



# REGIONAL MARKET ACCESS SEGMENTATION

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## CONFLICTS OF INTEREST



- Pr. at the University Lyon I France
- Leading consultant at Creativ-Ceutical consulting firm for Industry and Health Authorities
- No stock in any life sciences industry
  
- The UK segmentation was funded by Lundbeck as an academic exercise; the current further development other countries and cross borders clustering is funded by the University Lyon I and is an academic research project.
- The research is still progressing in collaboration with university of Bocconi (Pr C. Jommi and Dr M. Otto)

## CONTENTS



- Introduction to workshop
- Regional market access in Catalonia
- Regional market access in Italy
- Regional market access segmentation
  - Objectives
  - Methodology
  - Future directions

## OBJECTIVE



- Appreciate the importance of regional access through example of Catalonia (Spain) and Italy
- Example of regional clustering methodology in UK and Italy
- Example of methodology for regional multi-country clustering



**1ST EXEMPLE:  
SEGMENTATION IN  
ENGLAND**



**LOCAL MARKET ACCESS ORGANIZATION  
IN ENGLAND**



**Primary Care Trusts**

- PCTs are not similar
- Large range of variables allow differentiation
- A typology is possible

It allows { Targeting  
Strategic recommendation

**AVAILABLE INFORMATION - ENGLAND**



**POPULATION PROFILE**

Age  
Deprivation  
Foreigners...

**ECONOMIC &  
FINANCIAL**

Recurrent Baseline Allocation  
Closing Distance from Target  
Draft Accounts Outturn Turnover...

**ORGANIZATION**

Mental Health as a priority Plan  
QOF ratio  
Prevalence...

**PRESCRIBING**

Innovative indexes  
Black triangle & AD prescriptions  
Duloxetine & escitalopram guidance...

**PATIENT MANAGEMENT**

Medicine Management Score  
Scriptswitch score  
Sophistication Index...

**METHODOLOGY - ENGLAND**



- For quantitative variables, a PCA (Principal Components Analysis) was conducted
- For qualitative variables, an MCA (Multiple Correspondances Analysis) was conducted
- We use projections to conduct a cluster analysis

## RESULTS - ENGLAND

○ 5 clusters were identified:

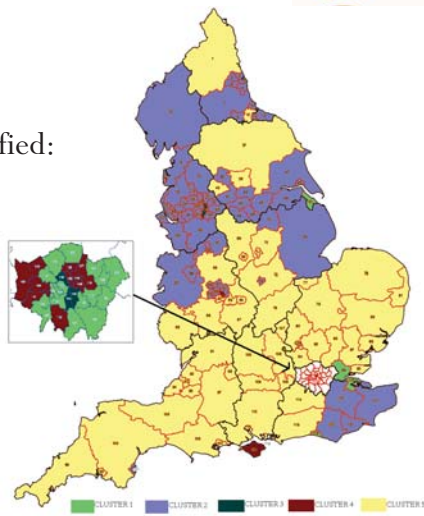
**Cluster 1: n=20**

**Cluster 2: n=61**

**Cluster 3: n=4**

**Cluster 4: n=14**

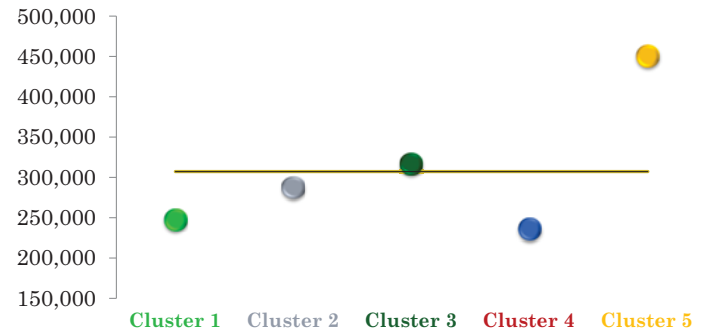
**Cluster 5: n=53**



## CLUSTER DESCRIPTION - ENGLAND



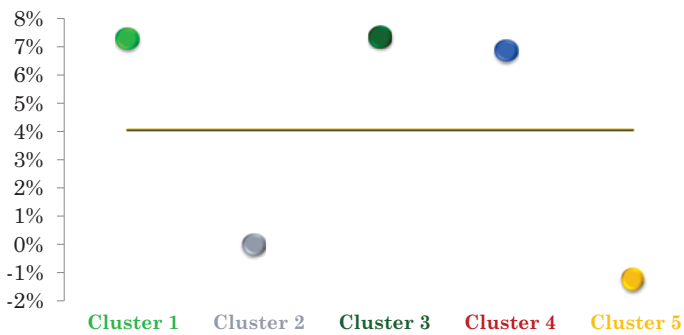
### Mean PCT population size



## CLUSTER DESCRIPTION - ENGLAND



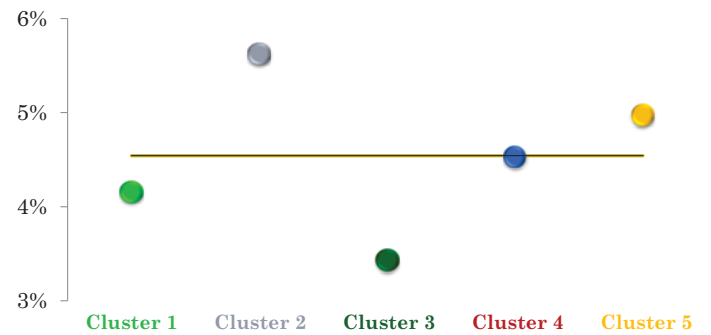
### Closing distance from target 2010/2011



## CLUSTER DESCRIPTION - ENGLAND



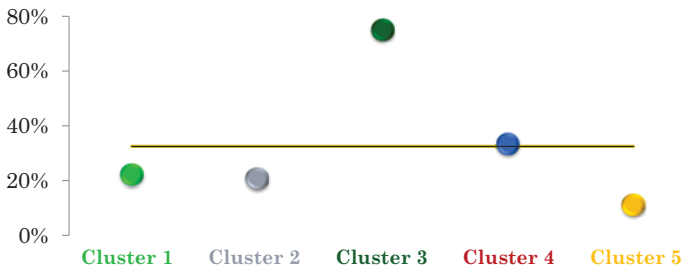
### Level of depression recognition (%)



CLUSTER DESCRIPTION - ENGLAND



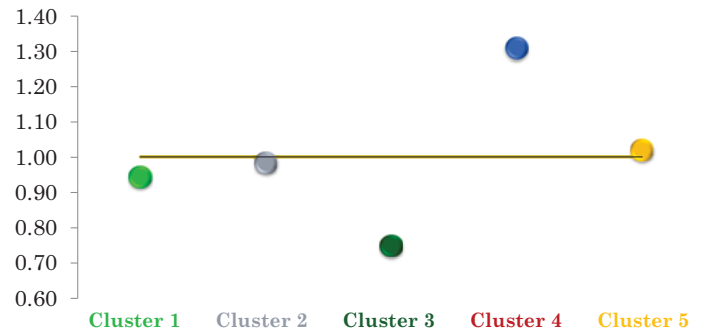
Percentage of PCTS having stated Mental Health as a priority in its Annual Operating Plan



CLUSTER DESCRIPTION - ENGLAND



Scriptswitch score



CLUSTER DESCRIPTION - ENGLAND



**CLUSTER 1**

pop=4 939 000  
A lot of freedom for GPs  
PCTs focalized on Mental Health Disorders

**CLUSTER 2**

pop=17 499 000  
Quality and quantity of prescriptions  
High focus on Mental Health

**CLUSTER 3**

pop=1 266 000  
Depression poorly recognized and treated

**CLUSTER 4**

pop=3 296 000  
  
Low recognition  
High level of care

**CLUSTER 5**

pop=23 868 000  
  
Budget container  
Not innovative



2ND EXEMPLE:  
SEGMENTATION IN ITALY

## AVAILABLE INFORMATION - ITALY



### POPULATION PROFILE

Population size  
Elderly

### ECONOMIC & FINANCIAL

Per capita public health care expenditure  
Per capita public pharma expenditure...

### ORGANIZATION

Genericated market (% over total retail market)

### PRESCRIBING

DDD per inhabitant

### PATIENT MANAGEMENT

Co-payment on drugs (% over gross retail pharm public expenditure)

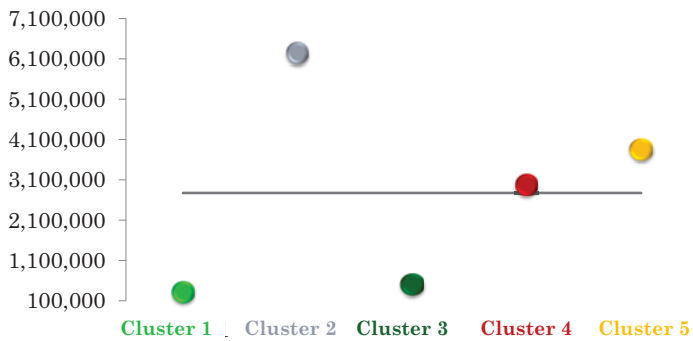
## CLUSTER DESC



## CLUSTER DESCRIPTION - ITALY



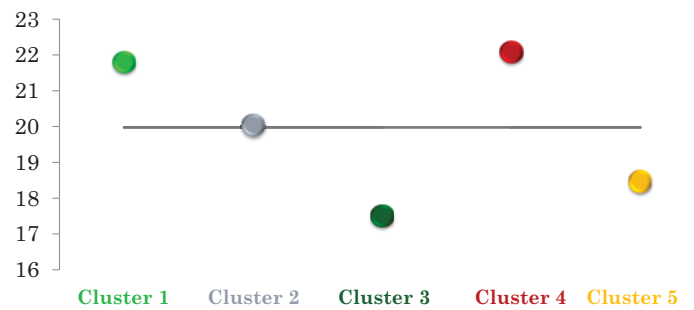
### Mean Population 2010



## CLUSTER DESCRIPTION - ITALY



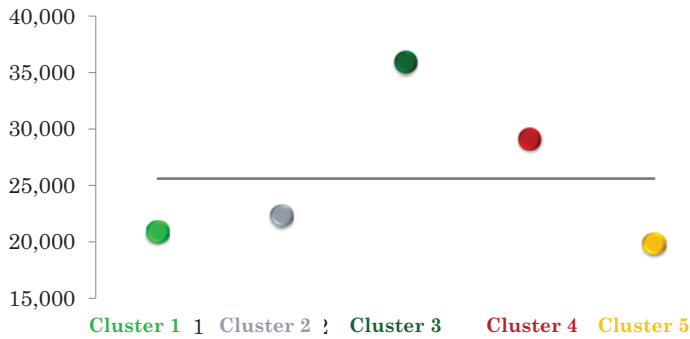
### Mean Population over 65 (% over total population) 2010



CLUSTER DESCRIPTION - ITALY



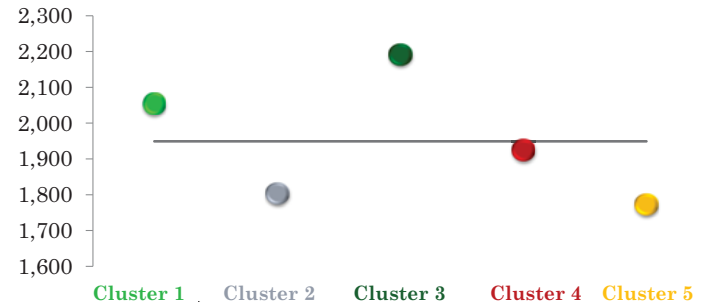
Mean Per capita GDP 2010 Euro



CLUSTER DESCRIPTION - ITALY



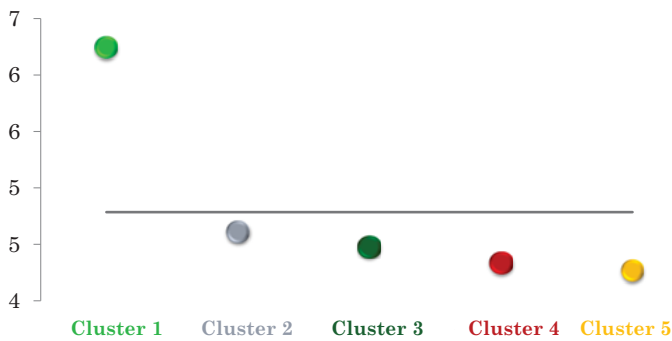
Mean Per capita public health care expenditure 2010 Euro



CLUSTER DESCRIPTION - ITALY



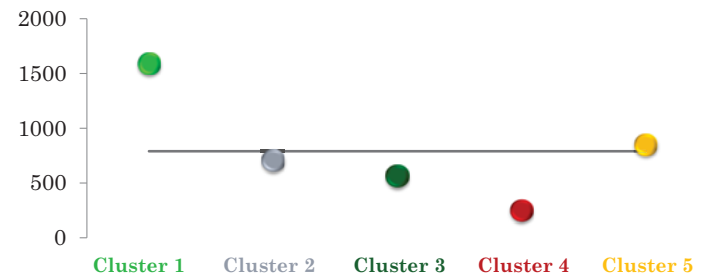
Mean Hospital Bed per 1,000 Population



CLUSTER DESCRIPTION - ITALY



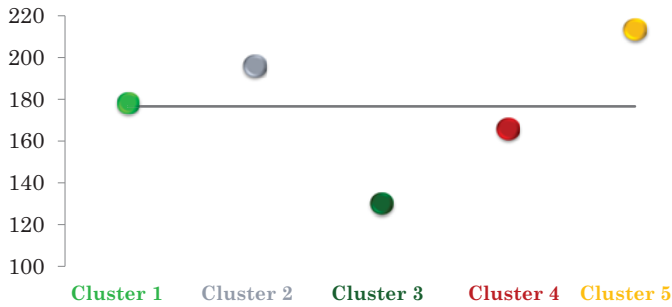
Mean Cumulated per capita deficit over public health care expenditure (2001-2010) (Euro)



## CLUSTER DESCRIPTION - ITALY



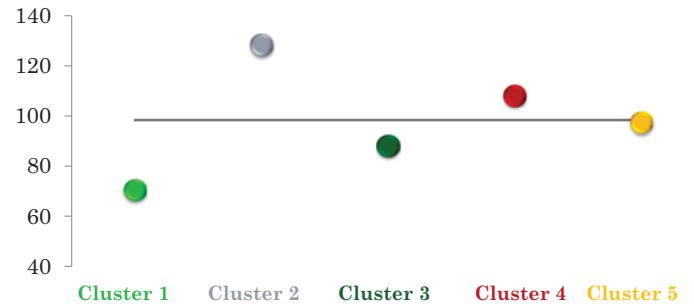
Mean Per capita public pharma expenditure 2010 (retail) Euro



## CLUSTER DESCRIPTION - ITALY



Mean Per capita public pharma expenditure 2010 (hospital) Euro



## NEED FOR A EUROPEAN SEGMENTATION

## NEED FOR A EUROPEAN SEGMENTATION



- Different regions within a country may require different strategies
  - Imagine the case:
    - 5 strategies by country
    - 10 / 20 countries
- } 50 / 100 strategies
- Is there a possibility to realize scale savings in strategy and dossier preparation?
  - Is a high level strategy possible?

## METHODOLOGY



- Illustration with several countries (extreme)
  - Italy (natural north/south segmentation)
  - UK (ultrasegmentation, many small quantities)
- If segmentation applicable with this example, next steps = several countries
  - UK / Italy / Sweden / Canada / Spain

## USE OF DATA



As objective is to provide similar strategies for several clusters **BETWEEN** countries:

It is necessary to mix the countries **BETWEEN** them

## CLUSTER DESCRIPTION – ENGLAND + ITALY



Clusters	IT	UK	
1	0	67	<b>67</b>
2	0	69	<b>69</b>
3	0	16	<b>16</b>
4	13	0	<b>13</b>
5	9	0	<b>9</b>
<b>Total</b>	<b>22</b>	<b>152</b>	<b>174</b>

## USE OF DATA



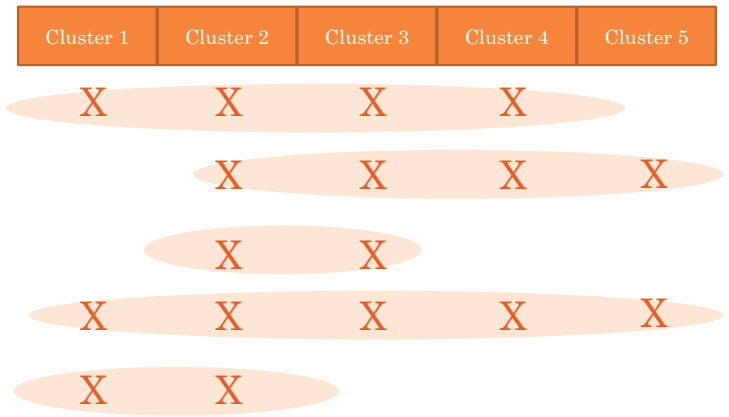
- 2 different ways to **harmonize** data across countries
- **Qualitative** process
  - Each variable for each region in 4 classes
  - Use the 4 quartiles by country
- **Quantitative** process
  - Calibration between 0 and 1
  - Example: UK: 80% generic, IT: 30% generic
  - 80% corresponds to 1 in UK, 30% corresponds to 1 in Italy

## CLUSTER DESCRIPTION – ENGLAND + ITALY



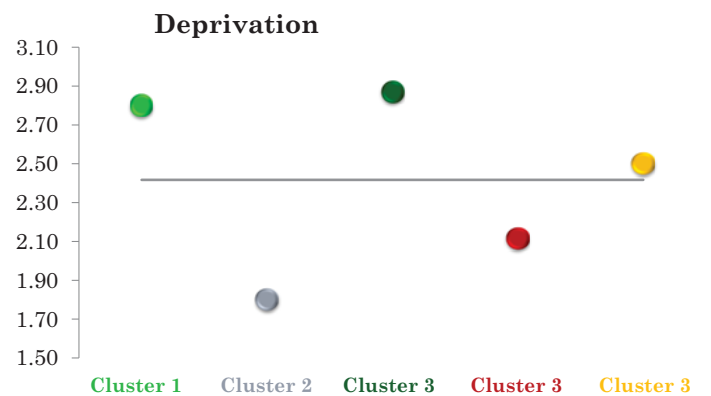
Clusters	IT	UK	
1	2	60	<b>62</b>
2	5	8	<b>13</b>
3	7	16	<b>23</b>
4	2	61	<b>63</b>
5	6	7	<b>13</b>
<b>Total</b>	<b>22</b>	<b>152</b>	<b>174</b>

## OBJECTIVE



## REGIONAL SEGMENTATION IN ITALY + UK

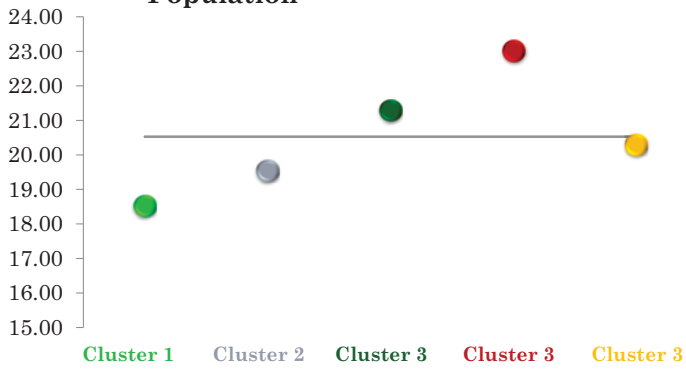
## CLUSTER DESCRIPTION – ENGLAND + ITALY



CLUSTER DESCRIPTION – ENGLAND + ITALY



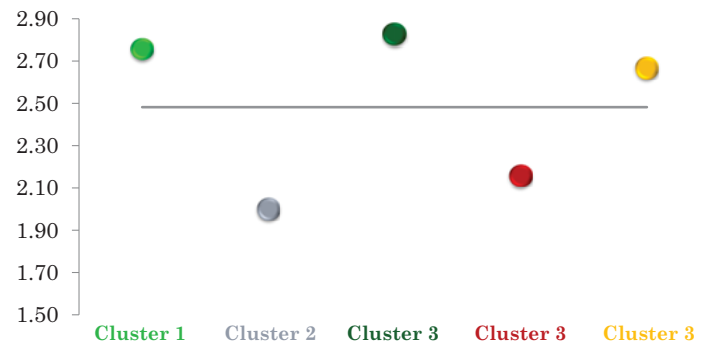
Population



CLUSTER DESCRIPTION – ENGLAND + ITALY



public health care expenditure



CLUSTER DESCRIPTION – ENGLAND + ITALY



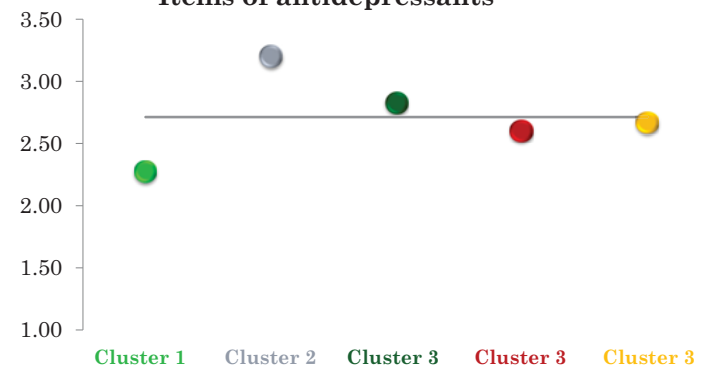
Services



CLUSTER DESCRIPTION – ENGLAND + ITALY



Items of antidepressants





## THANK YOU FOR YOUR ATTENTION!

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## OVERCOMING THE COMPLEXITY OF AN INCREASINGLY FRAGMENTED REGIONAL AND LOCAL MARKET ACCESS REQUIREMENT

### The Italian experience

**Monica Otto**

Coordinator of the Pharmaceutical Observatory

CERGAS, Bocconi University, Italy

Madrid, 8<sup>th</sup> of November 2011

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## The agenda

- Market access: the Italian environment
- Market access: the companies' perception
- Conclusions

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## Organisation of the Italian health care system Servizio Sanitario Nazionale (SSN)

The SSN was established in 1978 and subject to many reforms

Was modeled after the British NHS

Covers the entire population

Is tax-funded

Provides most of the health care services free of charge at point of service / with limited co-payment

Three tiers:

1. the Central Government at the top
2. 21 Regional Governments in between
3. at the bottom:
  - about 150 Local Health Units - LHUs (each responsible for the health of the entire population – 400,000 on average, in a given area)
  - 80 Independent Hospitals - 640 beds on average – IHS (similar to British NHS Hospital Trusts)
  - private hospitals (30% of total beds) and professionals, eligible for SSN reimbursement when "accredited" by the relevant Region



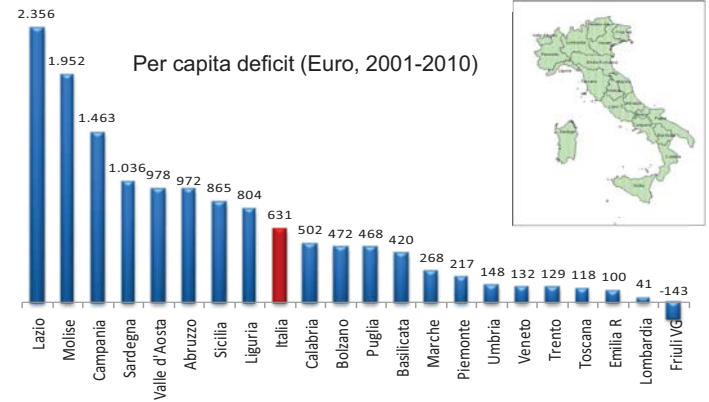
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## Regionalisation of SSN

- Regions are responsible for any deficit they incur on health care expenditure
- Regions decide the overall structure of their (regional) health care system (quasi-market mechanisms, accreditation, cost-containment actions including pharmaceuticals), provided that they give the "essential level of health care" determined by the Central Government
- Regions are responsible for budget on drugs used in hospital setting (2.4% of health budget)

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## Regions and deficits on health care budget



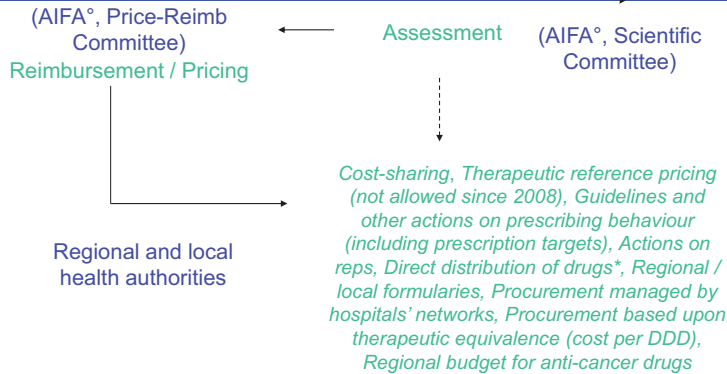
Source: RGSEP, 2011

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## Market access in Italy

A broad overview

EMA (Assessment)

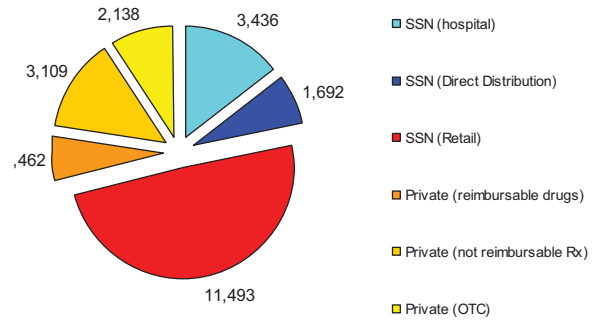


° Central Drugs Agency, Agenzia Italiana del Farmaco. The two committees include regional experts

\* Direct Distribution (DD) stands for distribution of drugs not used in hospital settings by hospitals

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## Pharmaceutical expenditure (2008, million of Euros)



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## Market access in Italy

Cost-containment as the most important driver

### Budget on health care expenditure

- Possible deficit is covered by regions (also through actions on pharmaceuticals)

Budget on **retail pharmaceutical expenditure** (including DD), as a % of health care budget (from 14% in 2008 to 13.3% in 2010)

- Possible deficit is covered by the industry (payback) and the distribution (discounts on margins)

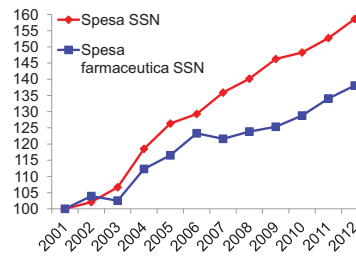
Budget on drugs used in **hospital setting** (2.4% of health budget)

- Possible deficit is covered by regions, unless they respect budget on health care

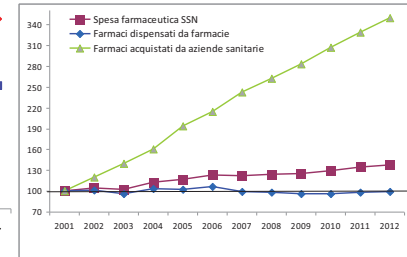
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## Public pharmaceutical and health expenditure (2001 = 100)

Health (blu) versus pharma (red)

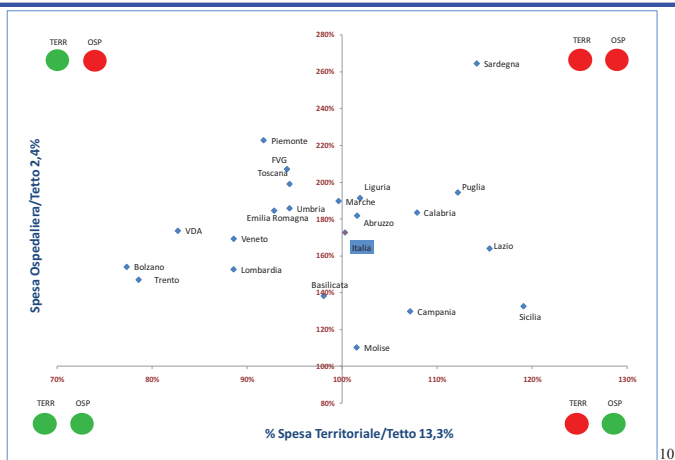


Pharma hospital (green) versus retail (blu)



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## Regions and pharma budget (2010)



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Source: OSFAR, Report 27 2011

## Market access: which policies at regional level?

- Cost-sharing
- Direct distribution of drugs
- Regional formularies
- Procurement
- Actions on prescribing behaviour / reps
- HTA (?) Programmes
- Extra-payment (regional budgets) for anti-cancer drugs

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## Cost-sharing

Flat-rate charge per prescription

- Decided by regions

Reference pricing on genericated molecules

- Nation-wide (reference price set as the minimum price; same pack - molecule, route of administration, doses)

Therapeutic reference pricing

(applied to PPI, not allowed since 2008)

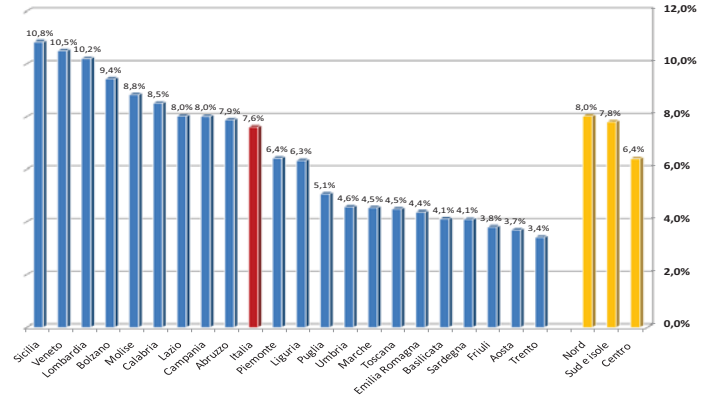
- Decided by regions



Source: Federfarma, 2011

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## Cost-sharing (% on gross retail public expenditure) (2010)



Source: Federfarma, 2011

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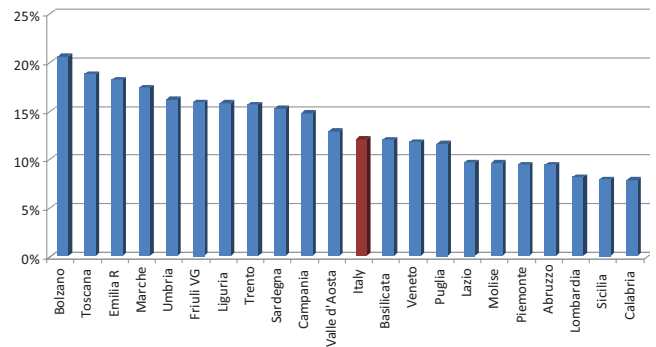
## Direct distribution of drugs by hospitals

*DD implies that health authorities do not pay distribution margins, may have discount over price (through tenders) and a tight control over volumes, but may limit access to drugs*

- Drugs included into a national list (PHT), possibly extended by regions
  - e.g. erythropoietin, interferon, blood derivate
- First therapeutic cycle after the discharge
  - decided by regions
- Drugs used in specific setting (e.g. home care)
  - decided by regions

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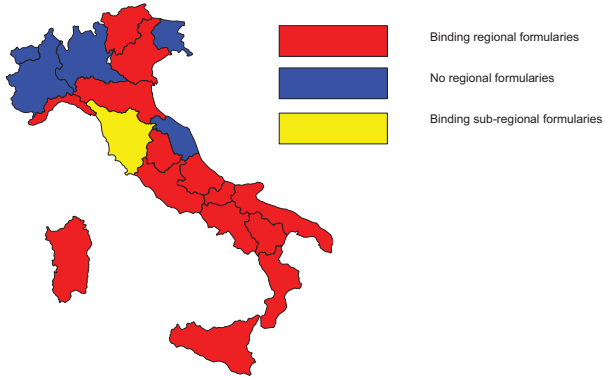
## Direct distribution (% on retail public expenditure)



Source: Aifa, 2009

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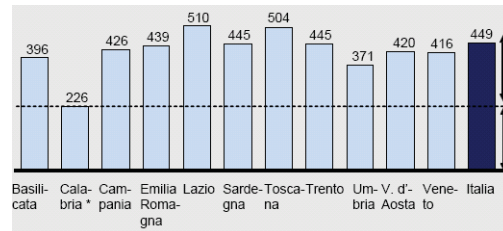
## Regional formularies: where?



Source: Pharmaceutical Observatory, Cergas Bocconi

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## Regional formularies: which consequences? Delays / differences as for market access



Time to market (Regions)

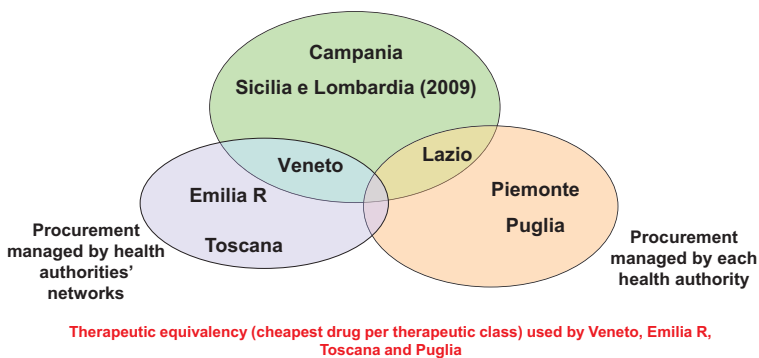
Time to market (AIFA)

Source: Farmindustria (2009)

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## Procurement: centralisation process

### Regional procurement



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## Prescriptions targets

- Prescription targets for genericated molecules
- Prescription targets for generics
- Public procurement for genericated molecules

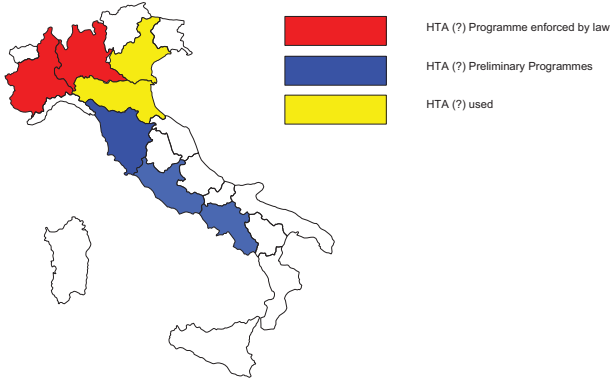


Recommendation on prescribing mix  
The Italian Drugs Agency recommendation on prescribing mix

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## Regional HTA (?) Programmes

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## Regional budget for anti-cancer drugs

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- Drugs used in hospital settings
- Fee-for-DRG does not cover costs (too high, too variable)
- Some Regions (Lombardia, Lazio) pay retrospectively for a limited list of drugs
- Some Regions (Veneto, Campania) has prospectively defined a budget
- Tough control over drug consumption and off-label use excluded from reimbursement (even if supported by evidence post Phase II)

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## The agenda

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- Market access: the Italian environment
- Market access: the companies' perception
- Conclusions

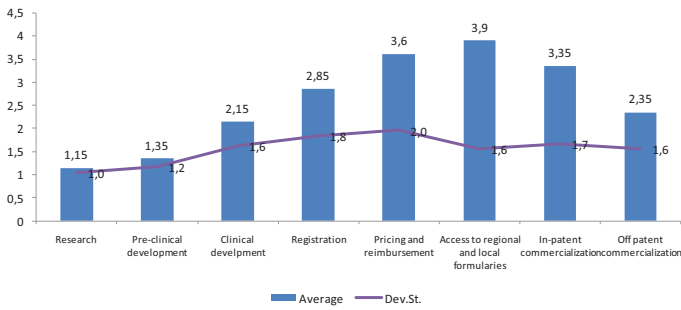
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## Definition of MA: results from a survey on 21 companies in Italy, accounting for 56% of total sales (2009)

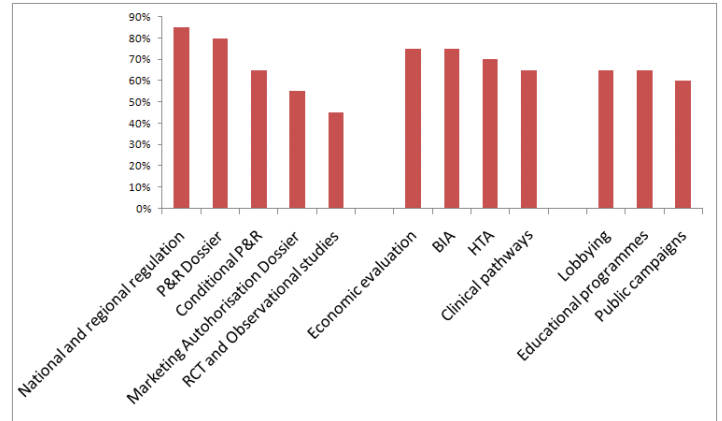
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- Only 50% of the companies has formally defined the concept of MA
- In most cases time to market and patients' access have been included into the definition
- In few cases value based pricing has been considered a crucial dimension of Market Access

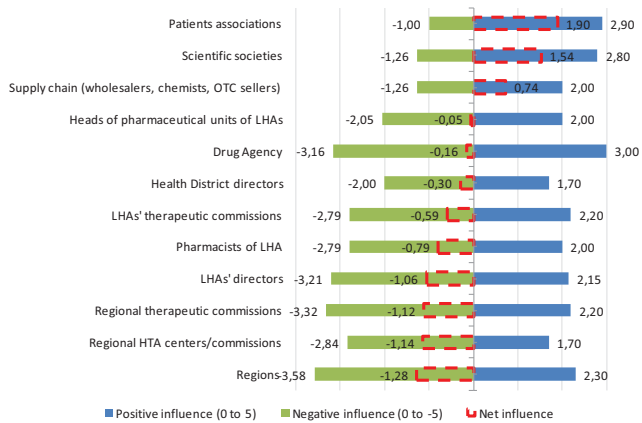
## MA: role in product's life cycle



## MA Tools



## Health care actors and MA



## MA and Performance Evaluation

MA performance evaluation criteria	% of responders
Accessing to regional formularies	81%
Time-to market	76%
Partnerships with public institutions	71%
Sales objectives	29%
Reimbursability and conditional price and reimbursement	5%

## The agenda

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- Market access: the Italian environment
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## Pharmaceutical policy in Italy

### Main aspects

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- Unique drugs agency at the central level (AIFA)
- Drugs budget as an important driver (retail and hospital)
- Ex factory prices and reimbursement simultaneously negotiated: innovativeness, prices in other countries, impact on drugs budget as the main criteria
- Regionalisation
  - In principle Regions more sensitive to the impact of drugs on the health care system
  - In practice, short-term approach and comparative analysis based upon cost per DDD / therapeutic cycle prevail
  - Equity issues

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**Thank you**

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[claudio.jommi@unibocconi.it](mailto:claudio.jommi@unibocconi.it)

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## Market Access in Spain: The Experience in Catalonia

ISPOR, Madrid, 8 November 2011

Antoni Gilabert-Perramon

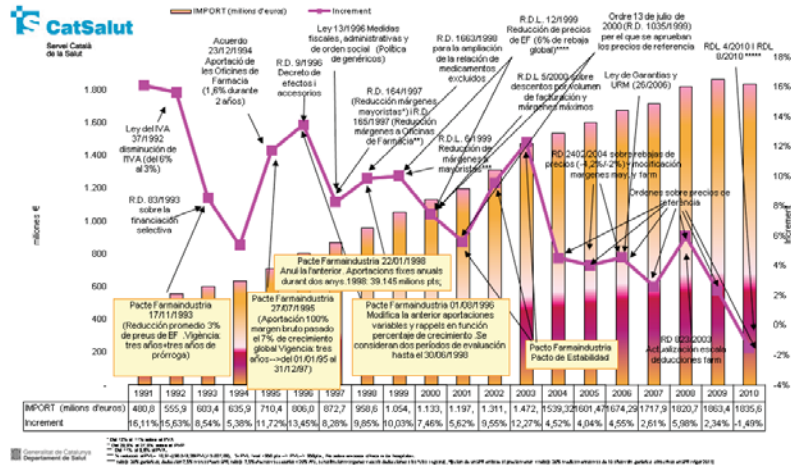
Managing Director of Pharmaceutical Care and Complementary Services



Generalitat de Catalunya  
Departament de Salut

# Our priority

To improve health outcomes within a financially sustainable environment



## Strategic plan and measures (2011-2014)

### Sharing responsibilities

- Sharing risk
- Providers (PCT/hospitals)
- Pharma industry
- Capitation financing system
- Professional incentives
- Health education
- Generics and RP
- Drug utility evaluation
- Economic evaluation
- High complexity treatments
- Advisory Committees
- Chronic prescription
- Clinical practice guidelines
- Drug formularies

### Redefinition of services

- Pharmaceutical care
- Coordination PC-HC
- Primary care pharm.
- Geriatric/home care
- Community pharmacy services
- Contract objectives evaluation
- Invoicing control
- Promotion control
- Farmacovigilance
- Fraud control

### Information systems

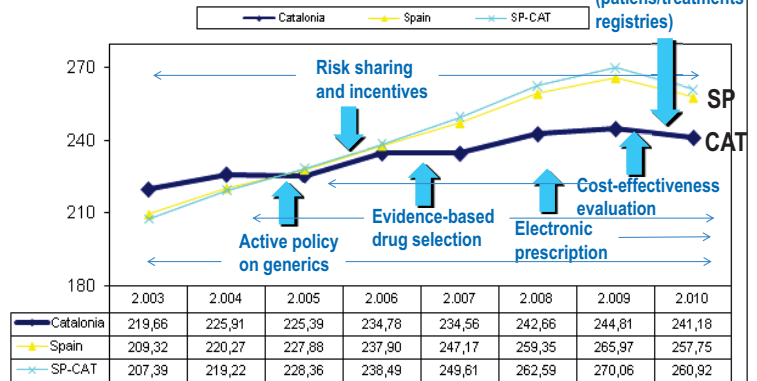
- DataMart
- Patient records DB
- Patient analysis prog.
- Benchmarking
- Bulletins and reviews
- Drug utilization studies
- Prescription digitaliz.
- Electronic prescrip.

### Quality/Efficiency

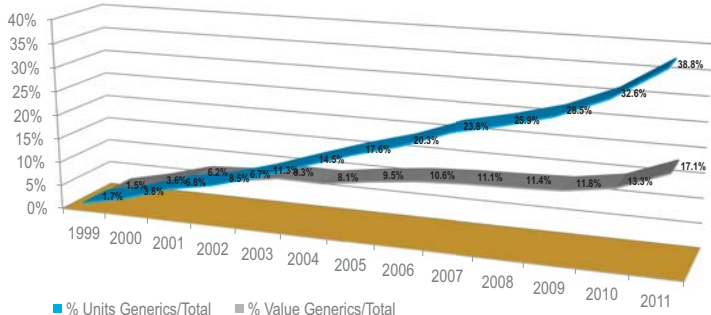
### Evaluation and control

## Expenditure per inhabitant

Health outcomes (patients/treatments registries)

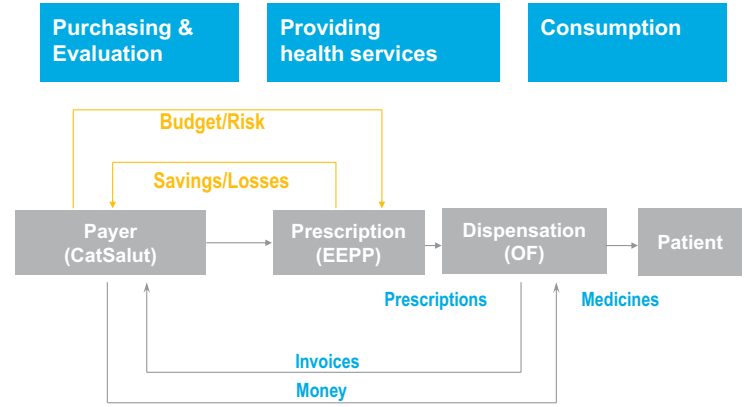


## Market Share Generics

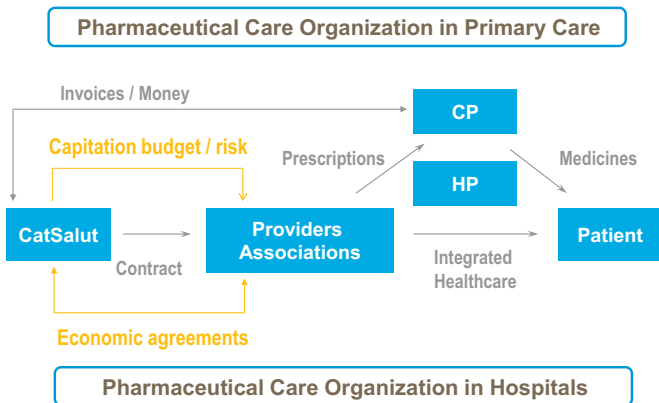


Generics count for 38,8% of the volume and 17,1% of the value of the pharmaceutical market

## Current Demand Model



## Capitation Financing System



## Market Access in Catalonia

FIELD	COMMITTEES	REVIEWERS	IMPLEMENTATION
Primary Care Medicines	CANM (Therapeutic Utility)	AIAQS (Catalan HTAA Agency)	Providers Agreements/ Incentives
Hospital Medicines (MHDA)	CFT-CatSalut (Harmonization PHMHDA)	CFT Hospitals (Pharmacotherapy Committees)	Transparency & Participation
High Complexity Treatments (TAC)	CAMUH / CATFAC (Criteria to be used TAC - PASFTAC)	CAMed. (Advisory Committees)	Spreading Web CatSalut
	CAEIP (Economic Evaluation)	ICF (Catalan Institute of Pharmacology)	Benchmarking between Providers
	COPIF (Provision & Financing)		Risk-sharing Agreements



## Conclusion

### Sustainability

#### Efficiency Co-responsibility

(Selection, Harmonization  
Economic evaluation)

(Risk sharing)



# Thank you!

[tgilabert@catsalut.cat](mailto:tgilabert@catsalut.cat)

[http://www10.gencat.net/catsalut/cat/prov\\_farmacia.htm](http://www10.gencat.net/catsalut/cat/prov_farmacia.htm)