

The impact of pharmaceutical policy measures: a structural-break approach

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Motivation

- Health care spending has grown 5x over the last 30 years
- Pharmaceutical spending is an important part of it and more so in Portugal than elsewhere
- Concerns with increasing health expenditure has lead to interventions aimed at controlling it
- This is clearly visible in the pharmaceutical market as well

Motivation

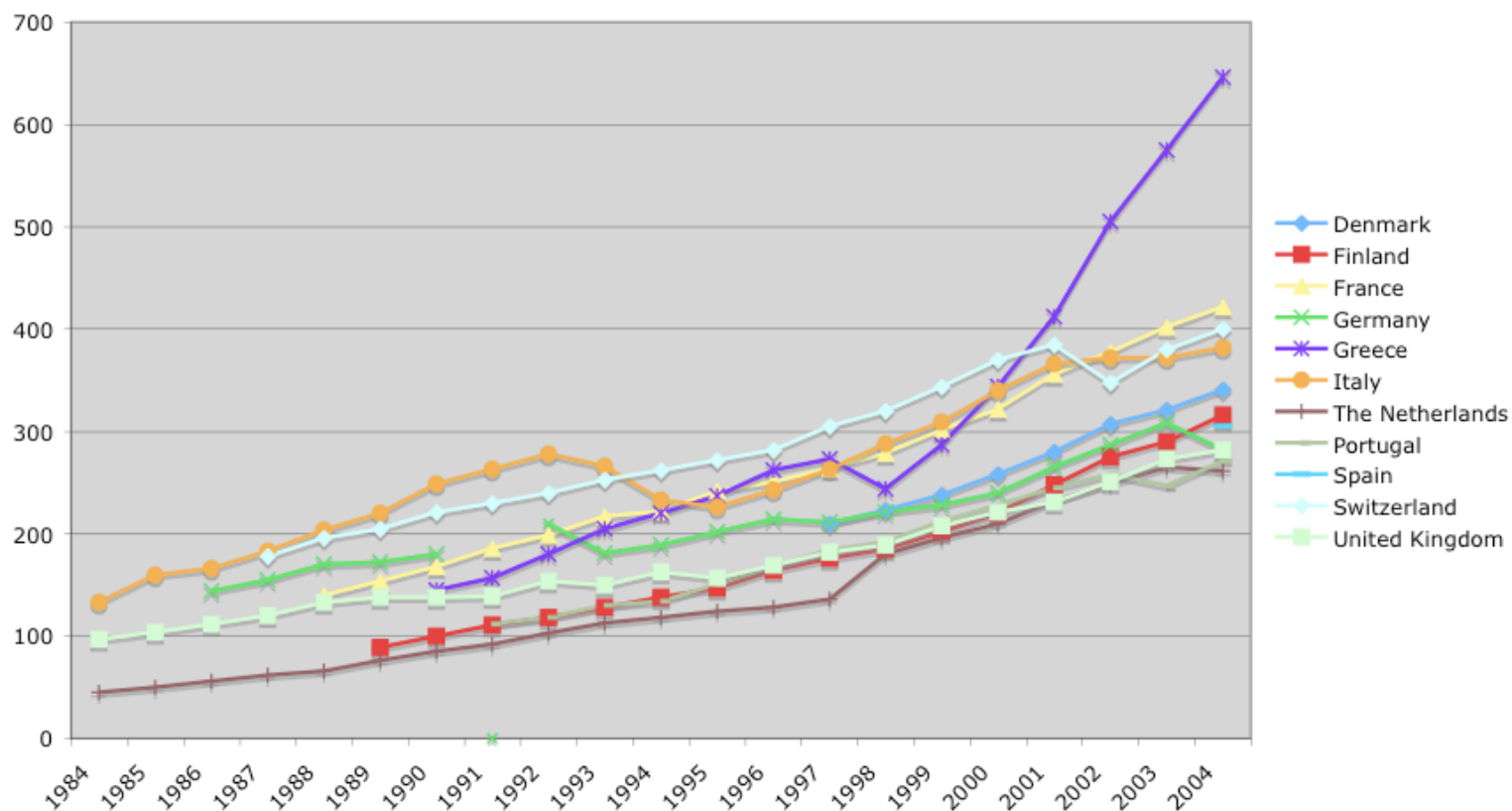
- The main question is WHAT WORKS?
- Here, in terms of policy measures aimed at the pharmaceutical market
- Our main conclusion:
 - Most measures do not work
 - Only one type of measures seems to produce effect

Agenda

- Some information on the pharmaceutical market
- Some information on the policy measures adopted
- Description of methodology
- Results
- Concluding remarks



Per capita expenditure (USD Purchasing Power Parity)



Per capita expenditure increased nominally 3x – 4x



Common pattern: strong growth

- Mossialos et al. 2006 – review of measures across countries
- most policies have no impact, or at the most only a temporary effect
- The “prescription” from Mossialos *et al.* (2006): a) create the conditions for competition in the generics market and b) integrate price and reimbursement decisions for on-patent pharmaceutical products

- Both have also been attempted in the Portuguese market
- Reference pricing – As market-based mechanism – reimburse only up to a level, after it consumer pays all difference – keeps competition at the margin while giving insurance protection
- Generics promotion – substitute cheaper product for branded, ex-patented, product

General types of intervention

- Demand side
 - Patients: co-payments and education programs
 - Medical profession: pharmaceutical budgets, protocols for prescription and promotion of generic drugs
- Supply side
 - Price controls, profit controls, entry controls (white list / black lists), regulation of detailing and marketing

Major measures in Portugal

- (since 2005)
- Enactment of regulation promoting the use of generics
- Introduction of reference pricing system
- Overall agreement between Government and industry to limit growth of public spending
- Administrative cuts in prices (unilaterally decided by Government – 6% in late 2005 and 6% in early 2007, 30% in generics in 2008)

Questions

- Can we see any change in aggregate series of pharmaceutical spending?
- If there is a change, can it be linked to a particular measure?
- Are the market-based mechanisms able to work?

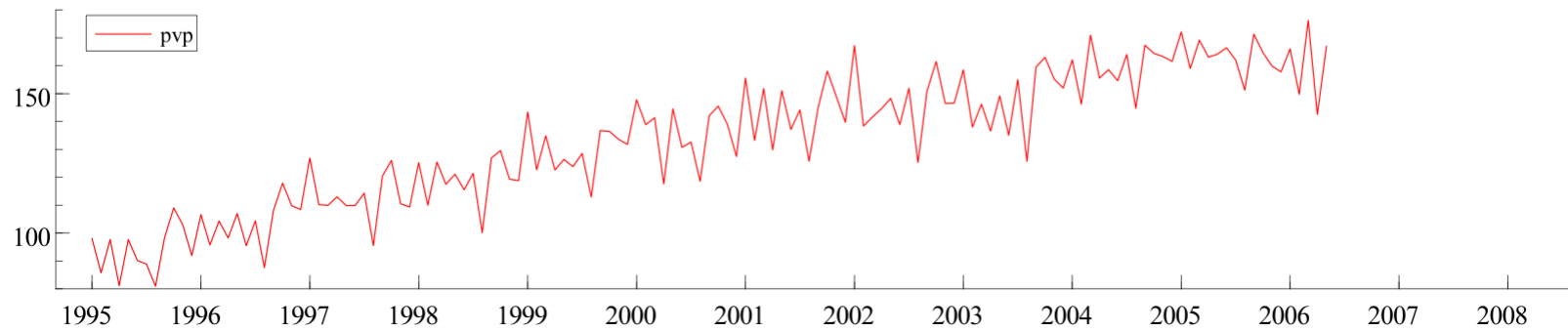
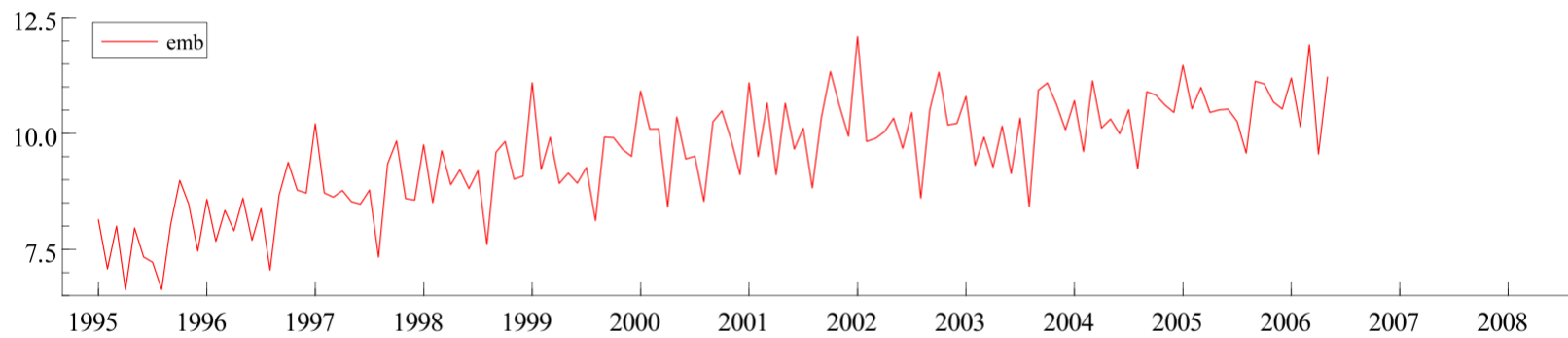
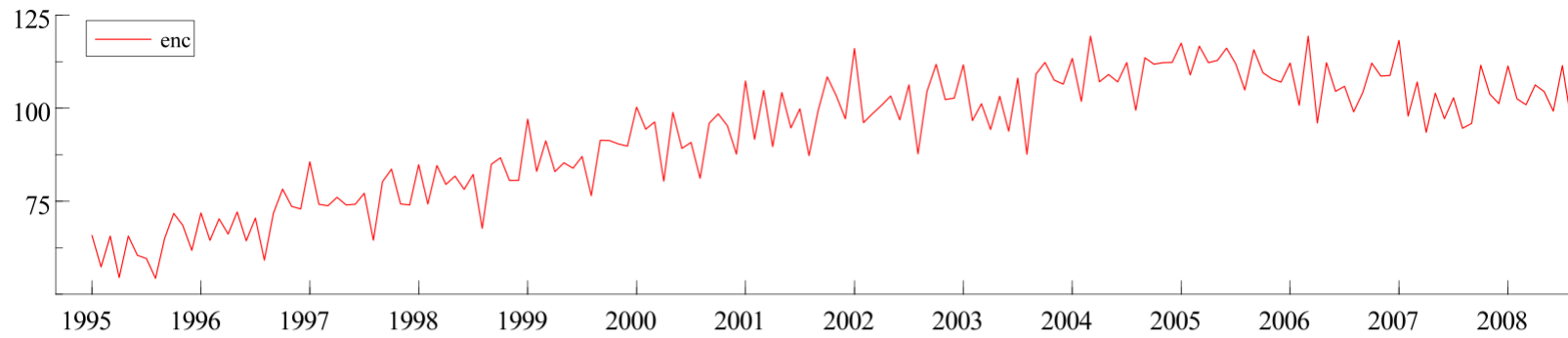
Methodological approach

- Use three data series: payments made by the NHS, total sales and number of boxes sold (proxy for quantity)
- Publicly available data from Infarmed
- Deflate series with CPI
- Take logs and see common movements across time
- Look for breaks in series – if they are found, can a policy measure be associated with it?



Methodological approach

- Endogenous structural breaks in series, looking simultaneously at the three series
- All three series have a similar pattern: growth up to 2005, then levels up
- 2003 seems to have something special



Methodological approach

- Basic structural model (Harvey 1989) – stochastic trend + seasonal component + error

$$y_t = \mu_t + s_t + \varepsilon_t, \quad \varepsilon_t \sim \text{NID}(0, \sigma_\varepsilon^2)$$

μ_t	$=$	$\mu_{t-1} + \beta_{t-1} + \eta_t$	$\eta_t \sim \text{NID}(0, \sigma_\eta^2),$
β_t	$=$	$\beta_{t-1} + \zeta_t$	$\zeta_t \sim \text{NID}(0, \sigma_\zeta^2),$

$$s_t = s_{1t} + \dots + s_{6t}$$

$$\begin{pmatrix} s_{j,t+1} \\ s_{j,t+1}^* \end{pmatrix} = \begin{bmatrix} \cos \lambda_j & \sin \lambda_j \\ -\sin \lambda_j & \cos \lambda_j \end{bmatrix} \begin{pmatrix} s_{j,t} \\ s_{j,t}^* \end{pmatrix} + \begin{pmatrix} \omega_{j,t+1} \\ \omega_{j,t+1}^* \end{pmatrix}$$

with frequency $\lambda_j = \pi j / 6$, for $j = 1, \dots, 6$

- Structural changes – dummy variables, $I = 1, \dots, K,$

$$y_t = \mu_t + s_t + \sum_{i=1}^K \alpha^i I_t^i + \varepsilon_t$$

- Outlier observation – 1 in one period, 0 others
- Level change – 1 in one period, 1 afterwards
- Temporary change – affects the level, but not the slope



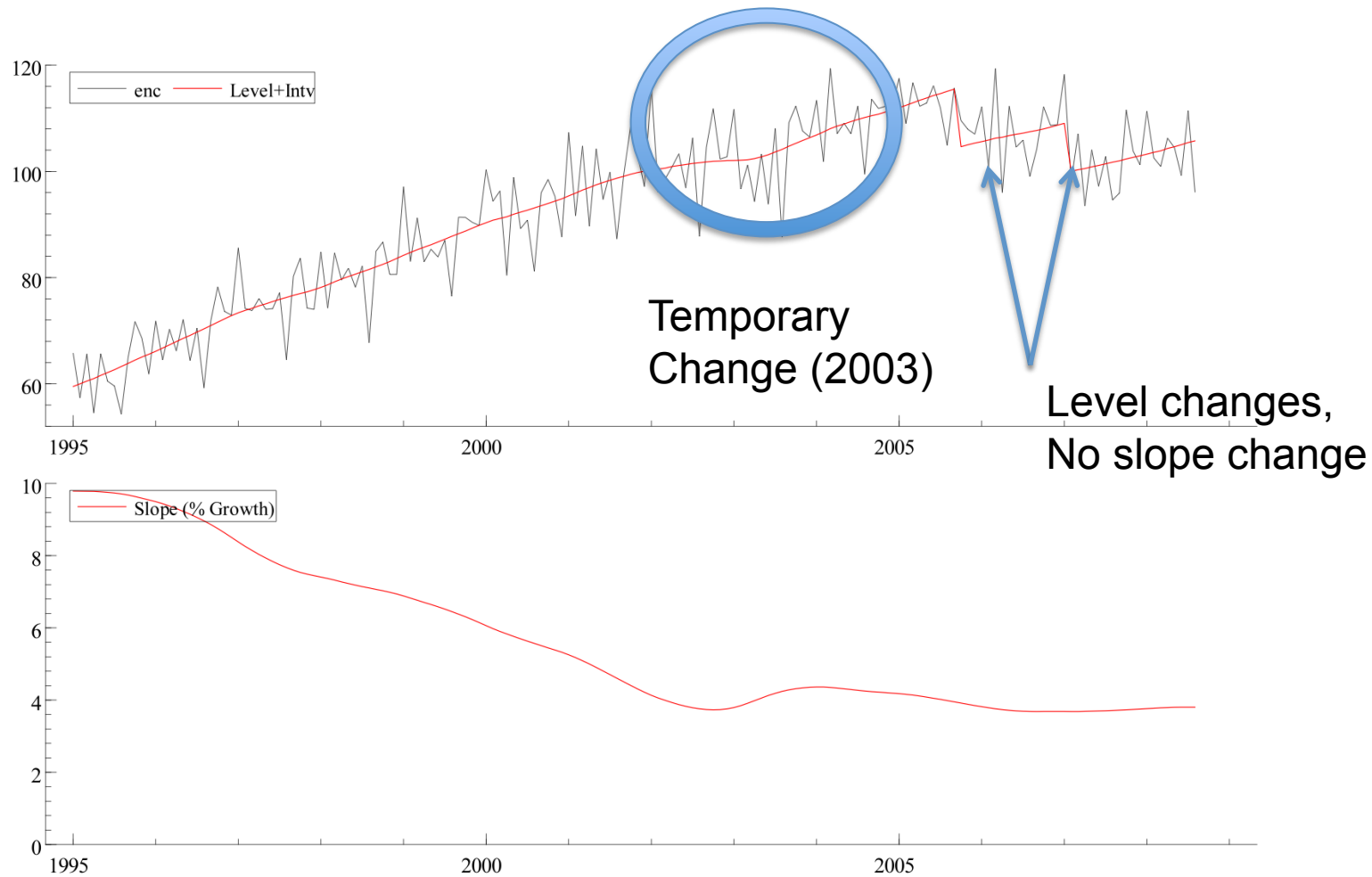
- Number, type and location of structural changes are determined endogenously
- Steps:
 - 1) estimate model with no breaks
 - 2) use residuals to identify location and type of structural changes
 - 3) estimate the model with changes
 - 4) re-estimate keeping only significant changes
- Do it next in multivariate setting

Results

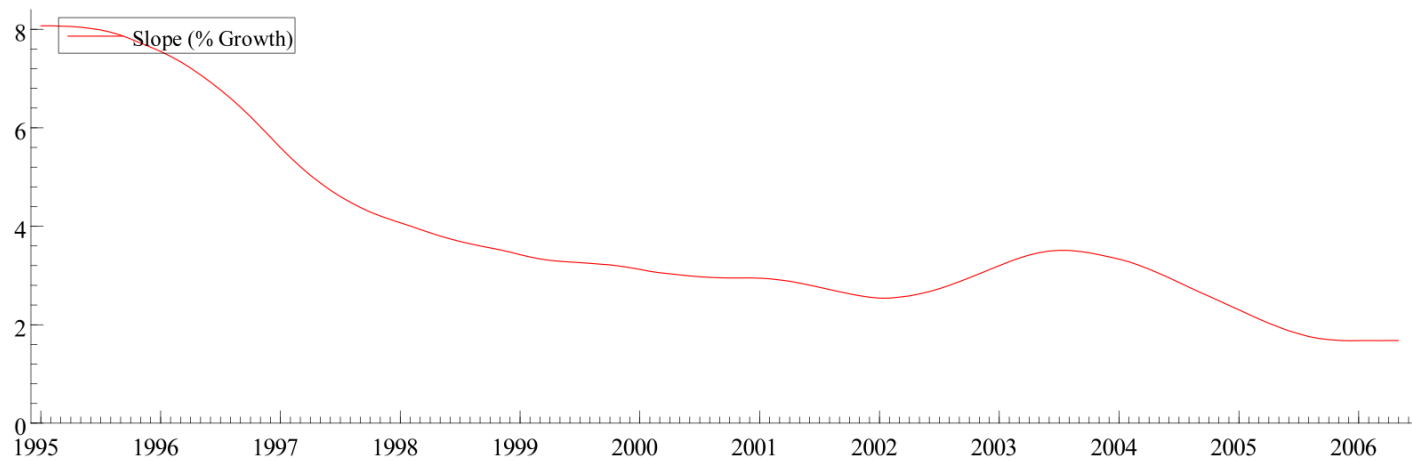
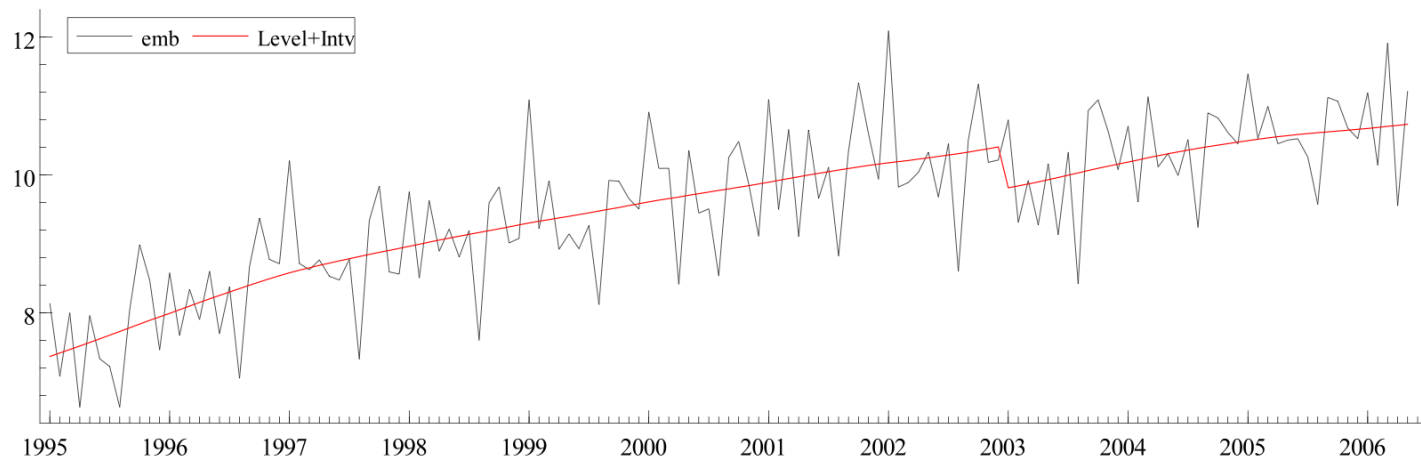
- Individual series
 - Outlier – April 2004 / total value of sales
 - Level shifts:
 - total value of sales and payments by the NHS on October 2005;
 - payment by the NHS on February 2007
 - No trend changes



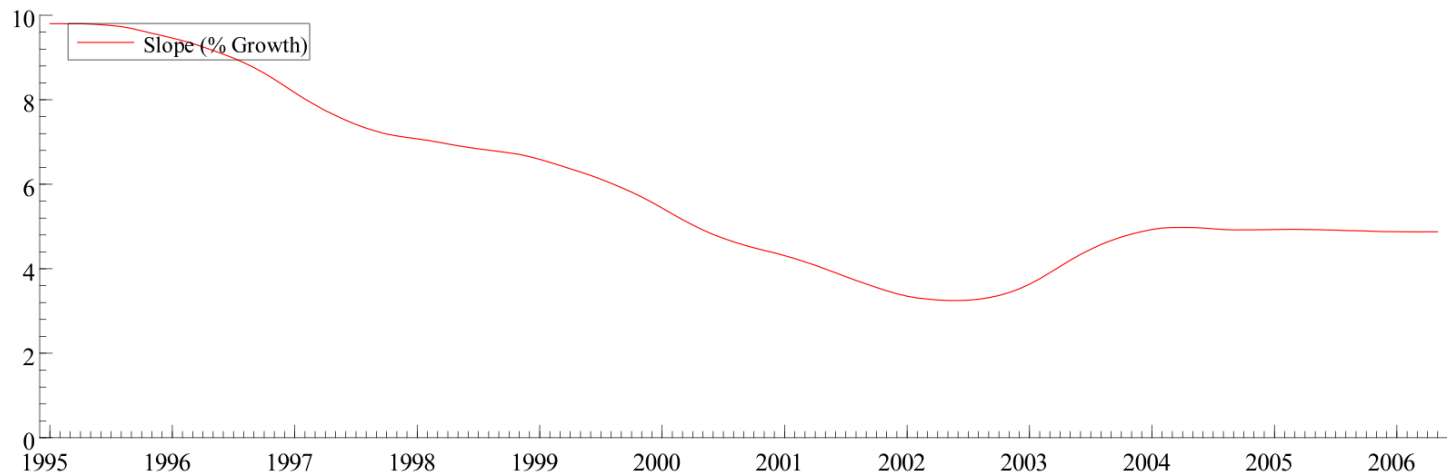
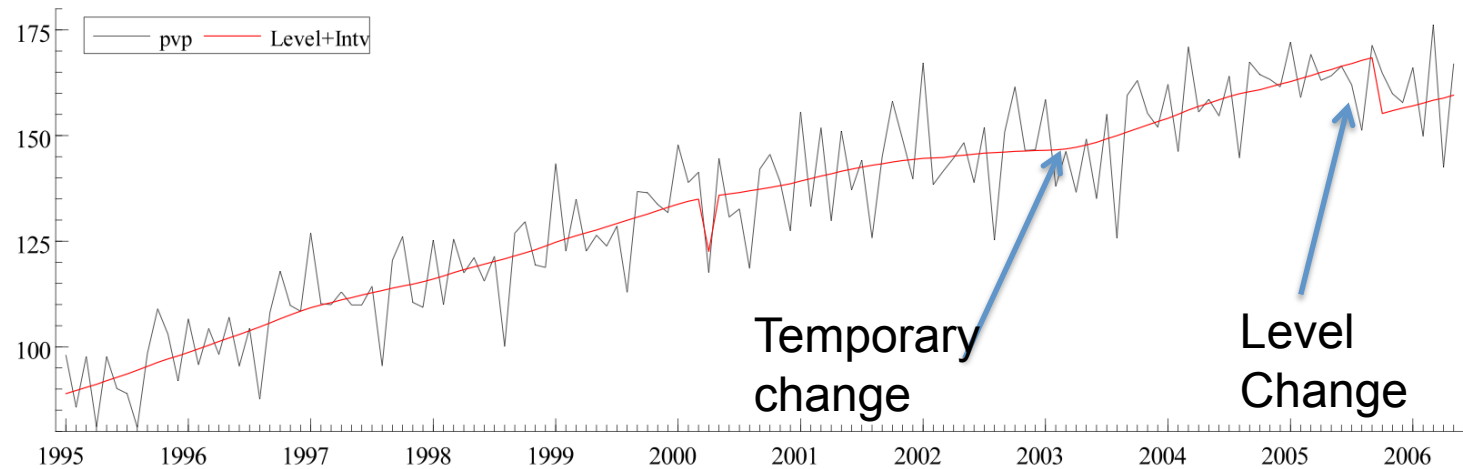
NHS payments



Number of boxes



Total sales values



Can we match this with measures?

Date	Legal document	Content
7 th October, 1998	Law-Decree 305/98	Changes in the co-payment regime. It imposes the need for an economic evaluation study for drugs to be listed for NHS reimbursement.
1 st September, 2000	Law-Decree 205/00	Changes in the co-payment regime, giving 10% more in the reimbursement rate to generics.
5 th September, 2000	<i>Ordinance</i> 79/2000	Price changes: new pharmaceutical products must be at least 5% cheaper than existing alternatives in the market. Rules for delisting are also established.
7 th June, 2001	<i>Ordinance</i> 577/201	Price changes, namely the rules for generic drugs' prices (generics' prices must be at least 35% below the price of the branded drug).
5 th December, 2002	<i>Ordinance</i> 1492-A/2002	Establishes changes of pharmaceutical prices, with increases in most cases between 1.5% (products with prices in the range 5-10€) and 5% (products with prices below 5€).
2 nd December, 2002	Law-Decree 270/02	Creates the <u>reference pricing system</u> , reinforcing the role of generic drugs. The <u>reference price</u> in each homogeneous group of pharmaceutical products is determined by the highest generic price). Further legislation connected to this piece below. The system became effective in <u>March 2003</u> .

27 th September, 2003	Law-Decree 234/03	Extends the application of the Law-Decree 270/2002 (use of the reference pricing system) to public health subsystems.
1 st December, 2003	<i>Ordinance</i> 914/2003	Establishes changes in price setting for generic drugs (imposing that new generic products cannot enter with a price above the reference price).
6 th February, 2004	Law-Decree 31/04	Extends for one more year an extra co-insurance rate of 25% for generic drugs bought by elderly people.
21 st December, 2004	<i>Ordinance</i> 1471/2004	Establishes the rules to be followed in the definition of boxes of pharmaceutical products that have a share of their price reimbursed by the Government.
21 st December, 2004	<i>Ordinance</i> 1474/2004	Redefines the groups of pharmaceutical products, following the adoption of a new pharmacotherapeutic classification. Does not change the set of products covered by the NHS.
27 th June, 2005	<i>Ordinance</i> 618-A/2005	<u>Sets an administrative price reduction of 6% in all pharmaceutical products. Complemented with <i>Ordinance</i> 826/2005 of 14 September, about sales of existing stocks at previous prices (until 31.10.2005). Effective 15.10.2005.</u> It opens an exception for products of companies investing more than 5M€ in R&D in Portugal. It reduces margins for wholesale and retail distribution.
11th August, 2005	<i>Law-Decree</i> 129/05	Changes again the reimbursement system: reduces by 5% the highest co-insurance rate of the NHS coverage of pharmaceutical products. Eliminates the extra coverage rate associated with generic products. It provides additional reimbursement coverage for the poor elderly (defined as those with pensions below the minimum wage).



10th February, 2006	<i>Protocol</i> nº7/2006	Agreement between the pharmaceutical industry and the Government to set a ceiling for the growth of public spending with pharmaceutical products. If the growth of public pharmaceutical expenditure exceeds a limit, then a fraction of that excess is paid back by the industry.
4 th July, 2006	<i>Decree-Law</i> 127/06	Reduces from 30% to 20% the extra co-insurance rate given to generic drugs acquired by NHS patients included in the special regime (poor and pensioners).
5 th January, 2007	<i>Ordinance</i> 30-B/2007	<u>Reduces the price of all pharmaceutical products included in the NHS coverage by 6%.</u> It reduces wholesale and retail margins. Effective <u>31.01.2007.</u>
14 th March, 2007	<i>Law-Decree</i> 65/07	Imposes a mandatory price reduction in prices of generic drugs whenever their market share gets above a certain threshold. Changes the international referencing procedure for pricing of new drugs.
19th March, 2007	<i>Ordinance</i> 300-A/2007	Establishes the possibility of pharmacies giving price discounts on the pharmaceutical products they sell (making prices set by the Government maximum prices instead of fixed prices) and details reductions of generic prices according to market share (as set by the general principle laid down in <i>Law-Decree 65/07</i>).

What works?

- A temporary effect in early 2003 coincides with the start of the reference pricing system
- But it lasts for about 6 - 9 months
- the underlying growth rate did not change (no break in slope), the historical trend resumed shortly thereafter

What works?

- No structural change in aggregate series (value of sales, number of boxes, payments by the NHS) are traceable to generics
- Generics sales have increased
- Compensated by other sales to keep total aggregate sales in historical trend
- (how?: question for future research)

- As no systematic change in the “quantity” measure (number of boxes sold) took place
- Conjecture: a move in sales from relatively low-priced drugs to high-priced ones following the 2007 administratively determined price decrease

What works?

- Market-based mechanisms seem to have at best temporary effects
- October 2005 & February 2007 – administrative price reductions of 6% each
- Change the level but not the slope – reduces nominally expenditure; does not control the underlying growth drivers
- the agreement to contain public expenditure, signed in February 2006 – flattening Govt payments but not total sales

Final remarks

- Effect of market-based policy measures?
 - pharmaceutical companies' adjustment may make it simply a matter of shifting financial burdens, and not one of fundamental change in consumption patterns
- Effect of administrative price reductions?
 - Level shift, dynamics unchanged
- The challenge to find what drives growth and which policy tool addresses the causes remains

