

# The drug market regulation in the context of the economic crisis in France

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**« La Prestación Farmacéutica frente a la Crisis Económica en Europa »  
Universidad Carlos III**

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Cemka-Eval  
Paris

# Summary

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- Overview of the French Healthcare system
- Drug market Regulation
- Future trends



# **Overview of the French Healthcare system**

# General features

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- ❑ Population ~65 Million
- ❑ Bismarkian system of compulsory health Insurance (Sickness Funds)
- ❑ Multiple Sickness Funds (salaried workers - 89%, self-employed, agriculture, etc)
- ❑ Centralized regulation (drugs. tariffs.etc) but regions are getting more and more responsibilities for organisation of health care provision (ARS)
- ❑ Full coverage of the French population
- ❑ Employer and Unions representatives jointly control the Funds under the State's supervision

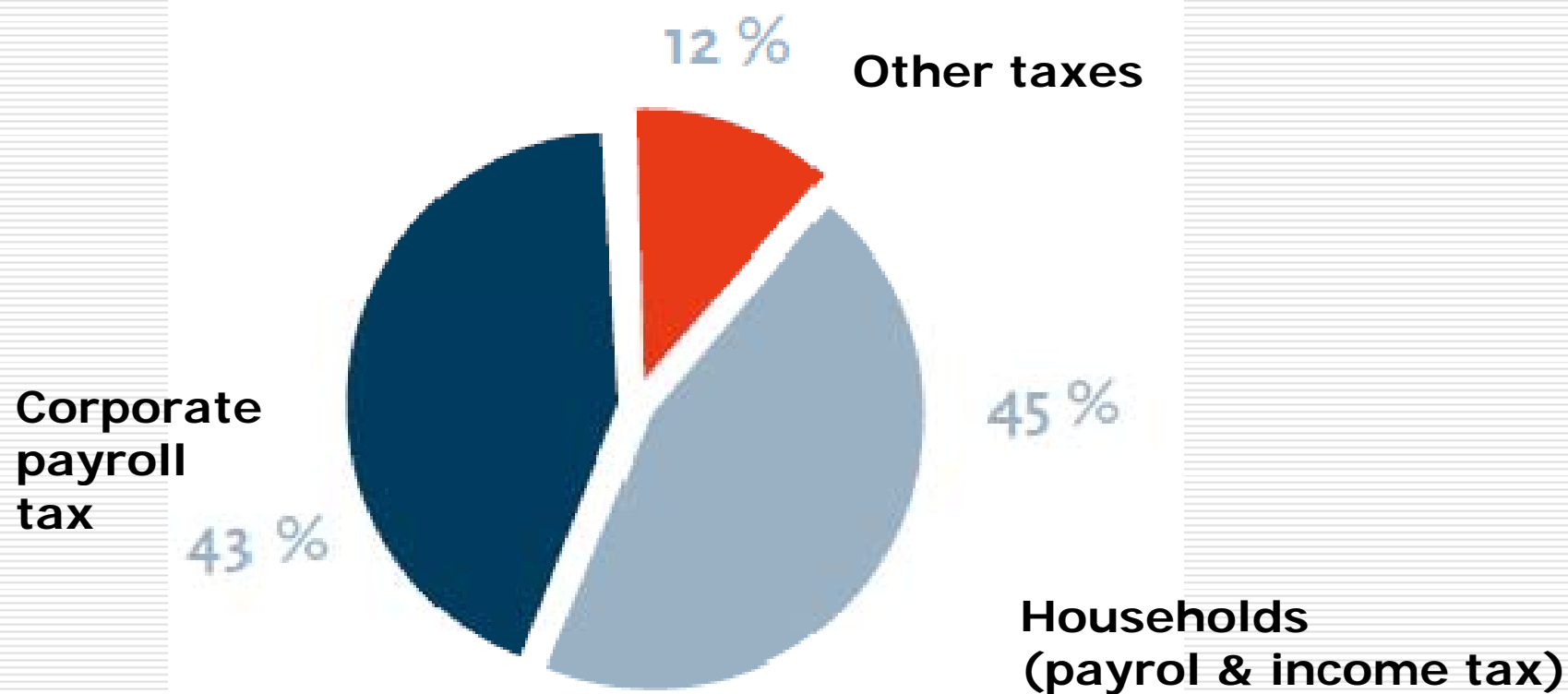
# Financing of Social Security

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- The financing is supported mainly by employers and employees payroll tax (57% in 2009). and personal income taxes (33%- CSG and other taxes in 2009).
- The working population has twenty percent contributions deducted at source to fund the social security system (all types of 'social risks': health insurance, family allowance, pensions, occupational risk).

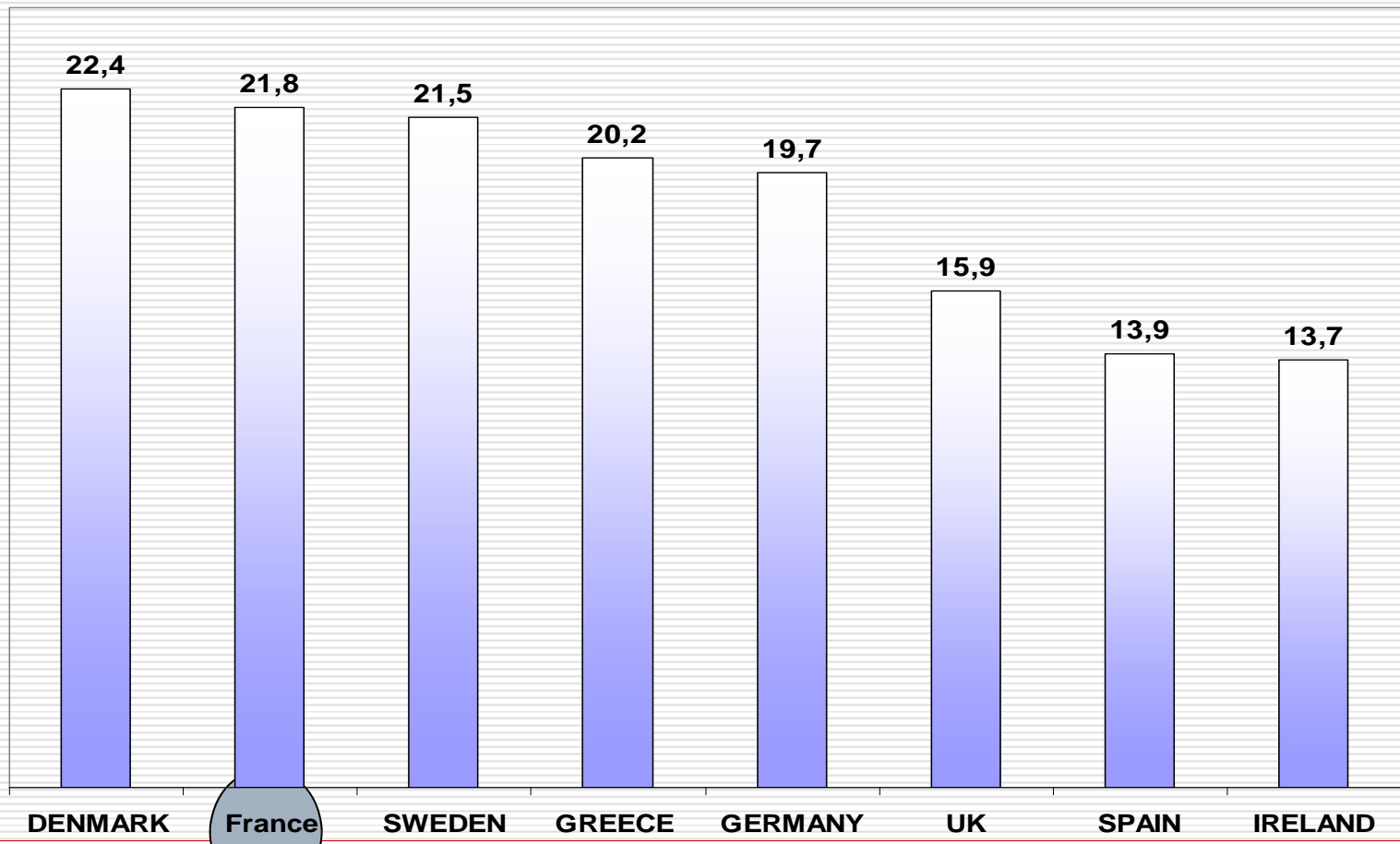
# Financing of social security (2009)

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# Cost of Social Security in % of GDP

(2008) source: Eurostat



# Copayment of health expenditures

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- ❑ Copayment of financial burden (except for patients presenting with a severe condition in a list of 30 diseases (« ALD ») – 9 million patients accounting for 60% of total health expenditures)
- ❑ Complementary insurance (Mutual Benefit or private insurance) in ~85% of population



# Structure of payment of health expenditures

	1995	2000	2005	2008	2009
<b>Sickness Funds</b>	77.1	77.1	77.0	75.5	75.5
<b>State</b>	1.1	1.2	1.3	1.3	1.3
<b>Mutual benefit/ private insurance</b>	12.2	12.8	13.2	13.7	13.8
<b>Out of pocket</b>	9.6	9.0	8.4	9.5	9.4
<b>Total</b>	100	100	100	100	100

# Provision of Health Care

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- ❑ Supply of inpatient care through a provision of public hospitals and private clinics (# 3.000 – 25% beds private)
- ❑ Ambulatory care based mainly on a solo fee-for-service network of GPs (# 60.000) and specialists (# 60.000) (density: 3.3/1000 inhab.of which 1.6 GP)
- ❑ Organised historically according to the principles of « liberal medicine »: freedom of settlement and practice and unrestricted access for patients (less and less true!)

# General principles for health expenses regulation

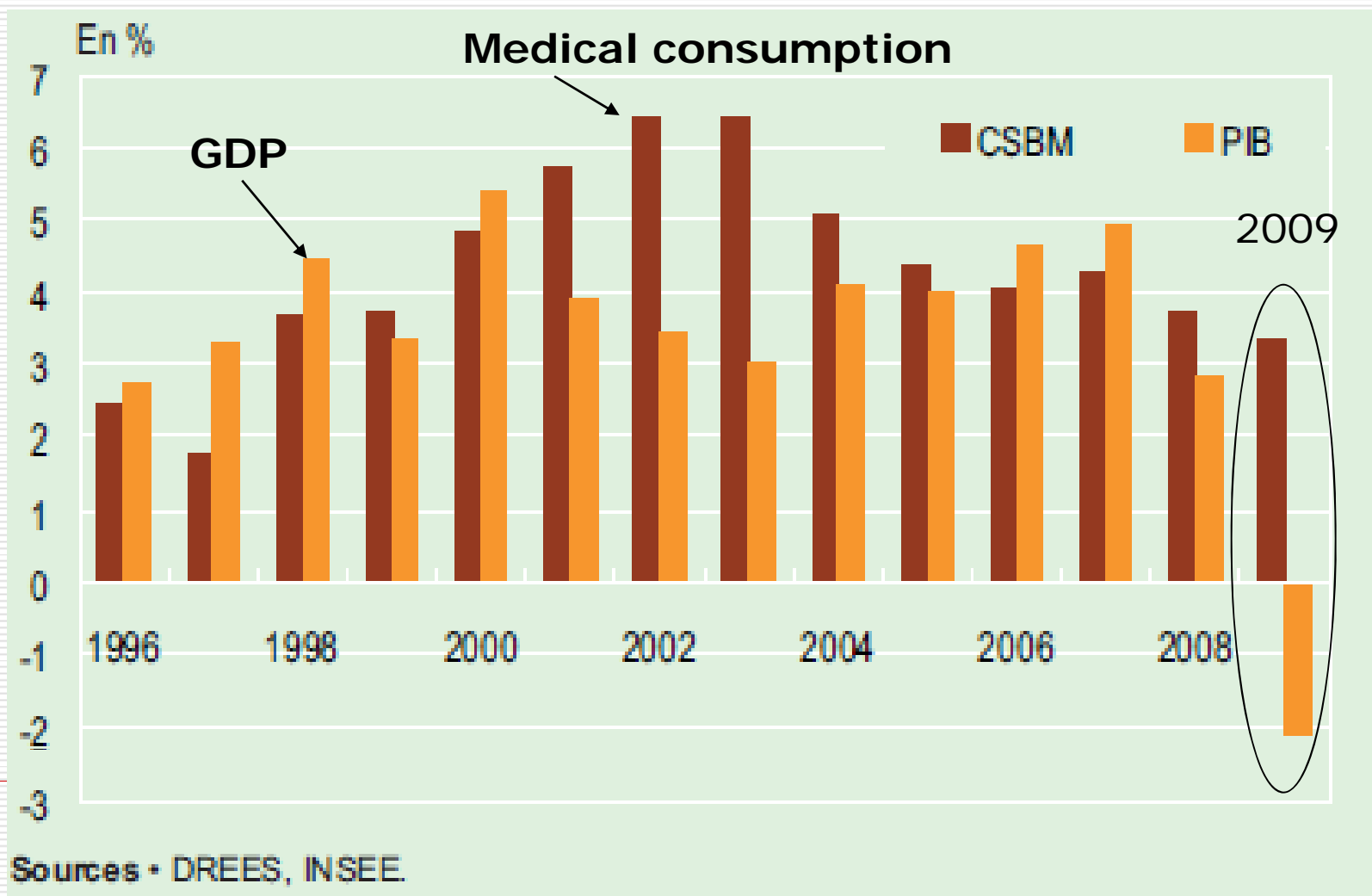
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- ❑ Objective: Maintain the part of health expenses paid by compulsory insurance (Sickness Funds) as a constant % of GDP.
- ❑ Definition of a « National Objective for Sickness Fund expenses » (ONDAM): an annual prevision of budget voted by Parliament each year within a Bill about the funding of Social Security (PLFSS)
- ❑ The Bill includes various conjunctural measures aimed at achieving the current ONDAM

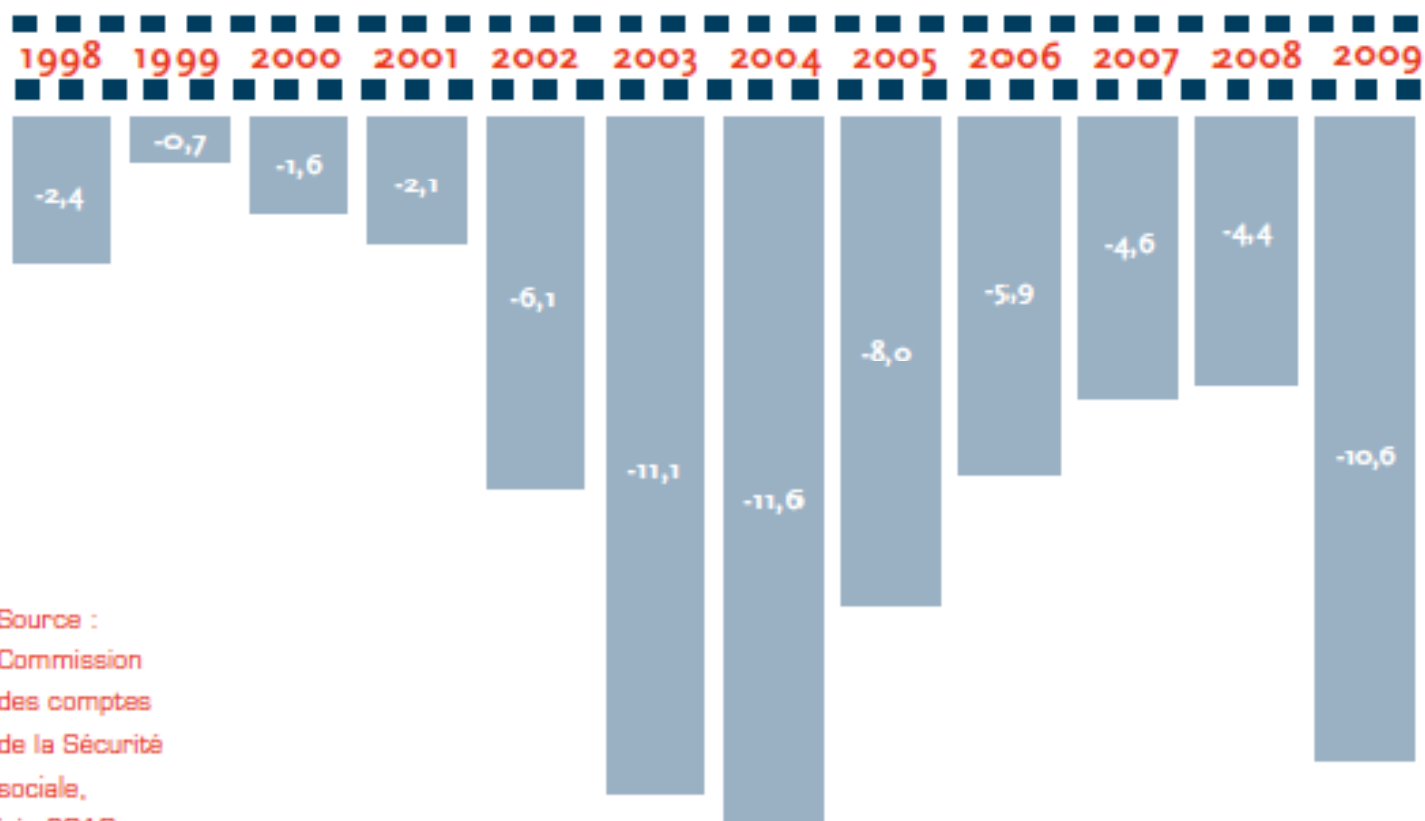
# Total Health Expenditures in % of GDP

	<b>2000</b>	<b>2005</b>	<b>2008</b>
<b>Germany</b>	<b>10.3</b>	<b>10.7</b>	<b>10.5</b>
<b>USA</b>	<b>13.6</b>	<b>15.7</b>	<b>16.0</b>
<b>France</b>	<b>10.1</b>	<b>11.1</b>	<b>11.2</b>
<b>Japan</b>	<b>7.7</b>	<b>8.2</b>	<b>na</b>
<b>UK</b>	<b>7.0</b>	<b>8.2</b>	<b>8.7</b>
<b>Switzerland</b>	<b>10.2</b>	<b>11.2</b>	<b>10.7</b>
<b>Canada</b>	<b>8.8</b>	<b>9.9</b>	<b>10.4</b>

# Growth rates of GDP and medical consumption over the period 1996-2009

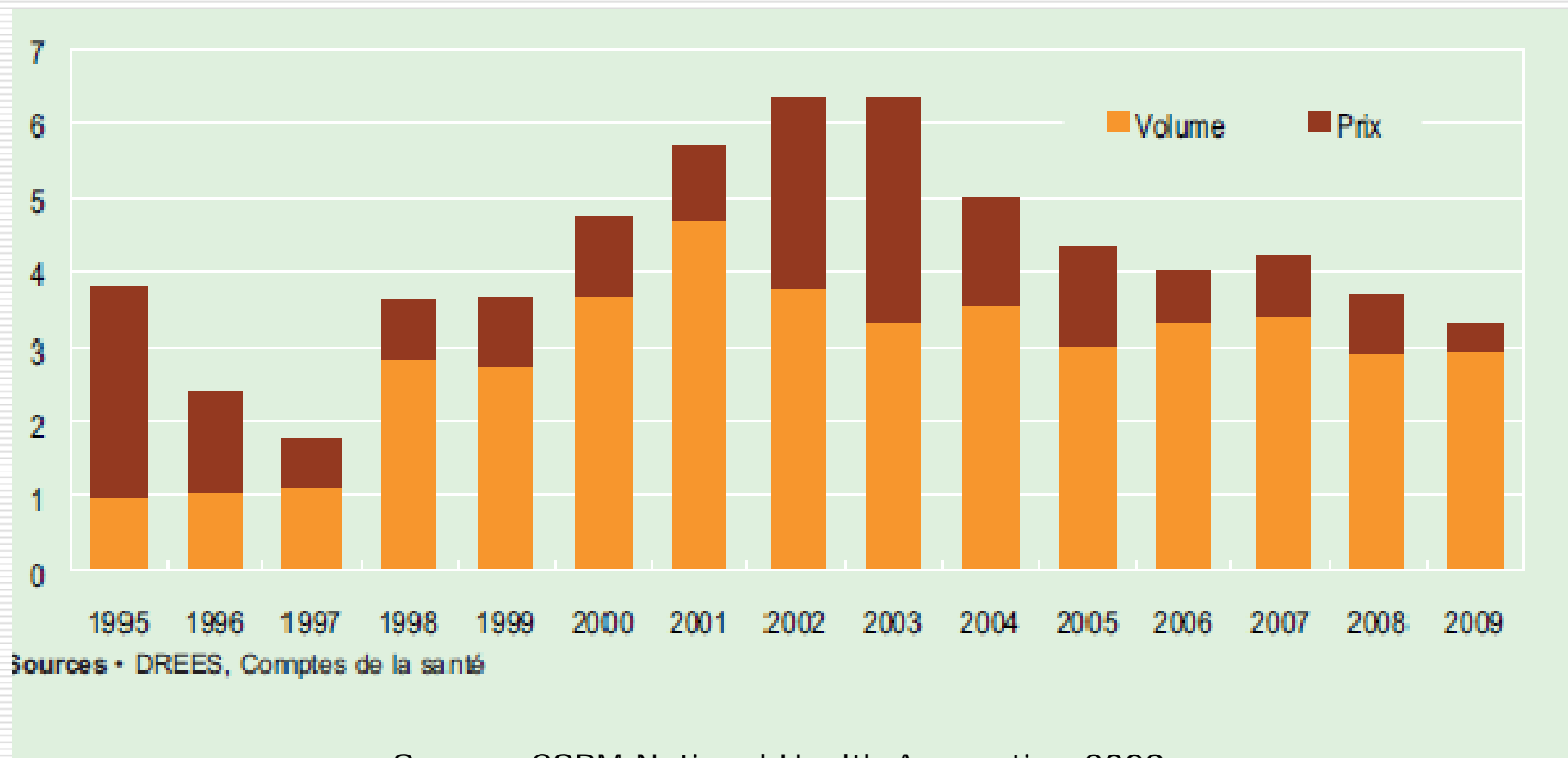


# Annual deficit of the Sickness Funds (€ Billion)



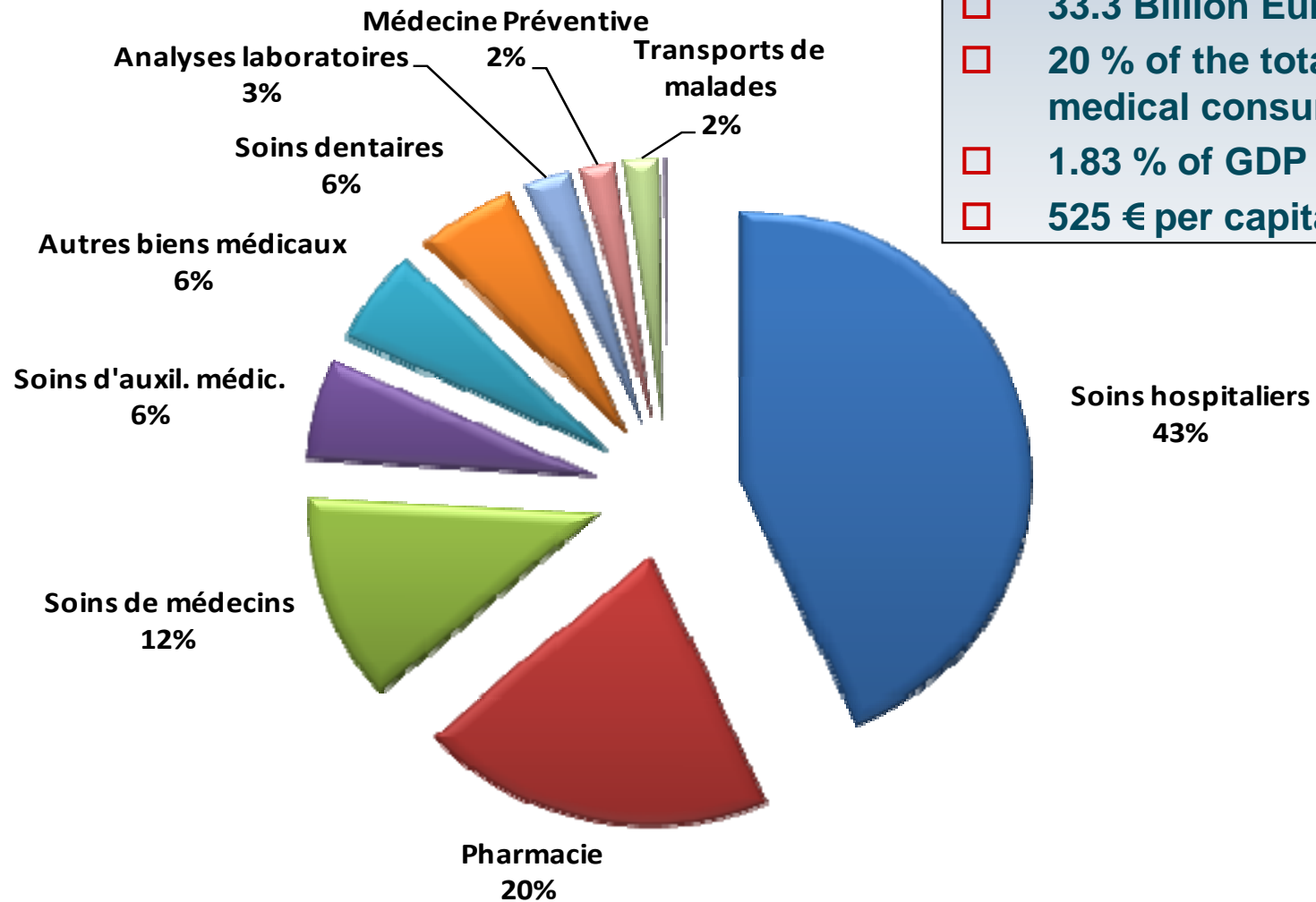
Source :  
Commission  
des comptes  
de la Sécurité  
sociale,  
juin 2010

# Breakdown (price /volume) of growth rates of medical consumption over the period 1995-2009



Source : CSBM National Health Accounting 2009

# Breakdown of total medical consumption in France 2007



In 2007. drug consumption

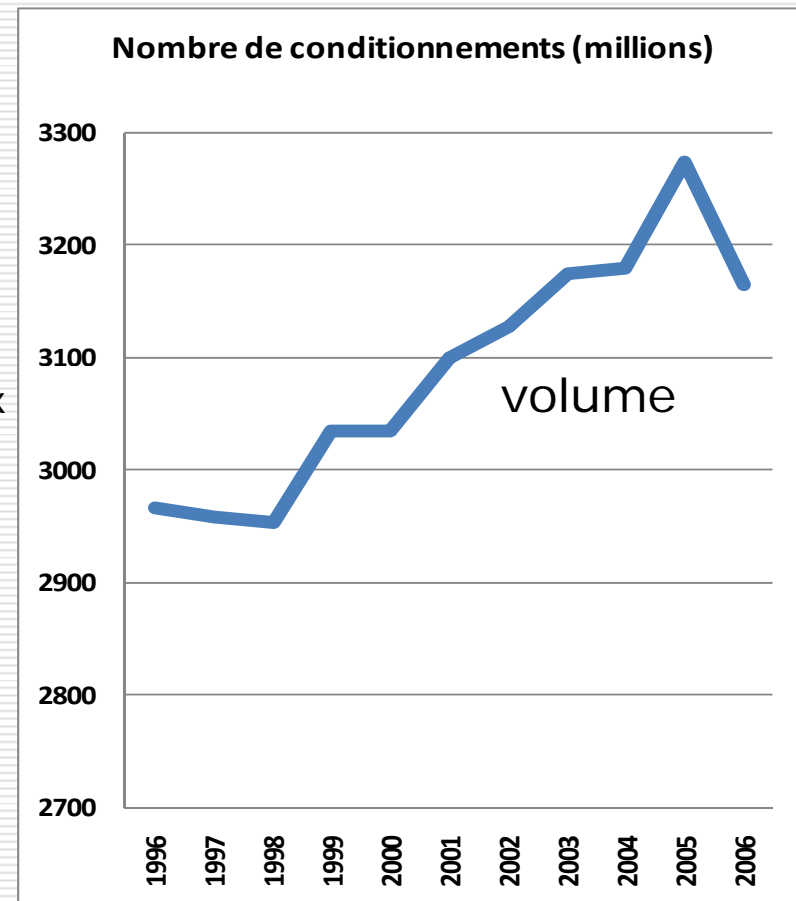
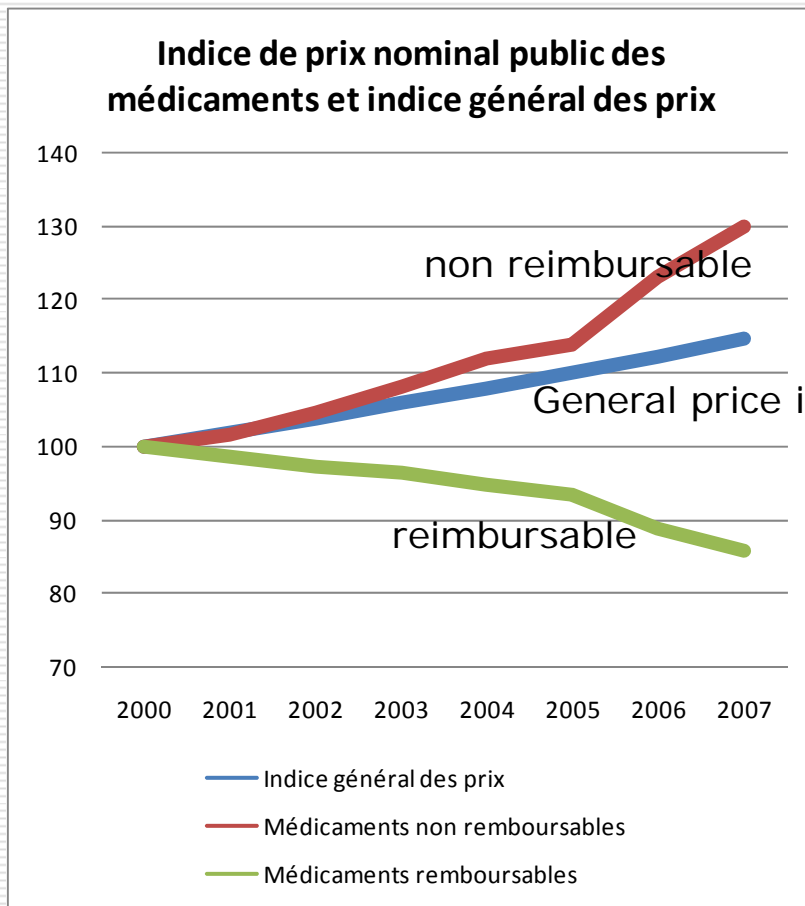
- 33.3 Billion Euros
- 20 % of the total medical consumption
- 1.83 % of GDP
- 525 € per capita



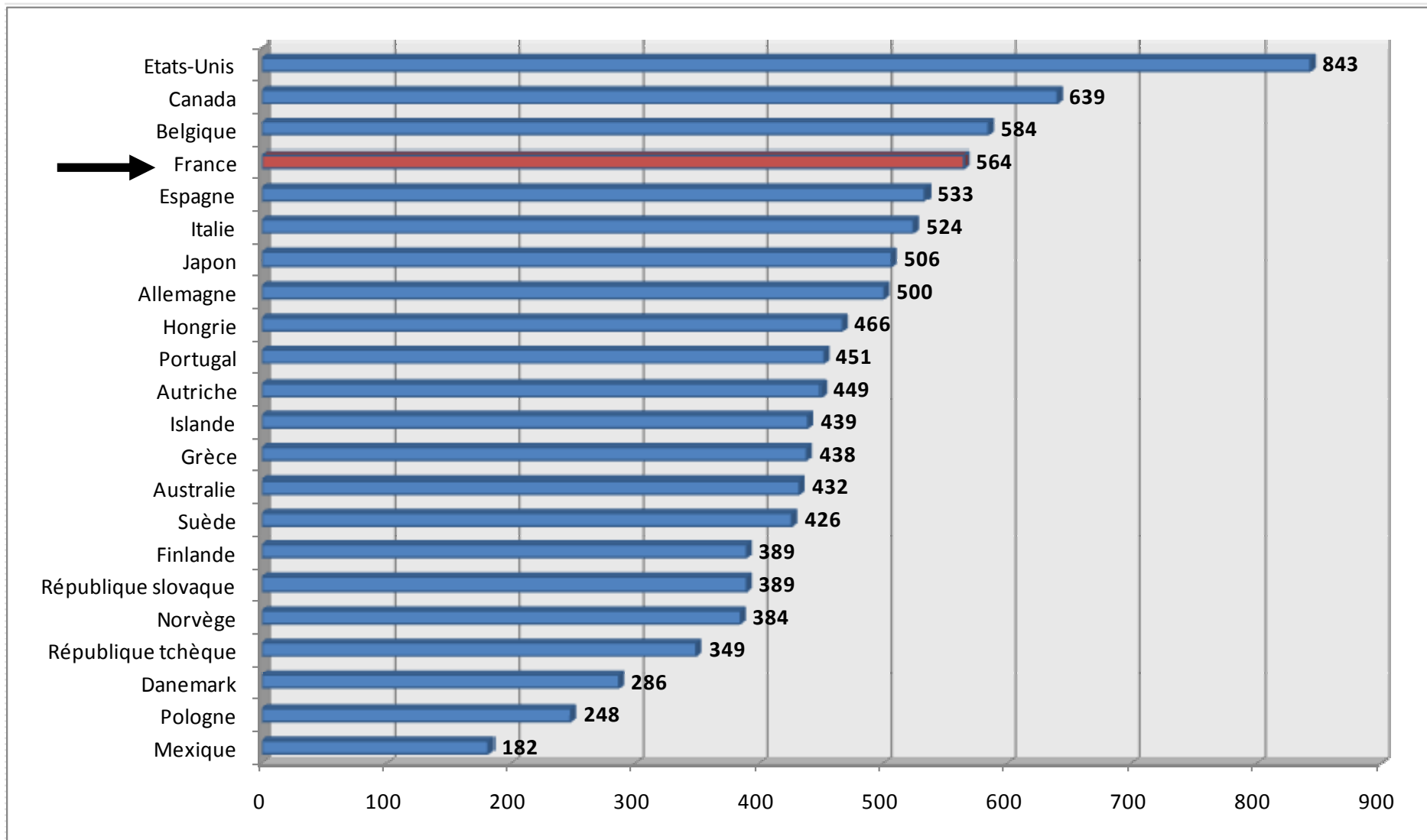
# Evolution of main categories of health expenditures in 2009

	<b>Volume</b>	<b>Price</b>	<b>Value</b>
<b>Hospital</b>	<b>+2.7%</b>	<b>+1.1%</b>	<b>+3.8%</b>
<b>Outpatient care</b>	<b>+2.2%</b>	<b>+0.8%</b>	<b>+3.0%</b>
<b>Transportation</b>	<b>+3.6%</b>	<b>+3.0%</b>	<b>+6.7%</b>
<b>Drugs</b>	<b>+5.2%</b>	<b>-2.6%</b>	<b>+2.6%</b>
<b>Other medical goods</b>	<b>+1.3%</b>	<b>+1.5%</b>	<b>+2.8%</b>
<b>Total</b>	<b>+3.0%</b>	<b>+0.3%</b>	<b>+3.3%</b>

# Evolution of drugs price index / volume in France(2000-2007)



# Per capita drug expenditures in 2006 (\$ PPP)



# Reason for the French appetite for drugs?

Results from a European GPs and general public survey  
(2004)

	France	Spain	Germany	Netherland
Mean annual Nb of visits to GPs	4.9	4.8	5.2	3.2
% visits including a drug prescription	90%	83.1%	72.3%	43%
Mean Nb of different drugs /prescription	1.6	1.2	1.2	0.9
% GPs declaring to feel a pressure from patients to prescribe	46%	36%	36%	20%

# A series of fragmented drugs sub-markets

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- ❑ Outpatient care (delivery by community pharmacists)/  
Inpatient care (hospital pharmacists)
- ❑ Hospital drugs reimbursed on top of DRG funding
- ❑ Drugs delivered by hospital pharmacist to ambulatory patients (« retrocession » of drugs prescribed only by hospital specialists »)
- ❑ Drugs reimbursable/non reimbursable
- ❑ Drugs with a mandatory prescription /non mandatory
- ❑ princeps / generics
- ❑ Prescription limited to specialists
- ❑ Prescription submitted to formal declaration (medicament d'exception)

# Overview of the French drug market from an industrial perspective

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- ❑ France has an important capacity for drug manufacturing (declining – lack of Biotech investment)
- ❑ 326 firms
- ❑ Sales revenues of € 47.3 billion (45 % from exports).
- ❑ 103,633 employees, including 22,594 in R&D.
- ❑ An added value of € 12.8 billion, i.e. 0.68% of commercial GDP.
- ❑ € 4.6 billion (12.3 % of sales revenues) invested annually in research for new medicinal products.

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# **Drug market regulation in France**

# The key role of the HAS

## (French HTA Agency)

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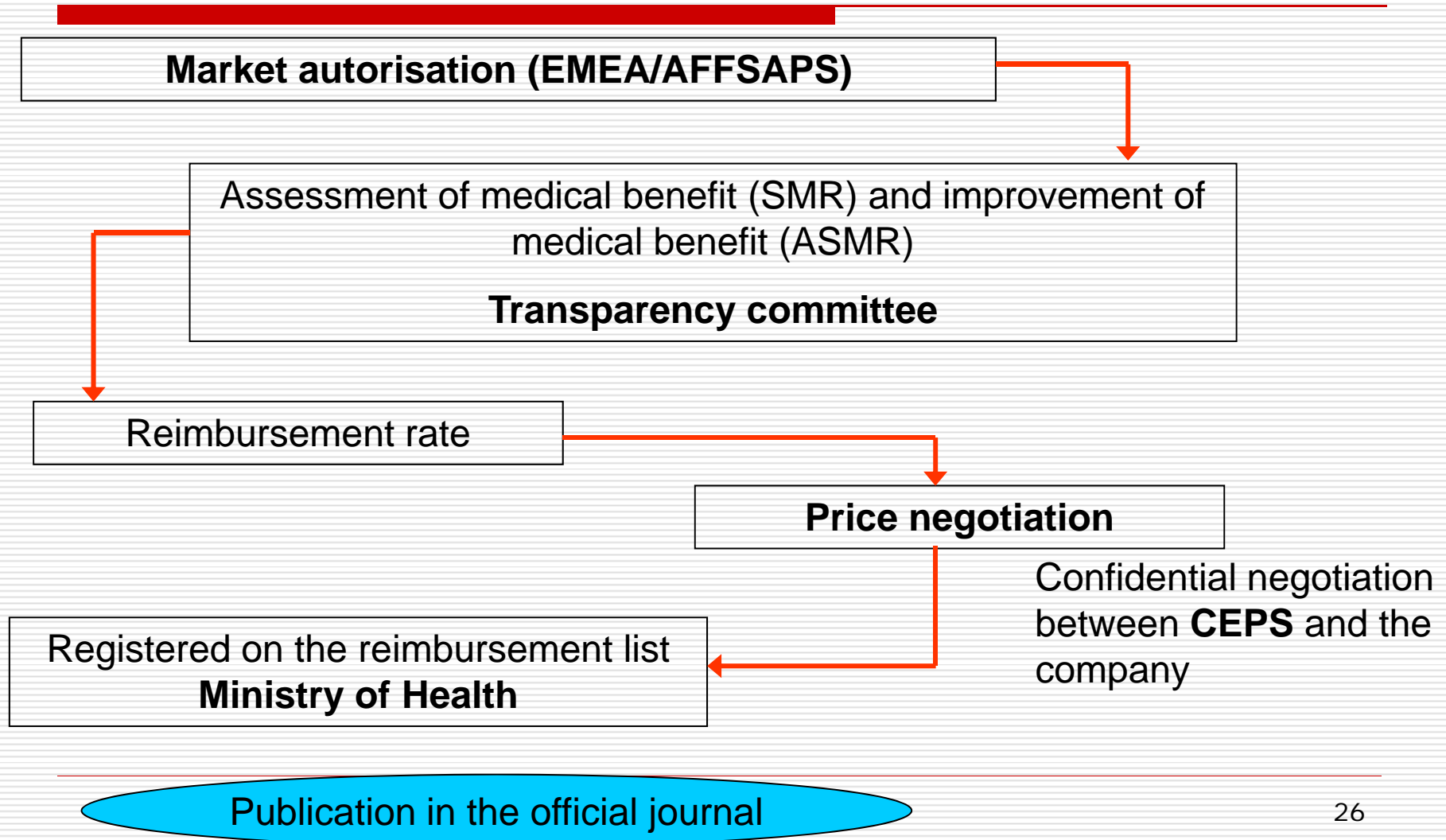
- **HAS (National Authority for Health)** is not a government body:
  - an independent public body with financial autonomy
  - mandated by law to carry out specific missions on which it reports to Government and Parliament
  
- A large range of activities:
  - assessment of drugs, medical devices, and procedures
  - publication of clinical guidelines
  - accreditation of healthcare organisations
  - certification of doctors
  
- It liaises closely with government health agencies, national health insurance funds, research organisms, unions of healthcare professionals, and patients' representatives



# HAS Assessment of Drugs

- ▶ **Initial listing: single technology assessment**
  - Timelines (less than 90 days)
- ▶ **Renewal: every 5 year (STA)**
- ▶ **Re-assessment of pharmaco-therapeutic classes (MTA)**
  
- ▶ **Proper use of drugs :**
  - Production of information for prescribers
  - Other HAS missions:
    - Certification of pharma sales representatives networks
    - Certification of Prescription softwares

# Retail drugs Pricing/ Reimbursement pathway





HAUTE AUTORITÉ DE SANTÉ

The legally binding text is the original French version

## TRANSPARENCY COMMITTEE

### OPINION

October 4, 2006

**[REDACTED] 150 mg, soluble powder for dilution for infusion purposes**  
**B/1 15 ml bottle (CIP: 562 103-7)**

**Applicant :** [REDACTED]

#### List I

Medicine for hospital prescription only.

To be prescribed only by oncologists or haematologists or physicians qualified in oncology.

Medicine requiring special monitoring during treatment.

First administration must take place in a hospital environment.

Date of the Marketing Authorisation (centralised): August 28, 2000 – Marketing Authorisation amendments: June 10, 2004 - October 22, 2004 - April 28, 2005 - May 22, 2006

Reason for request: Inclusion on the list approved for use by hospitals in the extension of indication:

"[REDACTED] is indicated for the adjuvant treatment of breast cancer with tumoral overexpression of HER2, after surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy (if applicable)."

# Content of a Transparency Committee Report

(accessible on internet)

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- 1. CHARACTERISTICS OF THE MEDICINAL PRODUCT
    - Active substance
    - Indications
    - Dosage
  - 2. SIMILAR MEDICINAL PRODUCTS
    - ATC Classification
    - Medicines in the same therapeutic category
    - Medicines with a similar therapeutic aim
  - 3. ANALYSIS OF AVAILABLE DATA
    - Efficacy: results of main clinical trials
    - Safety
  - 4. TRANSPARENCY COMMITTEE CONCLUSIONS
    - Actual Benefit (AB or SMR)
    - Improvement in Actual Benefit (IAB or ASMR)
    - Therapeutic use
    - Target population
    - TC Recommendations
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# Transparency Committee Recommendations

(detailed)

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- Scope of reimbursement (target group with reimbursement)
- Reimbursement rate (100/65/35/15%)
- Drug specific status (exception, reserved to ..)
- Request for a post-listing study

# SMR evaluation criteria

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- The transparency committee evaluates the degree of clinical utility (Actual Benefit or **SMR**) and medical benefit relative to other therapies (Improvement of Actual Benefit or ASMR)
- The **SMR** takes into account:
  - Efficacy and side effects;
  - Positioning of the treatment in the therapeutic strategy. particularly when compared with other available therapies;
  - Severity of the disease to which the treatment is intended ;
  - Preventive, curative or symptomatic characteristics of the treatment – public health interest
  - The SMR is qualified as important, moderated, low or insufficient to justify the different levels of reimbursement

# SMR and reimbursement rates

Service médical rendu	Severe condition	Non severe condition
Major (I) or important (II)	65 %	35 %
Moderate (III)	35 %	35 %
Low (IV)	35 %	35 %
Insufficient (V)	0 %	0 %

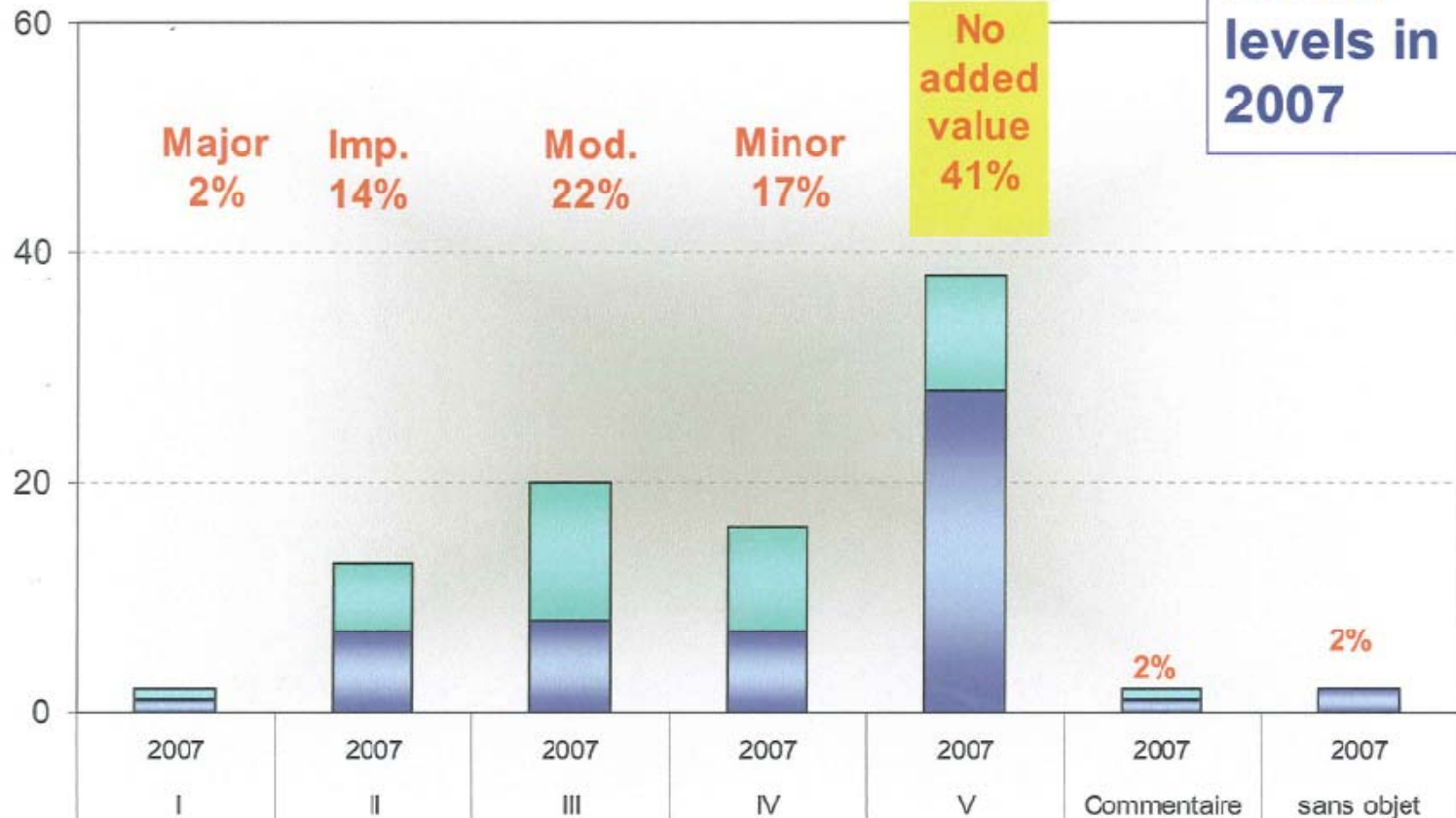
Patients presenting with a **severe / costly** disease included in a predefined **list of 30** diseases (ALD) benefit from full coverage for all medical expenses associated with treatment of this condition.

## Distribution of retail drugs according to reimbursement rate (2009)

	<b>Nbre of presentations</b>	<b>Market share (en %)</b>
<b>All</b>	<b>10 732</b>	<b>100.0</b>
<b>Non reimbursable drugs</b>	<b>2 673</b>	<b>9.0</b>
<b>Reimbursable drugs</b>	<b>8 059</b>	<b>91.0</b>
<b>15%</b>	<b>0</b>	<b>0.0</b>
<b>35%</b>	<b>1 308</b>	<b>11.3</b>
<b>65%</b>	<b>6 416</b>	<b>68.9</b>
<b>100%</b>	<b>335</b>	<b>10.9</b>



# ASMR for new drugs & new indications



# Drug pricing in France – The rules

## ▶ **Sale Price :**

- Set by the Economic Committee for Health Products after negotiation with the company.

## ▶ **Account is primarily taken of:**

- the 'ASMR' (improvement in actual benefit) of the medicine,
- the prices of medicines serving the same therapeutic purpose,
- forecast or recorded sales volumes
- foreseeable and actual conditions of use of the medicine.

## ▶ **ASMR and price**

- V (no added value) : can be listed only if it bring savings
- I, II, III (moderate to major added value): Higher price possible
- IV (minor added value)

# Incentives for use of generics

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- **1999**: community pharmacists allowed to substitute brand-name drugs by generics.
- **2002**: authorization for physicians to prescribe drugs defined in INN. (International Nonproprietary Name -ICD)
- **2003**: a system of reference prices, known as the Reference Pricing Rate (TFR – Tarif Forfaitaire de Responsabilité) introduced for generic groups with insufficient market penetration
- **2006**: agreement with the College of Pharmacists about an objective of 70% of substitution in a predefined list of drugs (associated with a modification of margins)
- **2007**: incentive for patient to avoid an advance payment of drugs in case of substitution by generics
- Regulatory price discount for brand-name drugs going to generics: **1999**: -30% **2002**: -40%. **2006**: -50%. **2009**: -55%.
- **2009**: Pay-for-performance system (CAPI) proposed to GPs including a target % of prescription of generics

# Comparison of generics use in Europe

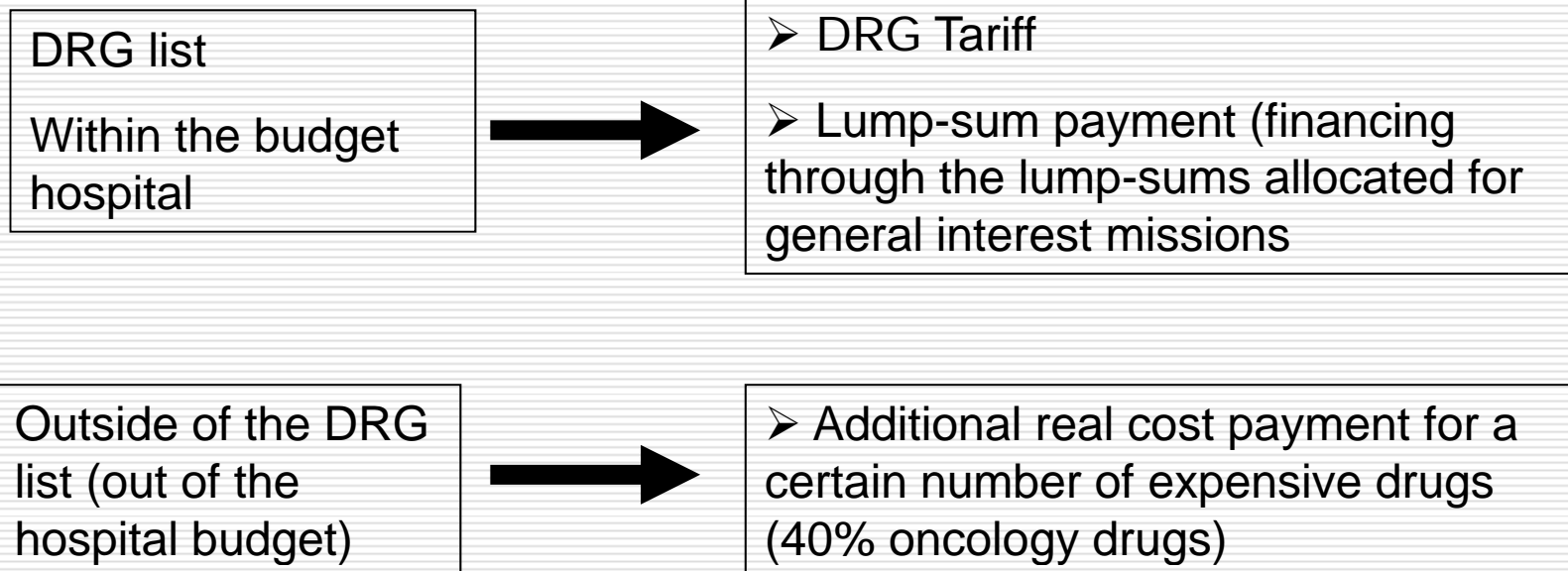
Sources : DSS/6B - IMS Health.

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<b>Countries</b>	<b>% generics (standard units)</b>
<b>All together</b>	<b>40</b>
<b>Germany</b>	<b>47</b>
<b>Denmark</b>	<b>53</b>
<b>Spain</b>	<b>34</b>
<b>France</b>	<b>33</b>
<b>Italy</b>	<b>31</b>
<b>Netherland</b>	<b>56</b>
<b>UK</b>	<b>49</b>

# Hospital funding system of drugs

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## Discussion: which role devoted to economic evaluation in the future?

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- How explain the reluctance of French Drug Authorities about cost-effectiveness?
- Reevaluation of class (statins, hypertension, etc)
- post-listing studies including impact on the system of delivery of care
- Availability of a comprehensive claim database for monitoring of medical practices and costs
- Risk-sharing and pay for performance approaches?