



# Implementing an Effective Generics Policy - What can Countries Learn from Each Other

## Generika – Wissenschaft oder Werbung – was wirkt wirklich? Generics – Science versus Fiction

**Austrian Ministry of Health**

22 March 2011

Prepared by Brian Godman

Division of Clinical Pharmacology, Karolinska Institute, Sweden

Mario Negri Institute for Pharmacological Research, Italy


Prescribing Research Group, University of Liverpool



UNIVERSITY OF  
LIVERPOOL



KAROLINSKA  
INSTITUTET

*ett medicinskt universitet* 

**MARIO NEGRI**  
ISTITUTO DI RICERCHE  
FARMACOLOGICHE



**g** BUNDESMINISTERIUM  
FÜR GESUNDHEIT



# 1. Introduction

2. Measures to obtain low prices for generics
3. Measures to enhance generic utilisation including dispelling myths
4. Conclusions and future considerations



## Increasing focus on drug expenditure across all sectors with pressures continuing

---

- Healthcare expenditure represents a significant proportion of national expenditure . Alongside this, European governments strive to maintain comprehensive and equitable healthcare with growing resource pressures
- Focus on pharmaceutical expenditure increased as:
  - ❑ Ambulatory care drug expenditure rising at 4% to 13%/ annum and now largest/ equal largest cost component
  - ❑ Considerable opportunities to enhance prescribing efficiency with global sales of \$100bn/ year (€70bn) of drugs likely to lose their patent between 2008 and 2013
  - ❑ Appreciable variation in generic prices (up to 36 fold for certain molecules) and their utilisation across Europe
  - ❑ European countries realise they must learn from each other to maintain European ideals. This includes generics



1. Introduction
- 2. Measures to obtain low prices for generics**
3. Measures to enhance generic utilisation including dispelling myths
4. Conclusions and future considerations



## Supply side reforms include pricing policies for the molecule or class, with new definitions

- Every European country has different regulations surrounding the pricing of generics . These can be:
  - ❑ prescriptive pricing approach (PP), e.g. established price reduction vs. originator pre-patent loss, e.g. Norway
  - ❑ market forces (MF), e.g. Sweden and UK
  - ❑ mixture of the two – mixed approach (MA), e.g. Austria
- Reference pricing in a class is different – based either on a pharmacological class, e.g. all PPIs, or all drugs to treat hypertension, is also prevalent in some European countries. Austria has 'voluntary reference pricing'
- Patients usually pay the difference for a more expensive product than reference molecule. UK is an exception but high INN prescribing

Ref: Godman, Shrank et al 2010 and 2011 McGinn, Godman et al 2010; Godman, Buscics et al 2008



## Three categories encompass the different approaches to the pricing of generics

### Definition

- **Prescriptive pricing for generics** – this can be either for the molecule (generic and originator) or just the generic. Health Authorities or Health Insurance Companies mandate price reductions for the first generic or generics to be reimbursed. This is either based on originator prices pre-patent loss, reimbursed prices of generics in other European countries or a mixture of both
- **Market forces for generics** – In some European countries there is no established price reduction for the first generic or generics to be reimbursed. This is left to market forces
- **Mixture of prescriptive pricing and market forces** – In some European countries the price reductions are established for the first generic or generics to be launched. Market forces after that to further drive down prices

Ref: Godman, Shrank et al 2010 and 2011



## Norway provides an example of a prescriptive pricing policy for generics

Launch of first generic	6 months following the introduction of the first generic	12 months or more after second step
Must be priced 30% below maximum pre-patent loss prices up to 12 months before to be reimbursed	<ul style="list-style-type: none"><li>• 55% to 75% price reduction (vs. pre patent loss prices)</li><li>• Reduction depends whether current annual sales estimated to be &lt; or &gt; 100mn NOK</li></ul>	<ul style="list-style-type: none"><li>• 55% increased to 65% reduction</li><li>• 80% reduction for annual sales between 30mn and 100mn NOK</li><li>• 85% reduction for annual reimbursed sales &gt; 100mn NOK (applies to generic simvastatin)</li></ul>

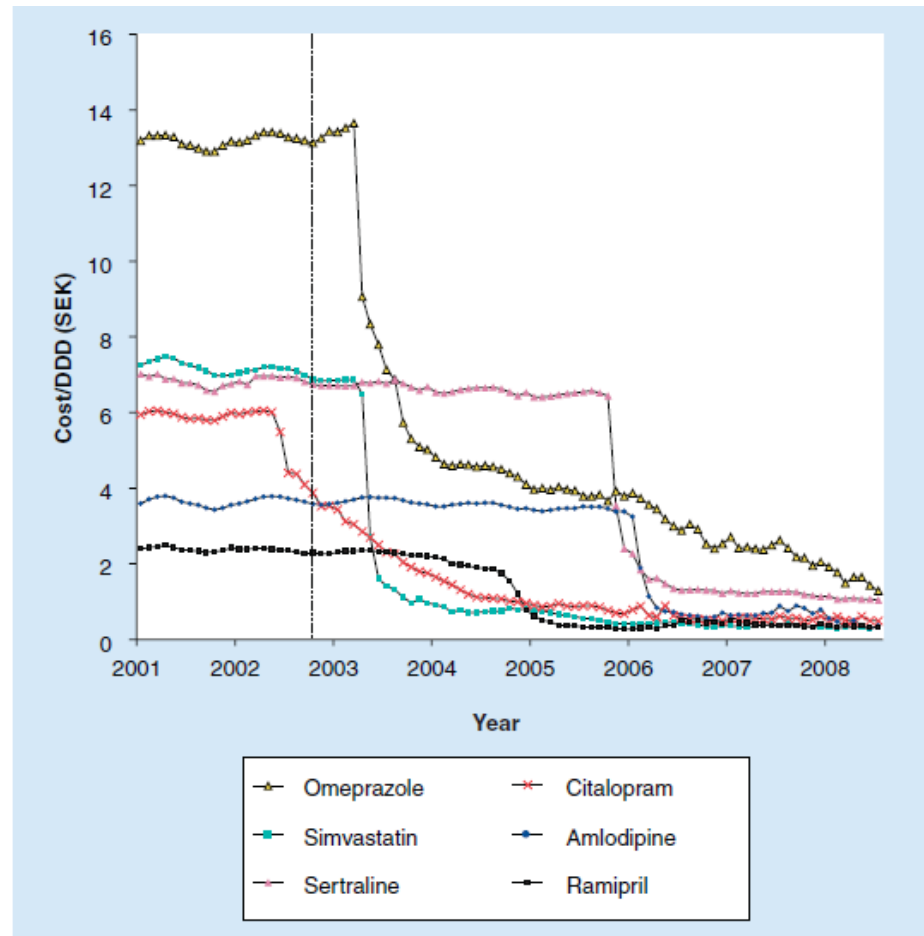
**NB: NOK = Norwegian Kroner (€1 =7.84 NOK, 0.86 GB£)**

Ref: Godman, Shrank et al 2010; Godman, Sakshaug et al 2011



## Market forces via compulsory generic substitution have lowered prices in Sweden

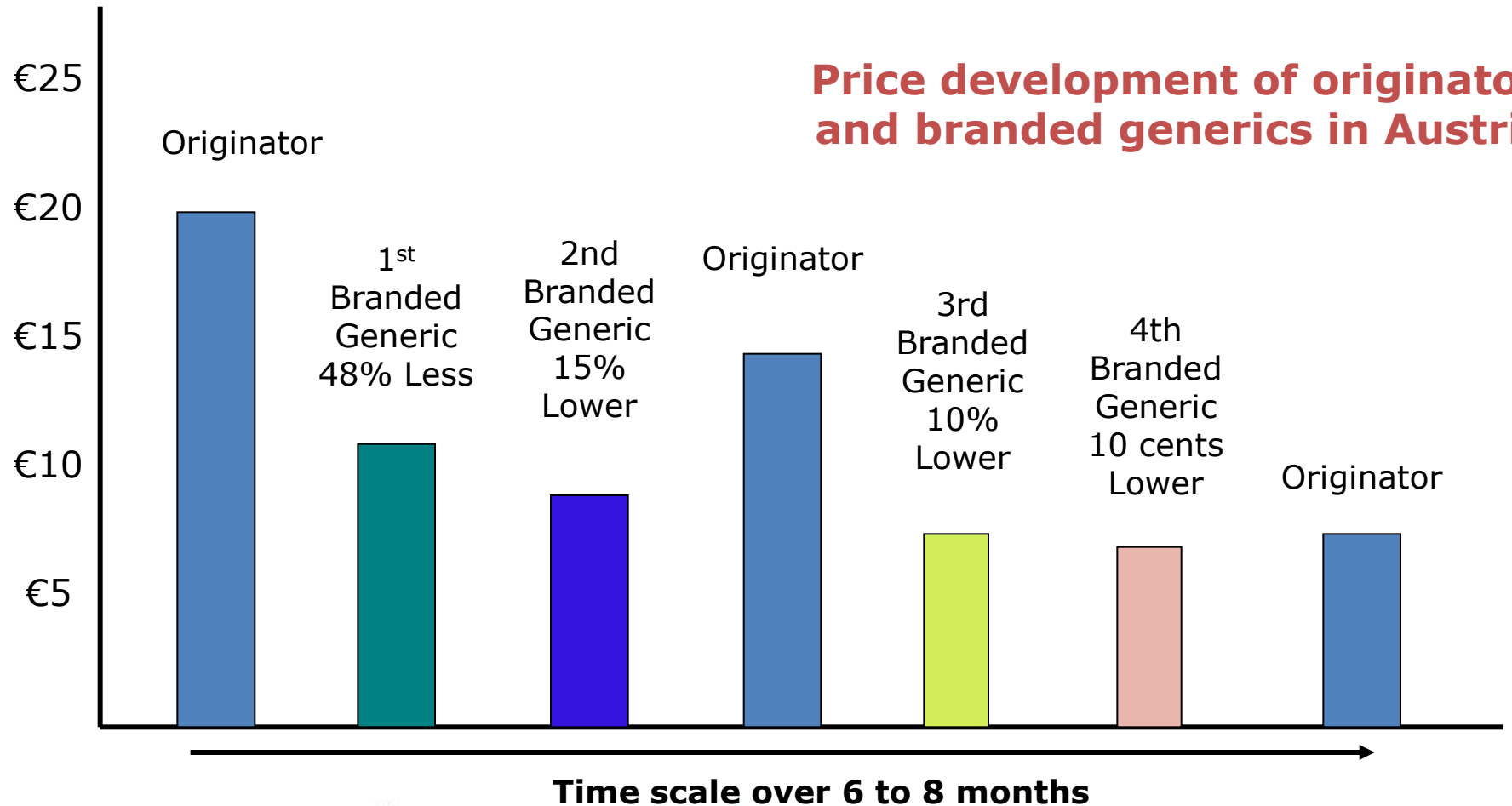
**Cost/DDD for 6 products in top 25 prescribed ambulatory care products in Sweden on a DDD basis. Generic prices 4% to 13% of pre-patent loss prices**





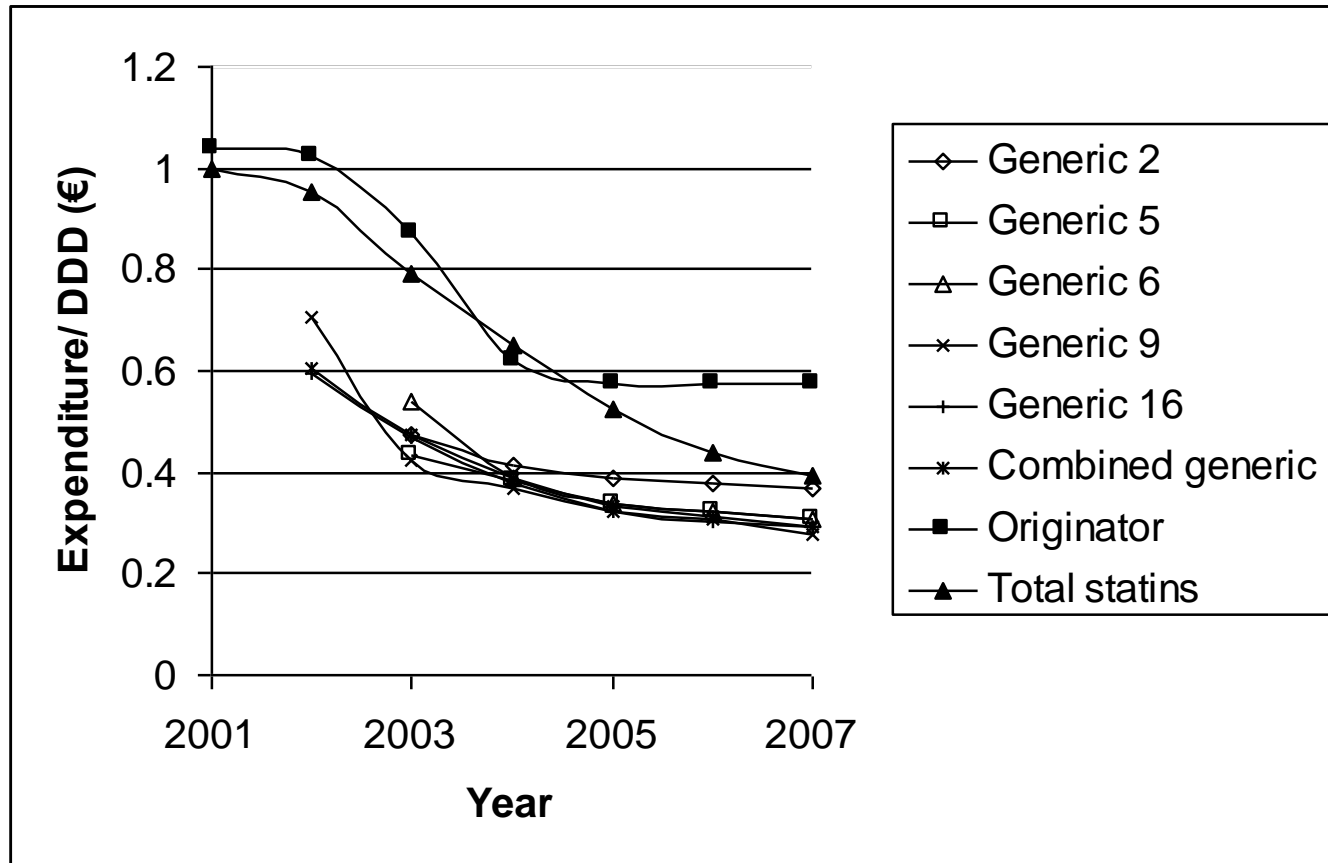
## Austria provides an example of a mixed approach with initial prescriptive pricing

Ex-Factory price/ standard pack



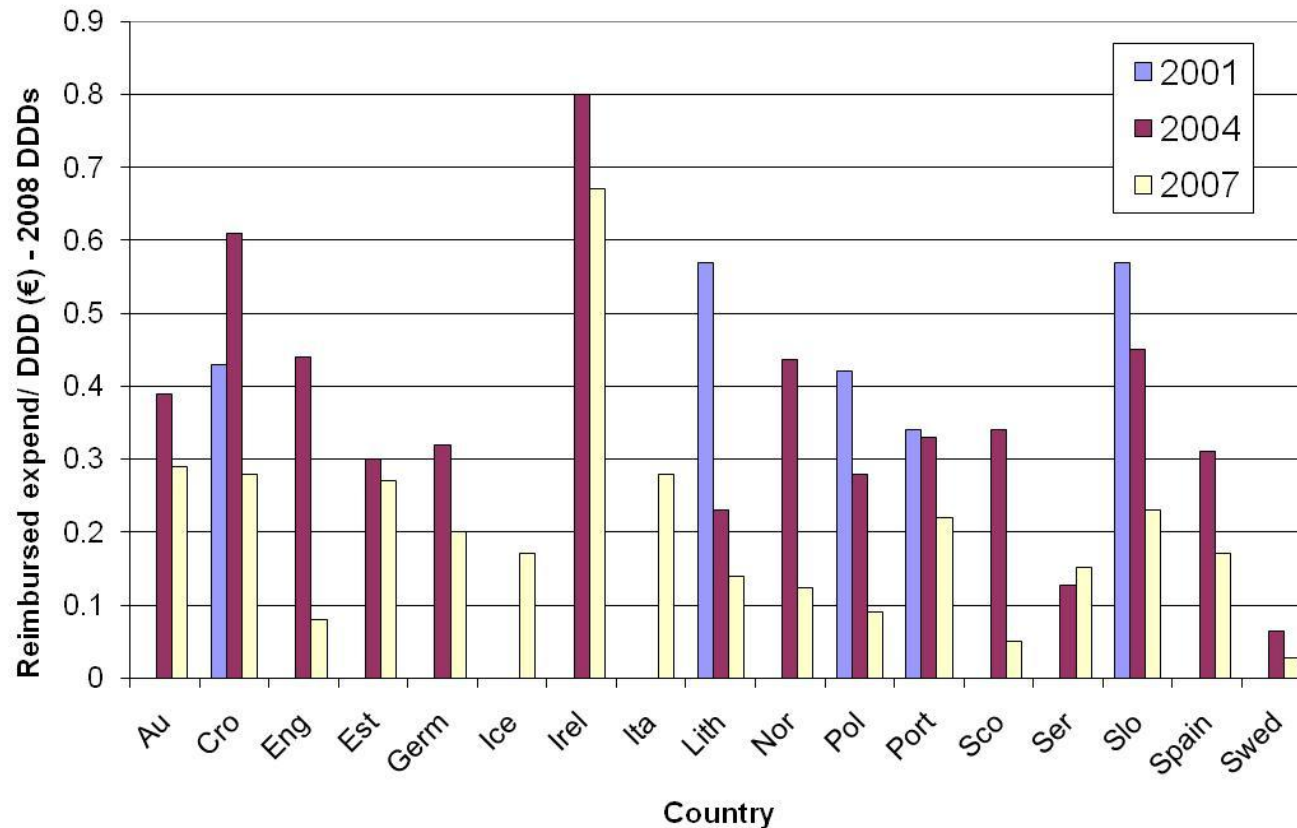


## Expenditure/DDD for selected simvastatin formulations and total statins in Austria following mixed approach





## Considerable variation though in expenditure/ DDD for generic simvastatin with Sweden and UK lowest





1. Introduction
2. Measures to obtain low prices for generics
- 3. Measures to enhance generic utilisation including dispelling myths**
4. Conclusions and future considerations



## Demand side measures based on 4 Es are growing in Europe to help conserve resources

- Demand side initiatives also growing across Europe to improve prescribing efficiency. These include initiatives to address concerns with generics with meta analyses and other studies showing no difference between generics and originators
- Demand side initiatives can be collated under 4 'E's':
  - **Economics** - financial incentives, budget devolution
  - **Education** - Academic detailing, guidelines, audits, benchmarking and formularies
  - **Engineering** - structural changes, prescribing targets, limiting pharmaceutical company activities
  - **Enforcement** – legally binding arrangements, restricted lists, rebates
- Do see appreciable differences among European countries in their nature/ intensity; consequently opportunities for savings

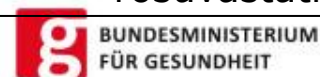
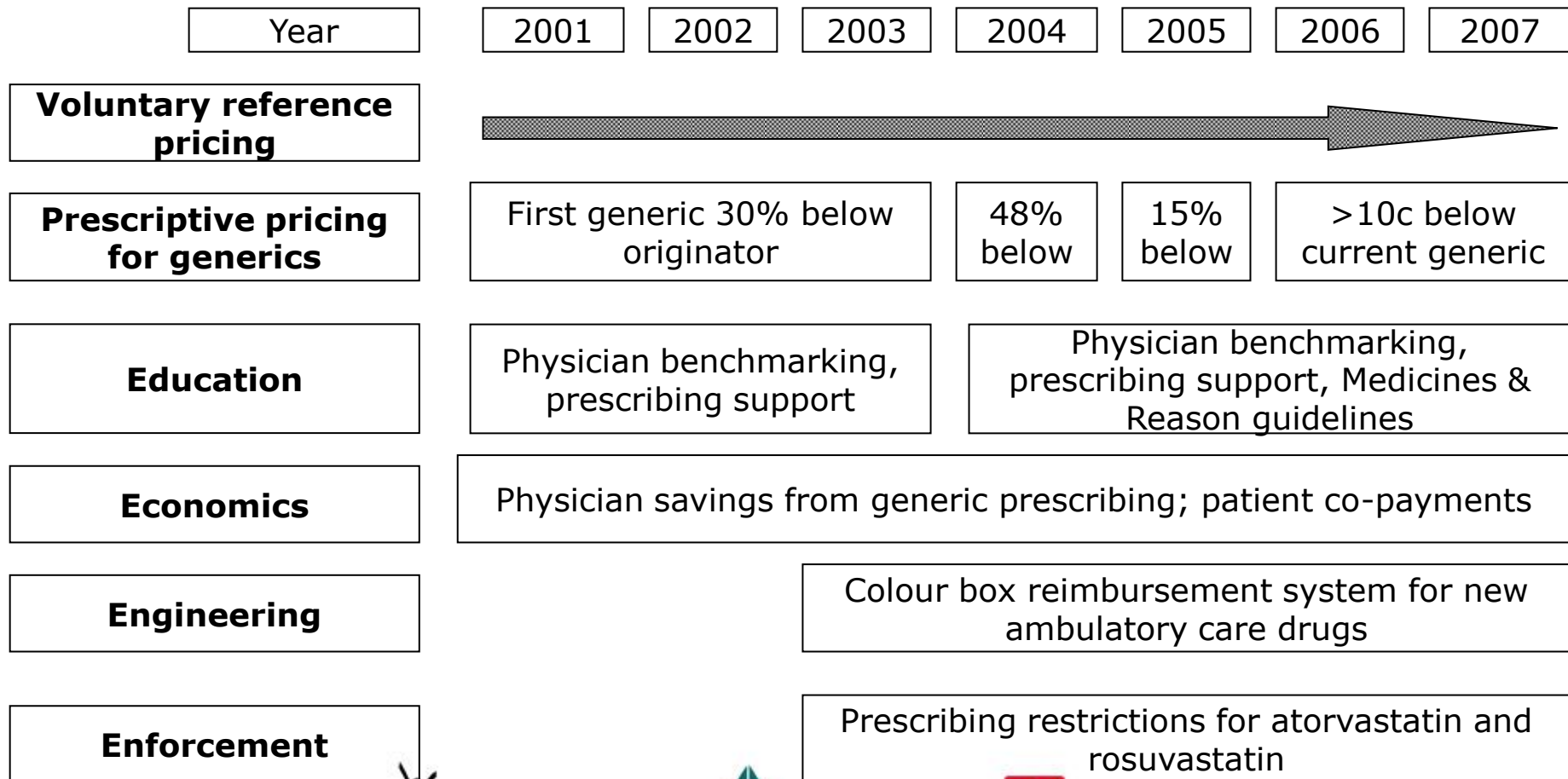


# EU countries have instigated policies to address concerns with generics to maximise savings

Key Stakeholder Groups	Activities
Physicians	<ul style="list-style-type: none"> <li>• Option to indicate no substitution on the prescription (generally rare in practice)</li> <li>• Only licensing generics where there are no concerns with their bioequivalence or therapeutic equivalence</li> <li>• Encouraging INN prescribing from the outset even when only single sourced products are available (country and product dependent)</li> <li>• Encouraging physicians to speak with patients where there is the potential for substitution to help allay any fears</li> <li>• Developing and adhering to an agreed list of non-substitutable products</li> </ul>
Pharmacists	<ul style="list-style-type: none"> <li>• Encouraging pharmacists to speak with patients when substituting to reduce concerns (country dependent)</li> <li>• Limiting the number of times products can be substituted where concerns</li> <li>• Access to databases in pharmacies giving access to prior prescribing history to avoid potential duplication</li> <li>• Adhering to an agreed list of non-substitutable drugs</li> </ul>
Patients	<ul style="list-style-type: none"> <li>• Information and other campaigns encouraging patients to accept INN prescribing from the outset (country dependent)</li> <li>• Promotional campaigns to allay fears regarding the effectiveness and safety of generics backed up by campaigns by health authorities and health insurance companies to enhance the acceptance of generics</li> </ul>

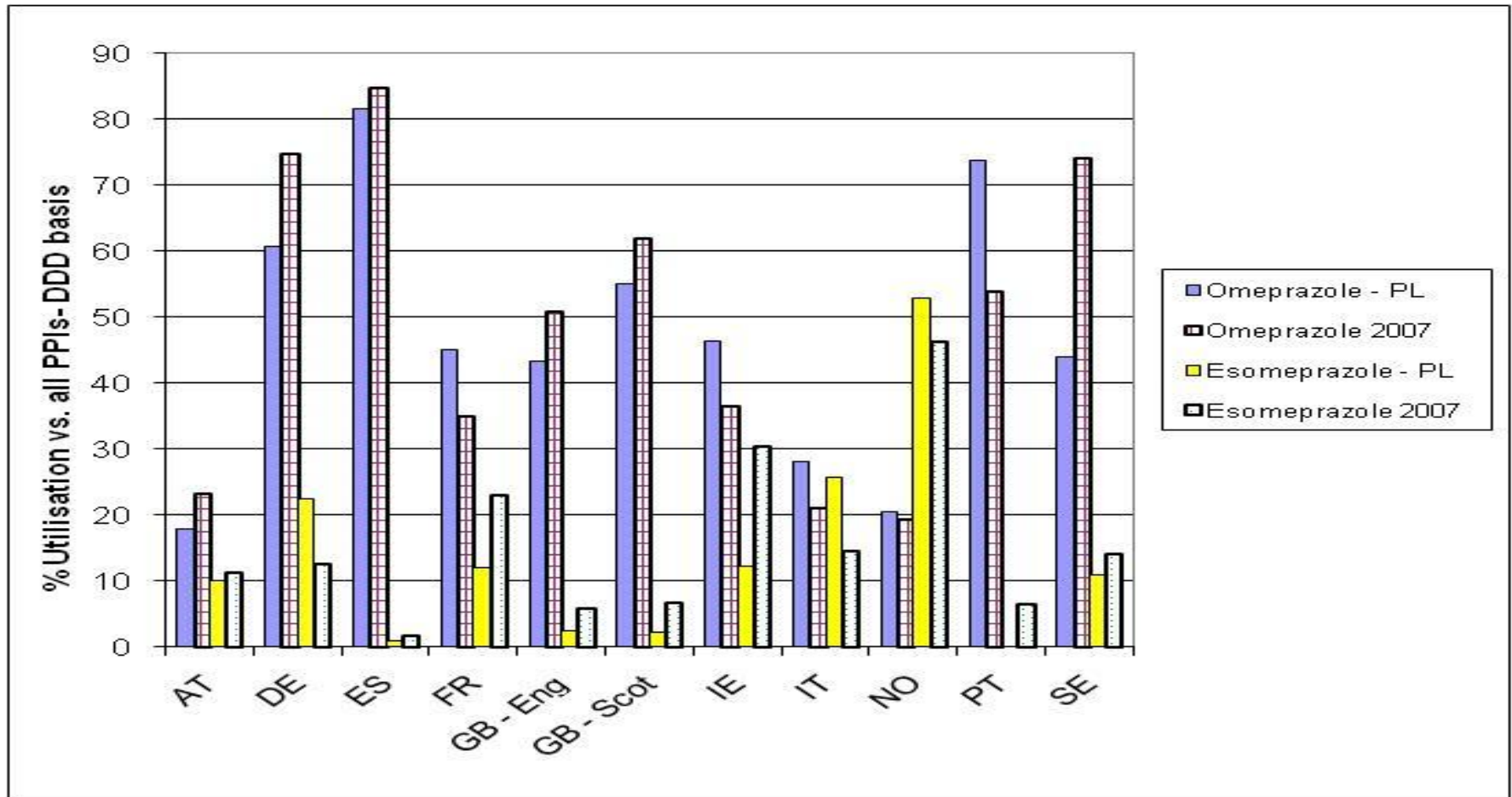


# Supply and demand side initiatives in Austria have enhanced prescribing efficiency for PPIs and statins



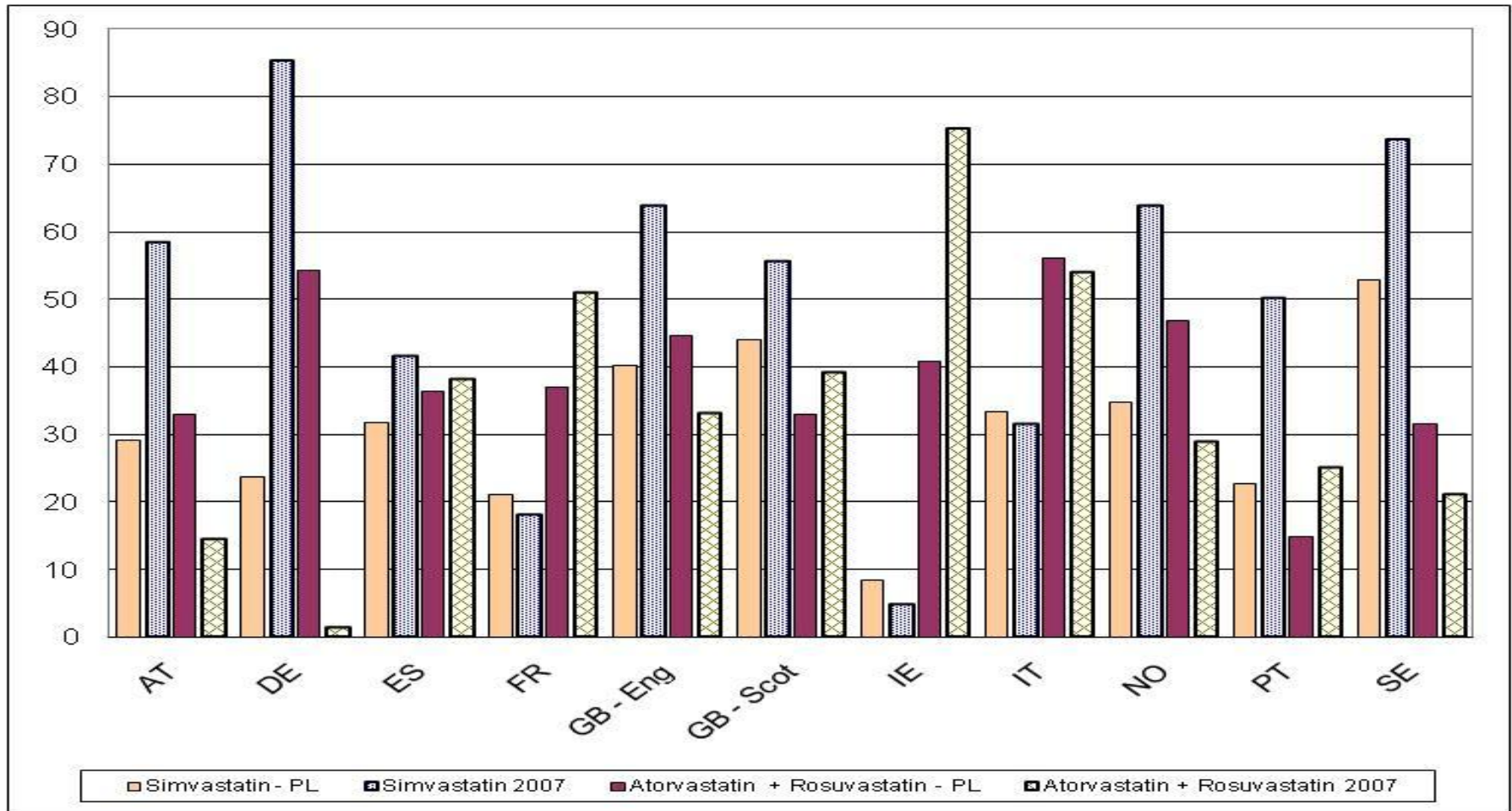


# The intensity and nature of the reforms impacts on utilisation, e.g. PPIs in NO and IE vs. DE, GB and SE



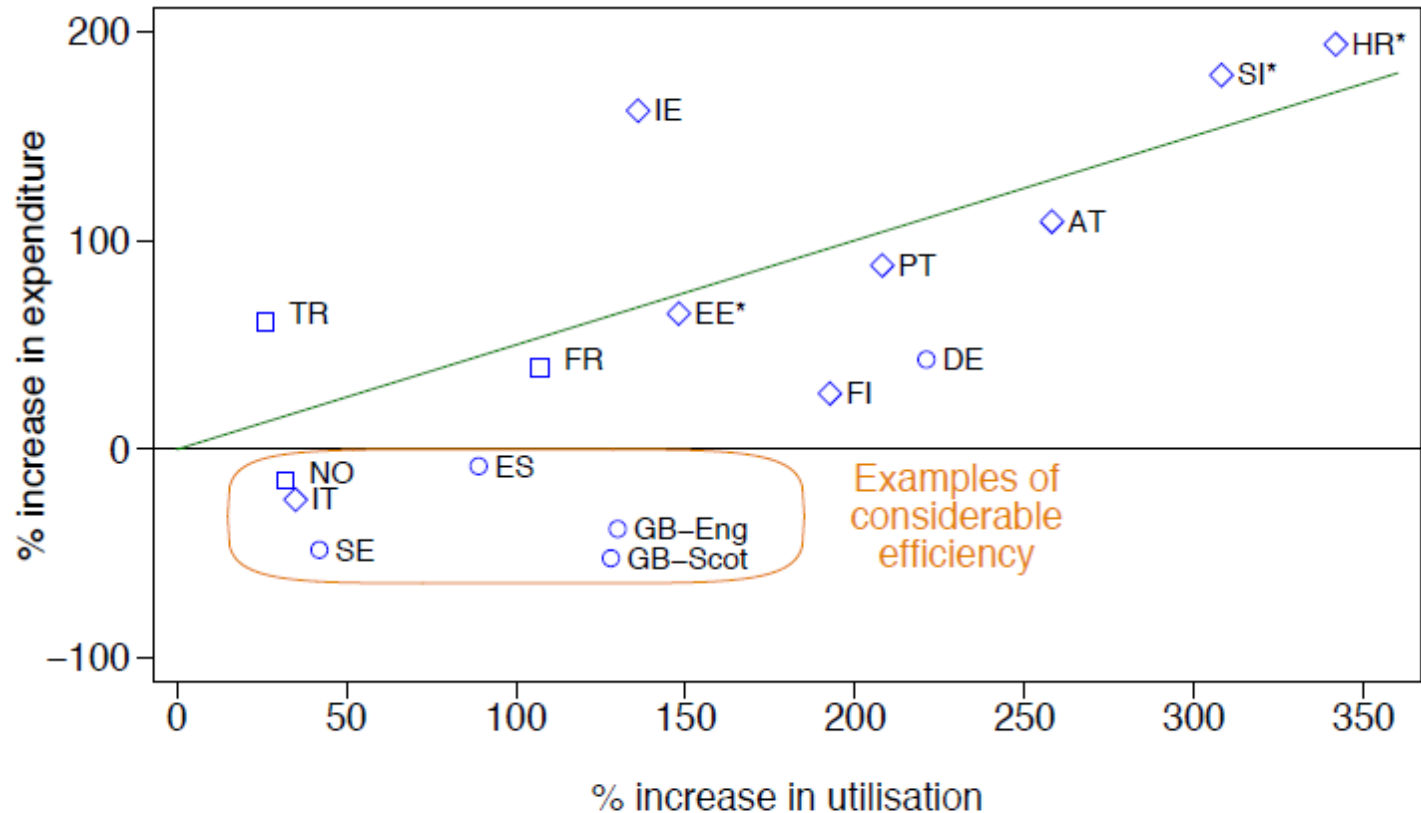


## The intensity and nature of the reforms impacts on utilisation, e.g. Statins in IE vs. AT, GB, NO and SE





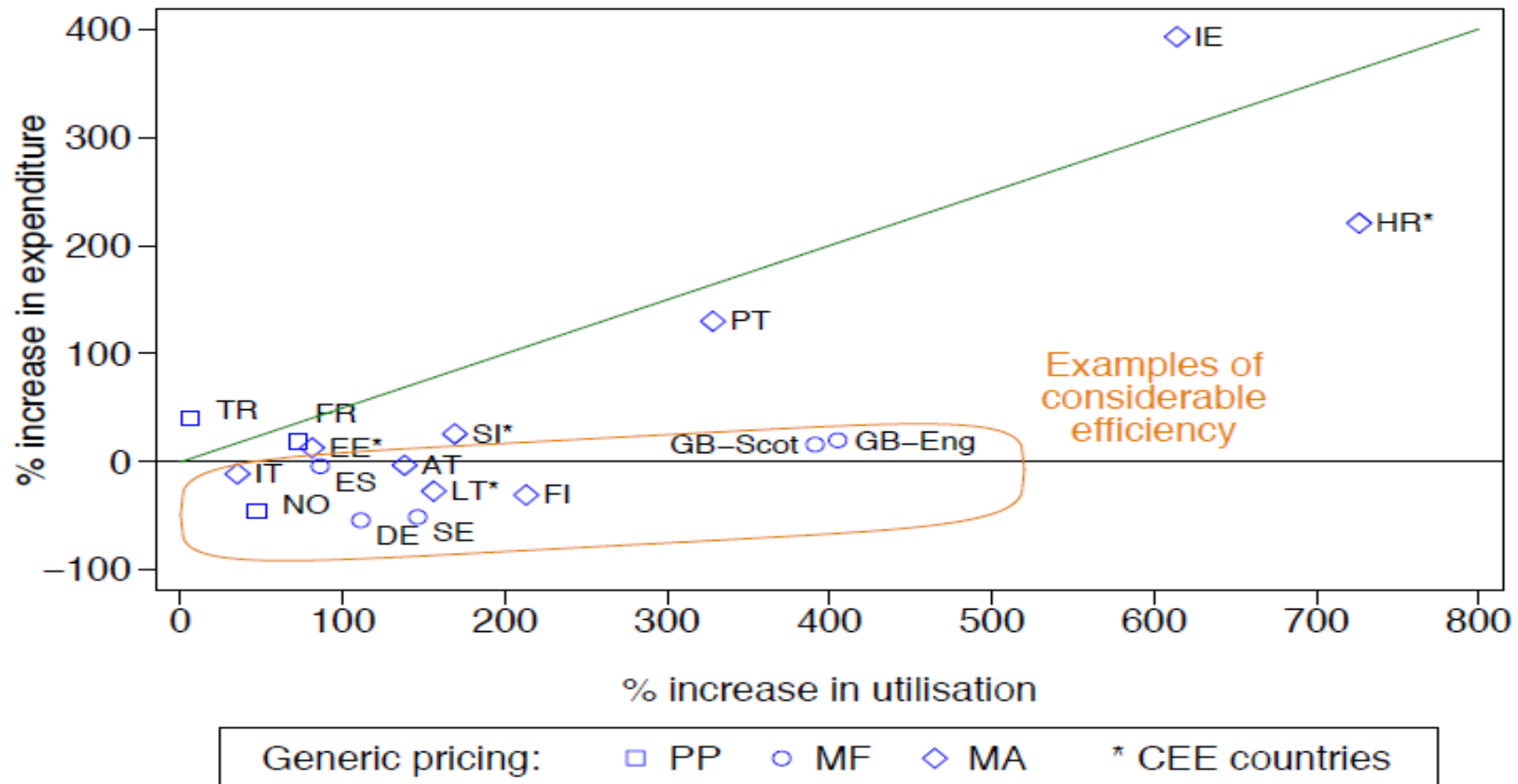
## Differences in intensity and nature of the reforms led to considerable differences in prescribing efficiency - PPIs



Generic pricing:    □ PP    ○ MF    ◇ MA    \* CEE countries



## Differences in intensity and nature of the reforms led to considerable differences in prescribing efficiency - statins





## Considerable differences in prescribing efficiency due to intensity of demand and supply side reforms

Country	Class	Utilisation 2007 vs. 2001	Expenditure 2007 vs. 2001	€/1000 inhabitants/year in 2007
AT	PPI	↑ 3.6 fold	↑ 2.1 fold	€19299
	Statins	↑ 2.4 fold	↓ 3%	€9555
DE	PPIs	↑ 3.2 fold	↑ 1.4 fold	€13864
	Statins	↑ 2.1 fold	↓ 54%	€6833
FR*	PPI	↑ 2.1 fold	↑ 38%	€15194
	Statin	↑ 72%	↑ 19%	€14896
GB – Eng	PPI	↑ 2.3 fold	↓ 38%	€6186
	Statin	↑ 5.1 fold	↑ 20%	€13439
IE	PPI	↑ 2.4 fold	↑ 2.6 fold	Over €60,000
	Statin	↑ 7.1 fold	↑ 4.9 fold	Over €60,000
SE	PPI	↑ 42%	↓ 48%	€5832
	Statins	↑ 2.5 fold	↓ 51%	€5192

\* In France co-pays up to 35% for each class; in Ireland , highly selected GMS population. In France, new CAPI initiative further improve efficiency



1. Introduction
2. Measures to obtain low prices for generics
3. Measures to enhance generic utilisation including dispelling myths
- 4. Conclusions/ future considerations**



## **European countries are learning from each other to release resources. This will continue**

---

- European countries are learning from each other regarding the pricing and utilisation of generics as resource pressures grow to help maintain comprehensive and equitable healthcare
- Cross country learnings will accelerate with estimated savings of over €1bn/ year alone with PPIs and statins in selected European countries
- This also includes greater pro activity to address concerns with generics that may arise. It also includes greater anticipation of their launch as proposed in England building on current activities, with estimated savings of over €1bn/ year



# Thank You

## Any Questions!

godman@ marionegri.it; Brian.Godman@ ki.se;  
mail@briangodman.co.uk

