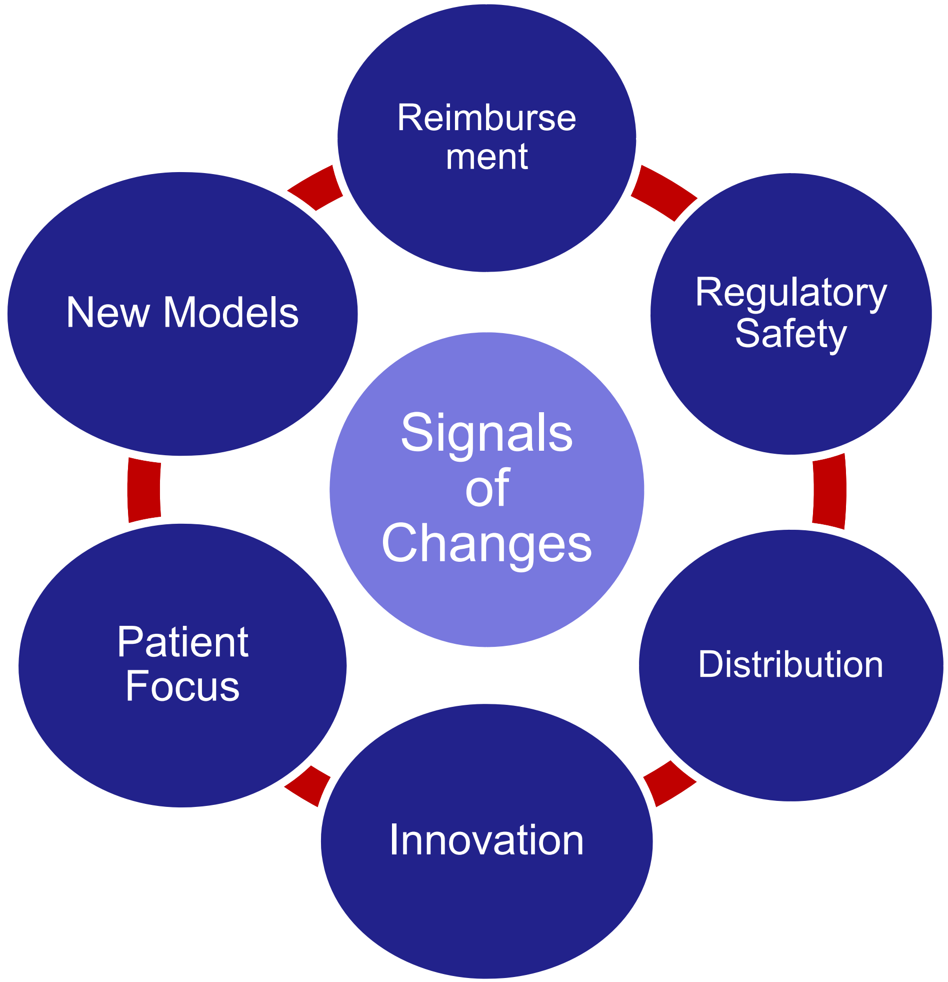


Source: ICON Clinical Research

The Signals of Change

The Signals of Change

The signals for changing are grouped in 6 bid areas



Source: Informe IMS Health. Intelligence 360 (2008)

The Signals of Change

- The **slow down economic activity** started in 2007 will continue. The future sales growth will be single digit.
- **Emerging countries** continue to be attractive but be caution.
- **Patent expirations** will strangle future revenues and will trigger mergers
- **Innovation** will be more difficult to demonstrate. End of blockbusters.
- Need to demostrate **value for money** and innovative pricing – reimbursement agreements

Specific Changes

Market

- Market growth very modest in the western world
- Strong economic restrictions to finance drugs by the states
- Emerging countries will be the engine: China, India, Sothafrica, Asia, Brasil…
- USA still a leadership
- Generics will continue growing
- Patient-consumer better informed

Specific Changes

Sector

- Strong changes in the pharmaceutical sector with new partners
- Strong investments to be a player
- Changes in the center of excellence
- Trend to relocation in the pharmaceutical industry
- Increase in all the type of strategic alliances and partnerships

Specific Changes

Technologies

- More dificult to demonstrate Innovations
- New technologies “from scratch”

16 Signals which anticipates changes

Reimbursement	• Conditional reimbursement with risk taking agreements • Generics • Germany adopts strong cost containment measure • Obama's health reform on a battle
Regulatory - Safety	• FDA more stringment safety measures • EU more concerns on safety (Avandia; Agreal; Acomplia…) • Stronger pharmacosurveillances
Distribution	• FDA starts approving pharmaceuticals manufactured in China • Generics manufactured in emerging countries • Parellel distributions
Innovation	• HTAs widely used. Severals in the same country • Health Evaluation Agencies financing comparative clinical trials
Patient focus	• Pharmas meet the patients • Patient Asociations stronger and in decision making processes
New Models	• Exubera (Pfizer) withdrawn • Outsourcings: Manufacturing, Clinical Research, Regulatory…

Fuente: Informe IMS Health. Intelligence 360 (2008)

Changes for today are realities for the future

6 Final Reflections

- A **medium size company** without “in-house” products will not survive
- It will be compulsory to **develop new company skills** like: Licensing-in, Business Development, Outsourcing etc.
- **Niche based R&D** with smarter budgets
- **Generics** will be a big market and a great oportunity for R&D based companies to expand thirs business
- **New strategies** to manage product life cycles
- **Size** IS important to to be competitive. New alliances underway

Muchas
Gracias

Back Up Slides

Strategies for life product management

- New Indications
- New Innovative Formulations with clinical relevance
- Repositioning of products
- Boost launches. Launch quicker and better
- Alliances. Licensing-in and Licensing-out
- Tailored target patient population
- Premarketing activities
- Comarketing, Copromotion, Codistribution, Co-research
- Fixed dose combinations
- Changes in marketing and sales

Estrategias para la gestión de la vida del producto

- **Nuevas Formulaciones**
  Losec (omeprazol AstraZeneca) cápsulas a comprimidos
  Zispin (mirtazapina Organon) comprimidos dispersables a comprimidos liofilizados.
  Tritace (ramipril Sanofi) de cápsulas a comprimidos

- **Formulaciones de liberación sostenida**
  Carduran (hipertensión) y Carduran XL (HPB)

- **Asociación de principios activos**
  Fosavance MSD (alendronato + Vit. D)

- **Isómeros / Racematos**
  Zirtec (cetiricina racemato) y Xyzal (Levocetiricina).Anti H1

Product Repositioning Strategy for Success.

Medicamento	Area terap. Original	Nueva area terap.
Talidomida	Hipnótico. Antiemético	Eritema nudoso leproso Alteraciones cutáneas VIH Anticancerígeno (mieloma)
Sildenafilo (Viagra, Pfizer)	Hipertensión Disfunción eréctil	Hipertensión pulmonar Prev. Toxicidad cardíaca por doxorubicina
Rituximab (MabThera, Genentech)	Limfoma no-Hodgkin	Artritis reumatoide Esclerosis múltiple
Bupropion (GSK)	Depresión	Dejar de fumar
Minoxidilo (J&J)	Hipertensión (oral)	Alopecia (cutáneo)
Duloxtina (Cymbalta)	Depresión / DPNP	Incontinencia Urinaria
Ropinirole (Requip; GSK)	Parkinson	Síndr. Piernas cansadas
Paclitaxel	Anticanceroso	+ Drug Eluting Stent para reducción re-estenosis

Product Repositioning Strategy for Success.

Medicamento	Area terap. Original	Nueva area terap.
Estatinas (Inh. HMG-CoA reductasa)	Hipolipemiantes	Alzheimer
Agonistas PPAR-γ	Hipoglucemiantes	Alzheimer
Tamoxifeno	Anticáncer	Trastorno bipolar
Imatinib (Gleevec;Novartis)	Anticáncer	Artritis reumatoide
Anticonvulsivantes	Antiepilépticos	Trastorno bipolar Estabilizadores del ánimo