




## Medicines Policy

*Surviving the crisis*

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INFARMED, I.P. – National Authority for Medicines and Health Products

Vienna, 30<sup>th</sup> of September 2011



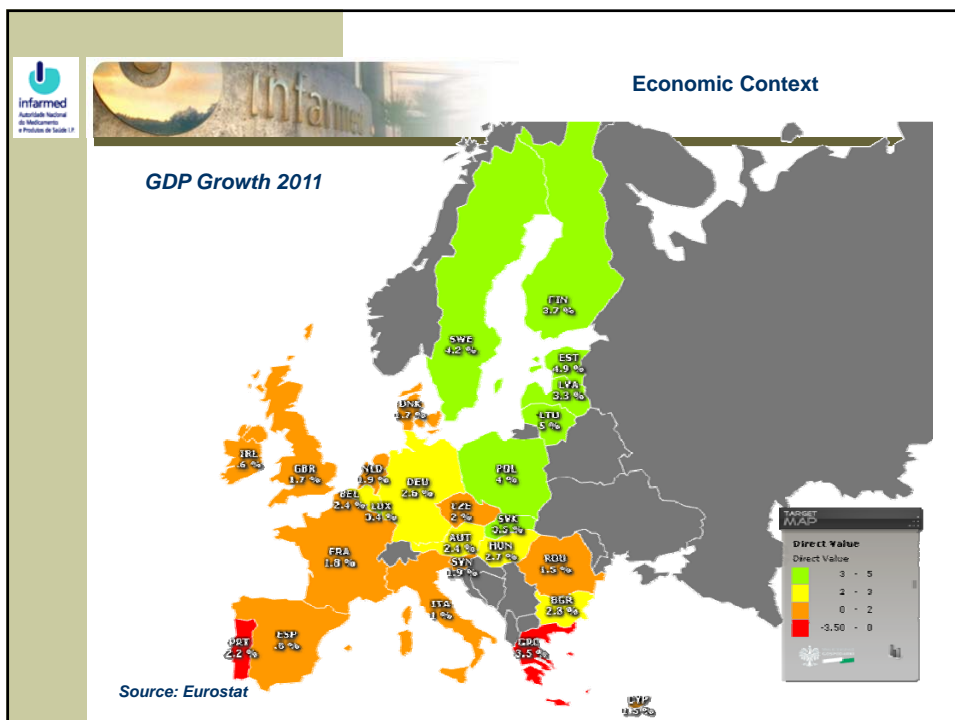
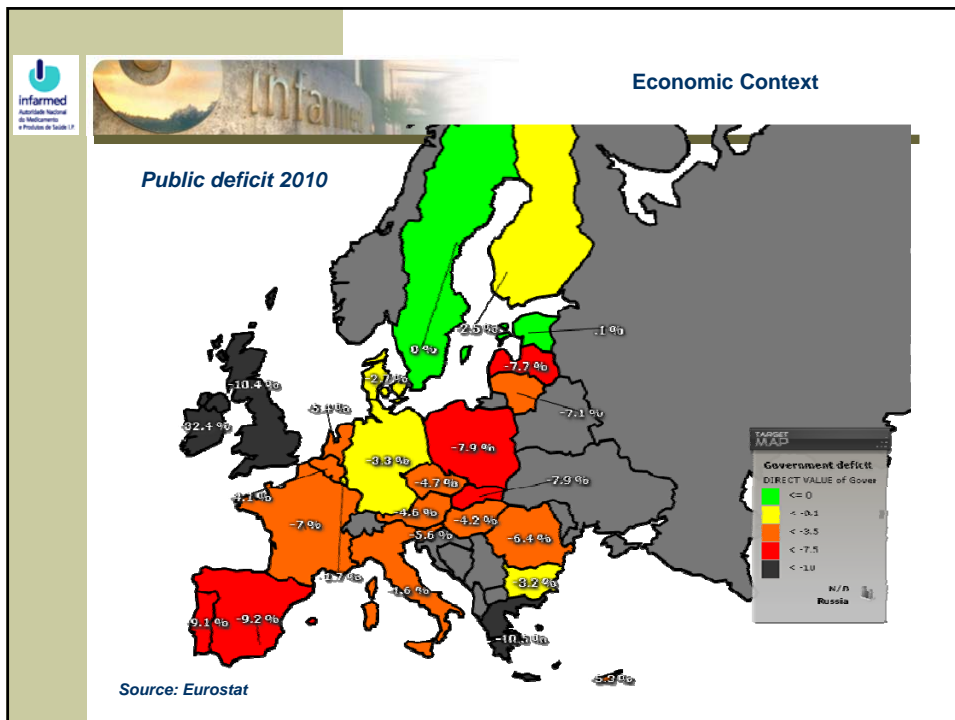
**PORTUGAL**  
10 Millions inhabitants

National Health Service  
Universal  
comprehensive  
free of charge  
covers 7 Millions inhabitants

Other Health Systems (Civil Servants, and other) responsible for 3 millions

All the inhabitants have the right to health to be delivered through NHS

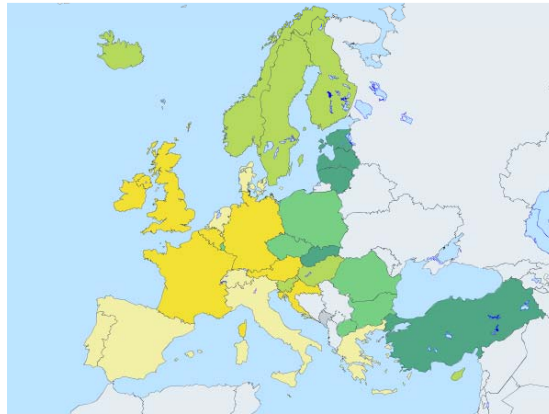
infarmed  
Autoridade Nacional  
de Medicamentos  
& Produtos de Saúde I.P.





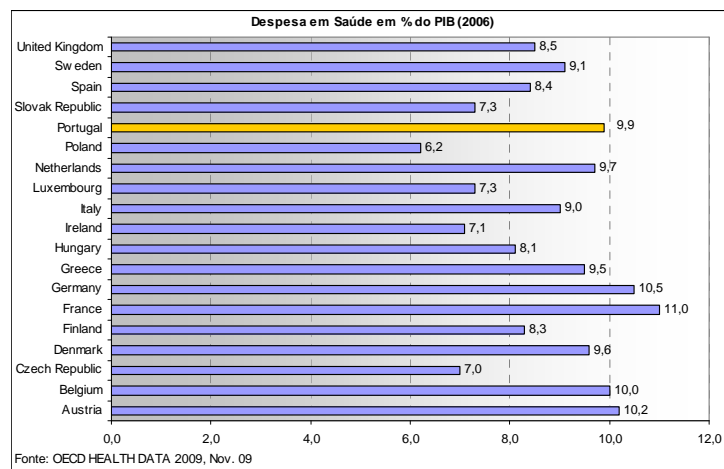
### Real GDP growth rate

Growth rate of GDP volume - percentage change on previous year - 2012



### Economic Context

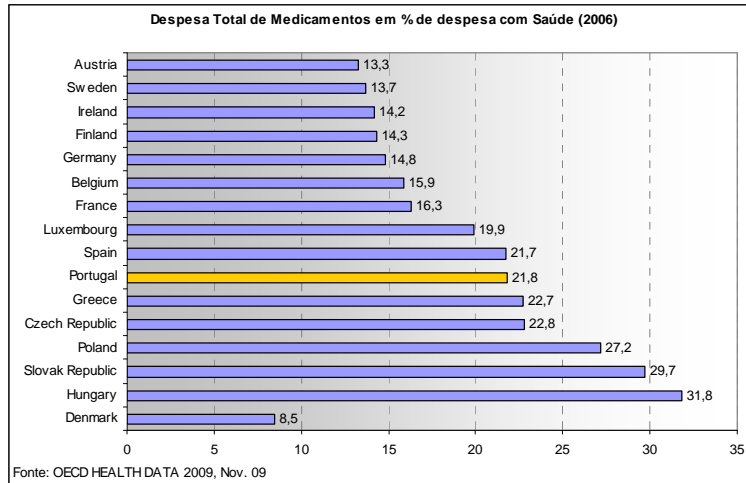
### Total Health Expenditure as % of GDP - 2006





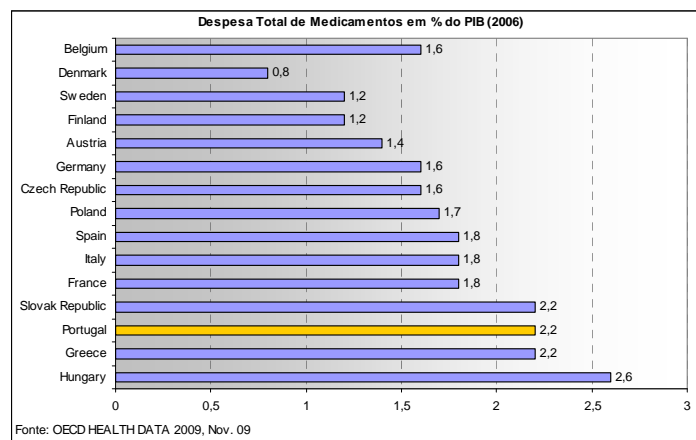
## Economic Context

### Total Medicines Expenditure as % of Total Health Expenditure - 2006



## Economic Context

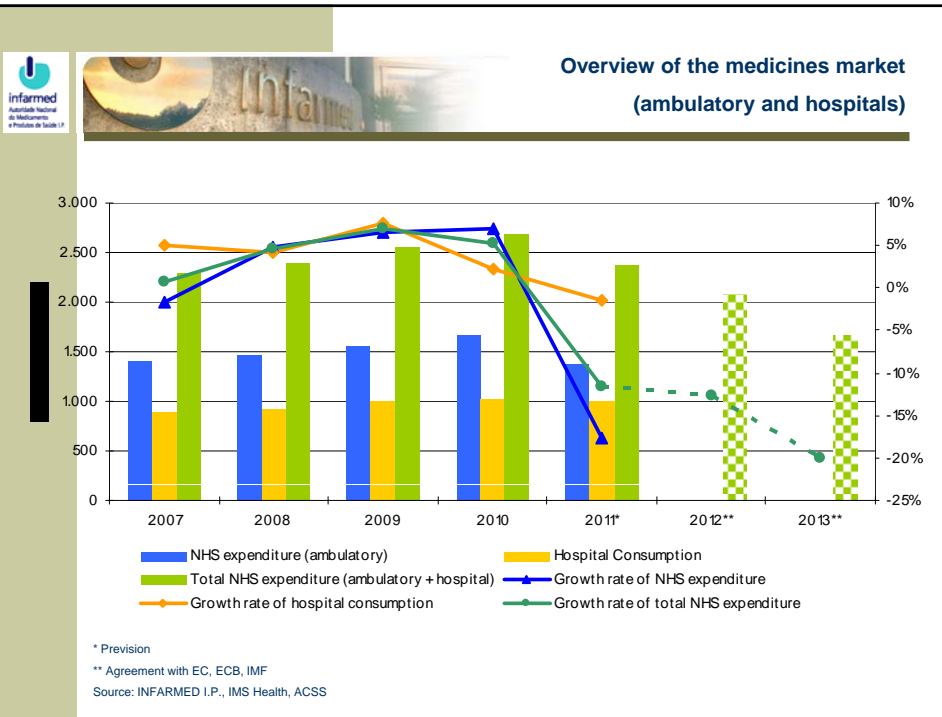
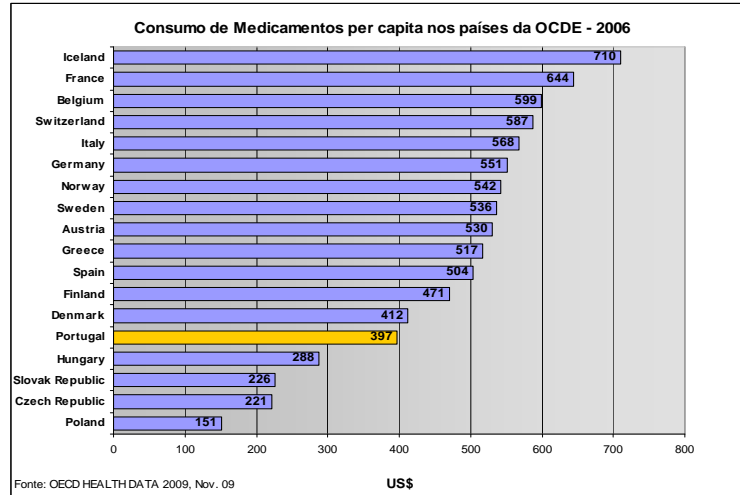
### Total Medicines Expenditure as % of GDP - 2006





## Economic Context

### Total Medicines Expenditure per capita - 2006





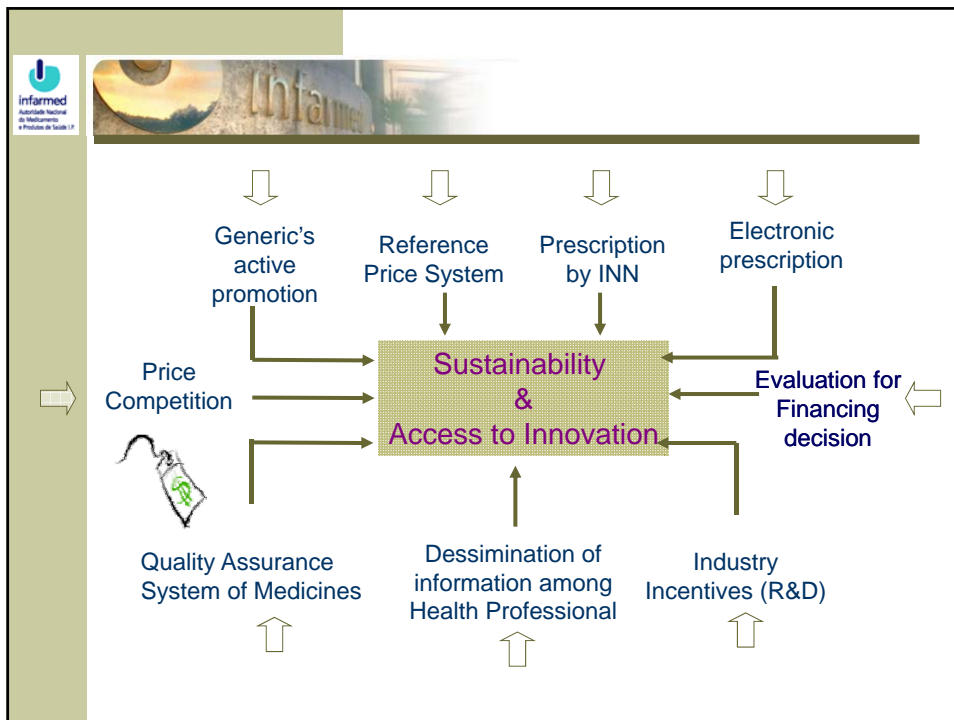
**📌 Reduction of the public health spending in medicines from 1,55% of GDP in 2010:**

- to 1,25% of the GDP until the end of 2012, around 525 Million€ reduction Vs 2010
- and to 1% of GDP in 2013, around 942 Million reduction Vs 2010

Note: With the measures already in place, Infarmed estimates a 20,3% decrease in the public health spending with medicines sold in pharmacies (aprox. 300M€).



- 📌 Generics maximum price is 60% of the branded medicine
- 📌 Change payment system to distribution and pharmacies
- 📌 Remove legal/administrative barriers to the Generics entrance in the market
- 📌 Establish guidelines for the prescription of medicines



- Types of implemented measures:**
- ✓ Protocols with industry – Sustained growth
  - ✓ Price reductions
  - ✓ Reduction of Reimbursement Rate Levels
  - ✓ Positive Reimbursement Lists
  - ✓ Promotion of Generics
  - ✓ Reference Pricing
  - ✓ Educational Campaigns for the Rational Use of Medicines
  - ✓ Dissemination of up-to-date Information to Healthcare Professionals
  - ✓ Development of Prescription Tools Supporting Prescribing Decisions



## NHS Sustainability & Access to Innovation

- Strong Therapeutic and Pharmacoeconomic evaluation
- Review therapeutic groups for reimbursement
- Price competition
- Quality Assurance System prescription of Medicines



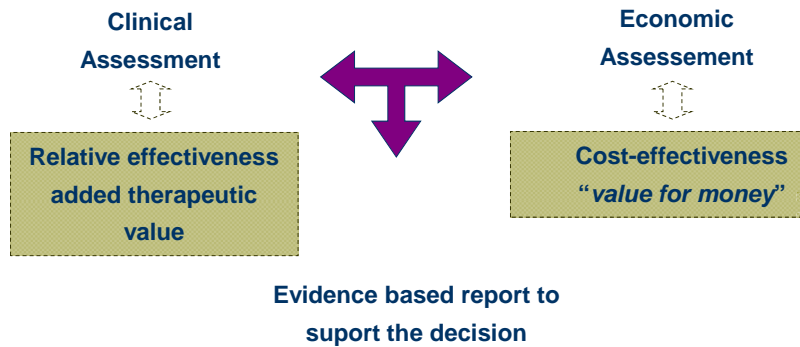
## Evaluation for Financing decision

- **Hospitals**  
NHS or third payer is **responsible for all the expenses** with in-patient consumed medicines
- **Pharmacies**  
NHS or third payer **is responsible for all or part of the expenses** with consumed medicines  
  
on the purchasing act the consumer does not pay or pay only a part of medicine's price





### Relative effectiveness and cost-effectiveness evaluation for reimbursement decision – ambulatory and hospital



### Clinical Assessment

- Identify if the medicine is for an unmet need
- Identify the relative effectiveness/added therapeutic value



Extent to which an intervention does more good than harm compared to one or more intervention alternatives for achieving the desired results when provided under the usual circumstances of health care practice.

*(Pharmaceutical Forum)*



## Economic Assessment

- Identify the value for money
  - Comparative price analysis for generics and medicines without added therapeutic value using equivalent daily posologies
  - Economic evaluation study for medicines that fulfil an unmet need or with added therapeutic value (innovative medicines) in order to identify the cost-effectiveness ratio
- Identify the implications for NHS budget



## Reimbursement level

- 📌 Reimbursement rates are 90%, 69%, 37% or 15%
- 📌 Reimbursement rate is increased by 5% (90%) or 15% (all other rates) for people earning retiring pensions below national minimum wage, which also have
- 📌 95% reimbursement rate on the 5 less expensive generics of the same homogeneous group



### Mesures Taken Q4 2010

- Decreased Anti – ulcer therapy from 69 to 37%
- Decreased Anti inflammatory from 69 to 37%
- Decreased Anti depressives from 95 to 37%
- Other changes in analysis



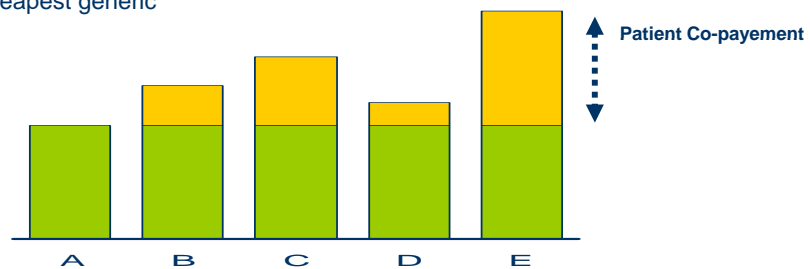
### General Rules

- Generic will be 50% (35% currently) cheaper than the reference medicine
- From the 5th Generic onwards applying for reimbursement decision, the price must be 5% cheaper than the latest generic submitted for reimbursement, regardless its decision
- There is an annual price revision based on the 4 reference countries (Spain, France, Greece and Italy)

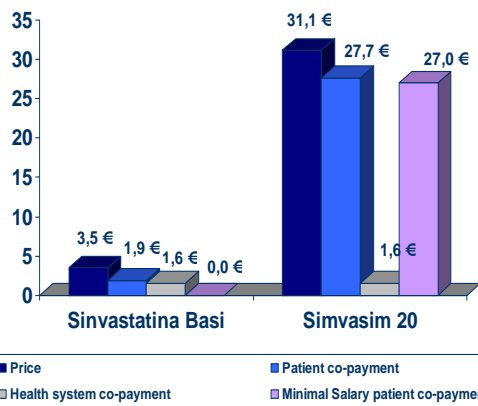


### Reference Price

- Reference price is set for the homogeneous group, which includes medicines with the same active substance, dosage, pharmaceutical form and administration route
- Reimbursement value is established by the average on the 5 cheapest generics ( from 2010 ) multiplied by the reimbursement rate
- Difference between to the medicines price (if higher) is to patient to pay
- Low income pensioners get 95% reimbursement for all classes if gives 5 cheapest generic

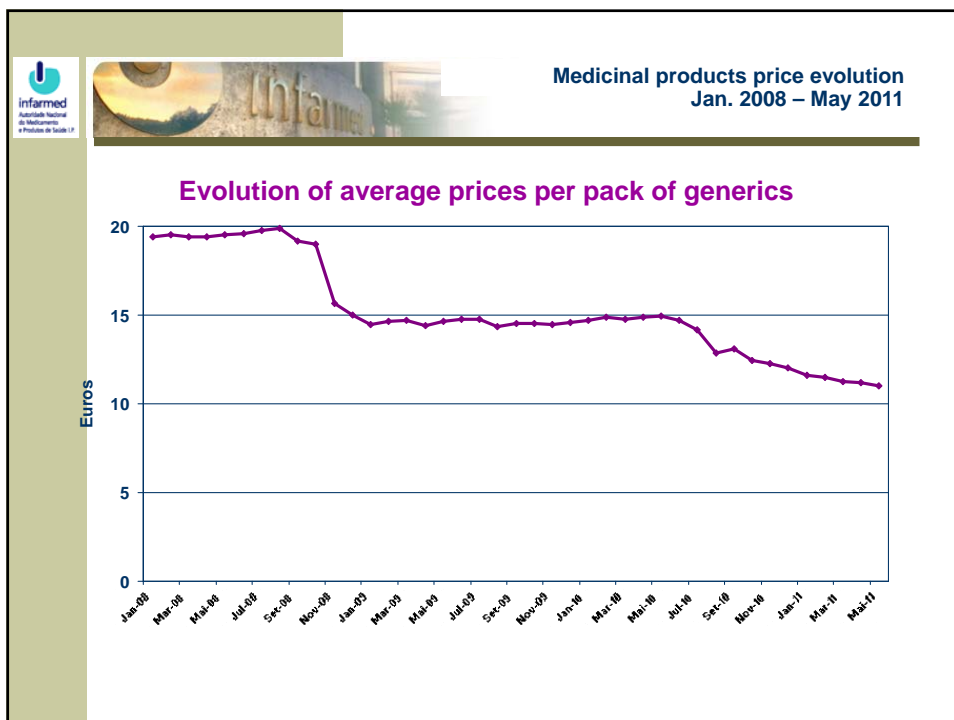
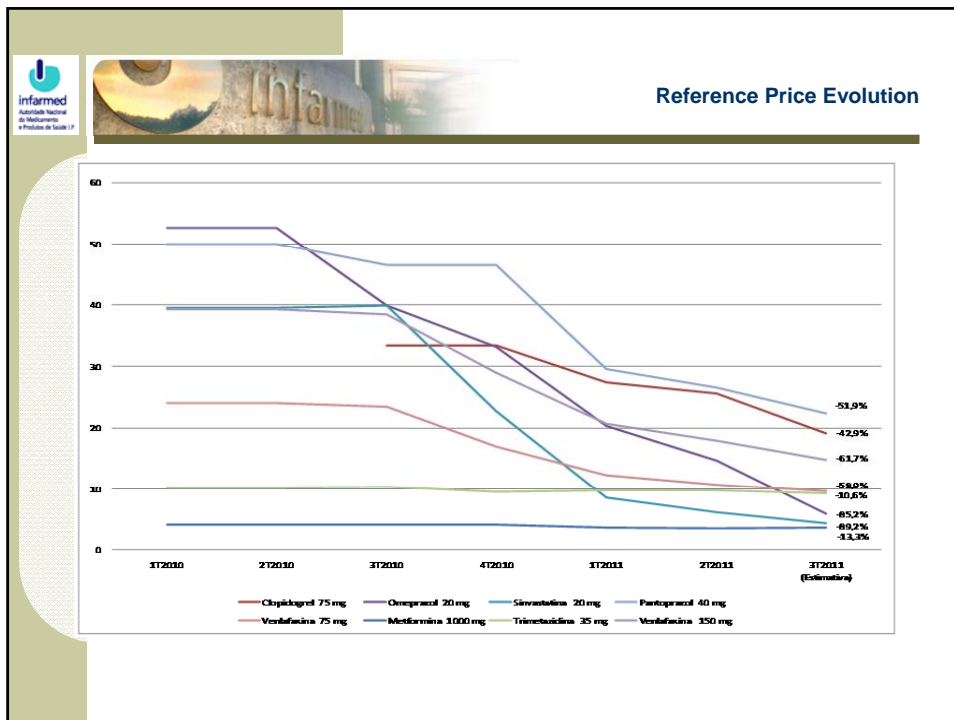


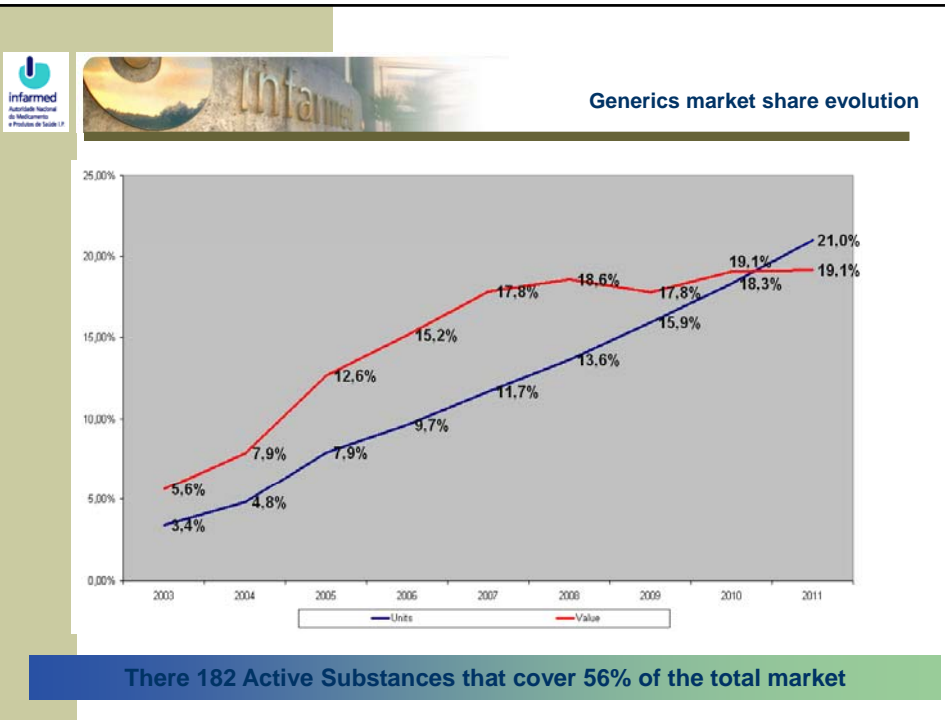
### Sinvastatine / 20 mg / 60 units



- Reference Price: 4,30€
- Reimbursement Rate: 37%
- Reimbursed value: 1,6€

Date: 15th September





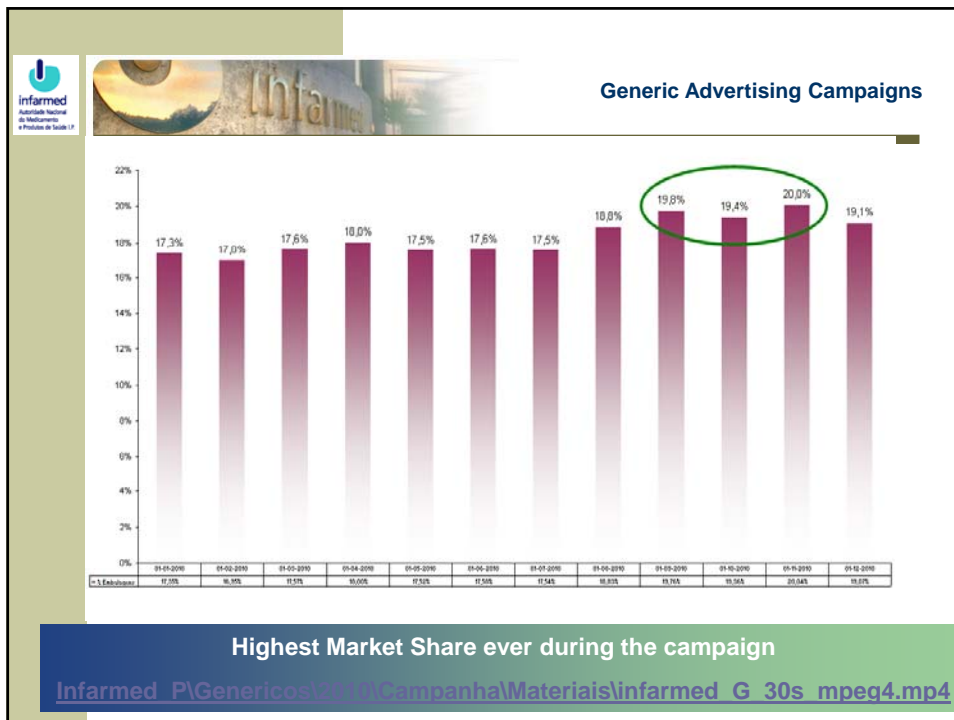
- ### Quality Assurance System prescription of Medicines
- Dissemination of information among Health Professionals
  - Generics advertising campaign
  - IT support to prescribers
  - Therapeutic guidelines
  - IT tools to monitor prescription



Dissemination of information to Healthcare Professionals



Advertising Campaign	Target	Materials	Year
Generic Medicines, find the differences	Patients	TV and POS material	2001
Generic Medicines, people deserve it	Patients	POS	2002 - 2003
Generics, equal quality different price	Patients	TV, Radio, Press and POS material	2004
Quality, Safety and Efficacy. Generics. You can trust.	Patients	TV, Radio, Outdoors and POS material	2007 - 2008
Don't you think that being ill already costs enough	Patients / Health Professionals	Internet and POS	2009
You save, we all save	Patients	<u>TV and Radio</u>	2010



**IT support to prescribers**

**Electronic Medical Prescription**

Development of prescription tools to support prescribing decisions

On-line prescription system:

- Up-to-date information
- Doctors get alerts pop-ups on the cheapest medicinal products
- Information given to the patient also included in the medical prescription about the amount that could be saved if the doctor would have chosen the cheapest medicine





## Electronic Prescription - price information

### Dissemination of information to Healthcare Professionals



## Additional measures being evaluated

- Changes in the distribution and pharmacies margins (MoU)
- Decrease in price of originals to generic level when first generic comes to the market
- Homogeneous groups to be created by therapeutic equivalence
- Lower price level for marginal innovation