Ongoing reforms to manage drug expenditures: impact and implications for the future

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1. Introduction (Part 1)

Part 2

2. New drugs

3. Established drugs

4. Learning opportunities and conclusions

Scrutiny over pharmaceutical expenditure is increasing - will continue as growing pressures

- Pharmaceutical expenditure has been growing at 50% in real terms in the past decade among OECD countries

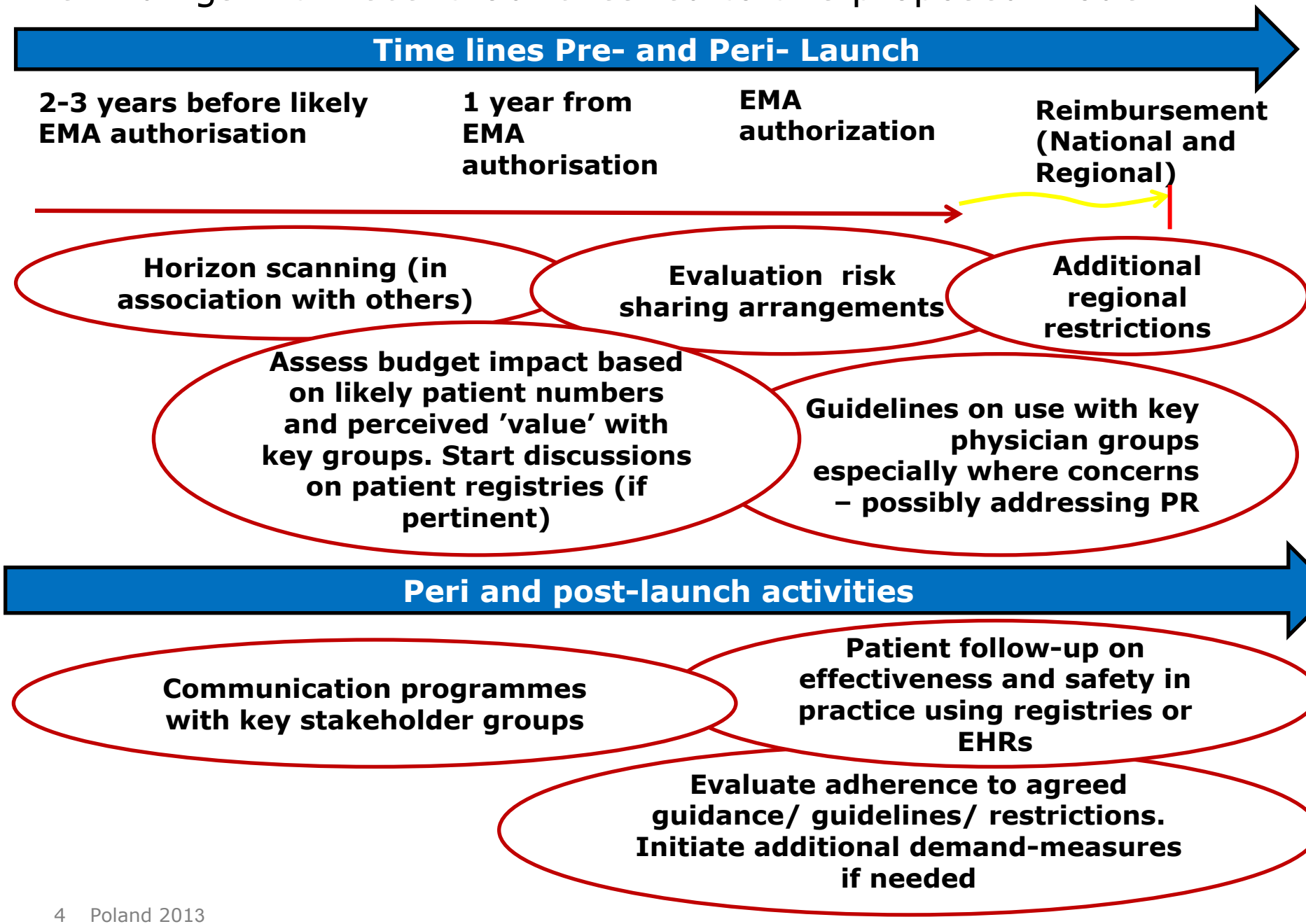
- This is set to continue unless addressed due to:
  - ageing populations
  - stricter clinical targets
  - continued launch of new premium priced products – especially with some at US$400,000/ patient/ year or more

- This has resulted in initiatives across Europe to 'optimise' the managed entry of new premium priced drugs - especially given the limited number of innovative products (5% to 10%)

- One output has been the development of a proposed new model to better manage the entry of new drugs

Ref: Godman et al 2012, 2013; Garattini, Bertele, Godman et al 2010; Malmstrom, Godman et al 2013; Prescrire 2011

The findings with recent launches led to this proposed model



Ref: Malmstrom, Godman, Diogene et al 2013

Typically across Europe this is resulting in greater assessment of new drugs and follow-up, e.g.:

Country	Strict criteria for assessment	Risk sharing/ patient access	Comprehensive models	Interface
Austria	√		Growing	Growing
Croatia	√	√	Growing	√
France	√	√	Growing	Growing
Germany	√	√		Growing
Italy/ Regions	√	√	√	Variable
Netherlands	√	√		
Slovenia	√	√	Growing	Growing
Spain (Regions)			√	√
Sweden	√	√	√	√
UK	√	√	√	√

Wettermark, et al 2010, Godman et al 2012, 2013; Björkhem-Bergman et al 2013; Malmstrom et al 2013

There are ongoing measures to release valuable resources from greater use of generics

Developments include:

- Ongoing measures to further lower prices of generics with some generics as low as 2-3% of originator prices
- Demonstrating different salts/ indications not a barrier if bioequivalence despite disinformation. Disinformation also currently a problem with biosimilars
- Demonstrating multiple initiatives are needed to favourably influence physician prescribing habits. This can lead to 10 fold differences in expenditure between countries without affecting patient care
- Countries continuing to learn from each other; this will grow as resource pressures intensify

Ref: van Woerkom et al 2012, 2013; Bennie et al 2013; Baumgartel, Godman et al 2012; Godman 2013

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Resource pressures have intensified payer focus on the costs of new drugs in recent years

- Increasing pressure on costs have intensified 'Payer' focus on requested premium prices for new treatments as:
  - ❑ Often limited data on efficacy and safety at launch versus known quantity for existing drugs
  - ❑ Health gain is often modest despite the 'hype'; however may be few alternative treatment options
  - ❑ Acquisition costs often high vs. current standards – which are increasingly available as low cost generics. This now includes biosimilars
  - ❑ Requested prices have increased with companies increasingly seeking orphan status, e.g. new cancer drugs
- This is leading to greater scrutiny over their potential role and value starting pre-launch. The alternative is limited funding for new drugs in the future

Ref: K Paterson 2011; Wettermark, Godman et al 2010; Godman, Finlayson et al 2013; Godman 2013

As a result, greater assessment of the value of new drugs and their follow-up, e.g.:

Country	Strict criteria for assessment	Risk sharing/ patient access	Comprehensive models	Interface
Austria	√		Growing	Growing
Croatia	√	√	Growing	√
France	√	√	Growing	Growing
Germany	√	√		Growing
Italy/ Regions	√	√	√	Variable
Netherlands	√	√		
Slovenia	√	√	Growing	Growing
Spain (Regions)			√	√
Sweden	√	√	√	√
UK	√	√	√	√

Wettermark, et al 2010, Godman et al 2012, 2013; Björkhem-Bergman et al 2013; Malmstrom et al 2013

Going back to our model to optimise the use of new drugs based on 3 pillars:

- Horizon scanning (in association with others)
- Assess the budget impact of new drugs based on critical drug evaluations/ likely patient numbers
- Start developing patient registries
- Start developing clinical guidelines/ guidance
- Start developing quality indicators

- P & R of new drugs based on a critical assessment of value
- Evaluate proposed risk sharing schemes including any price: volume schemes
- Finalise patient registries, guidelines and quality indicators for new drugs
- Initiate communication programmes with all key stakeholder groups

- Follow-up of the effectiveness and safety of new drugs in clinical practice using registries/ EHRs
- Assess prescribing against agreed quality indicators
- Evaluate adherence to agreed prescribing guidance/ restrictions
- Instigate any additional demand-side measures if needed

Ref: Accepted for publication Godman, Campbell et al 2013

Horizon Scanning activities growing to optimise resources. Italy and Sweden provide direction

- Horizon Scanning, forecasting and critical drug evaluation activities (HTA) are growing pre-launch across Europe - especially where budgets are devolved to regions

- The objective is to optimise resources whilst funding appropriate use of new expensive drugs helped by increasing use of low cost generics

- Processes generally start 18 to 24 months before likely launch dates. Key drugs include those likely to have a major impact on morbidity, mortality, service delivery and/ or costs – this includes new speciality drugs seeking orphan status

- Activities exist in e.g. Austria, Germany, Italy, Spain (Regions), Sweden, and UK (NICE/ SMC), with Italy and Stockholm County Council providing direction to others with their forecasting model. Activities also growing in other countries, e.g. Norway and South America

Ref: Garattini et al 2008; Godman, Wettermark et al 2009; Wettermark, Godman et al 2010; Malmstrom, Godman et al 2013

Multiple measures in Croatia have funded new drugs whilst reducing drug expenditure

Combined measures in Croatia for new and established drugs:

- **Education** – National formulary with benchmarking and visits from Croatian Institute for Health Insurance where concerns
- **Engineering** - price: volume agreements, curbing of pharmaceutical company activities
- **Economics** - higher patient co-payments for more expensive products that reference molecules and financial penalties for physicians for continued high cost prescribing
- **Enforcement** - prescribing restrictions/ penalties for abuse

- These combined with measures to lower generic prices and better regulate the price of new drugs resulted in 47 new products being added to the health insurance reimbursement list between 2009 and 2010. In addition, reducing health insurance expenditure by €0.2bn during the first 6 months of 2010 versus 2009

Ref: Voncina et al 2011, Brkičic L et al 2012; Godman, Bennie et al 2012

The situation in Germany is evolving with new regulations building on experiences of others

- Resource pressures are growing in Germany with now formal assessment of the value of new drugs (previously 'free pricing)

- Their value is assessed by an independent agency (based on HTA principles) and divided into 6 categories (similar to France):
  - ❑ substantial additional benefit vs. current standards
  - ❑ considerable additional benefit
  - ❑ small additional benefit
  - ❑ additional benefit not quantifiable
  - ❑ no evidence of additional benefit vs. current standards
  - ❑ less benefit than the comparator

- The perceived level of health gain drives subsequent discussions with the Sickness Funds on potential prices including discounts

Ref: Selke G Piperska Course Ljubljana; Godman, Paterson, Malmstrom et al 2012

Concerns with interface management is also growing resulting in new models to address this

- Models are being developed across Europe to enhance the co-ordination between hospital and ambulatory care to improve the rational use of medicine e.g.:
  - In Scotland, there is a mutual list of recommended drugs between primary and secondary care, with a requirement that prescriptions outside the list are endorsed by others
  - Indicators are being developed for both new and established drugs in Catalonia (Spain). This is enhanced by an IT system that incorporates all sectors whereby GPs can debate and challenge specialist prescribing if outside recommended guidance
  - This also includes Stockholm where its Model for the rational use of medicines including robust systems has resulted in high adherence rates for recommended drugs (over 77% of all prescriptions in ambulatory care)

Ref: Björkhem-Bergman, Andersén-Karlsson, Laing et al 2013; Gustafsson, Wettermark, Godman et al 2011

The Stockholm Model builds on a comprehensive approach to enhance rational prescribing across the interface between primary and secondary care. This includes a Wise Drug list for outpatients

Ref: Björkhem-Bergman, Andersén-Karlsson, Laing et al 2013

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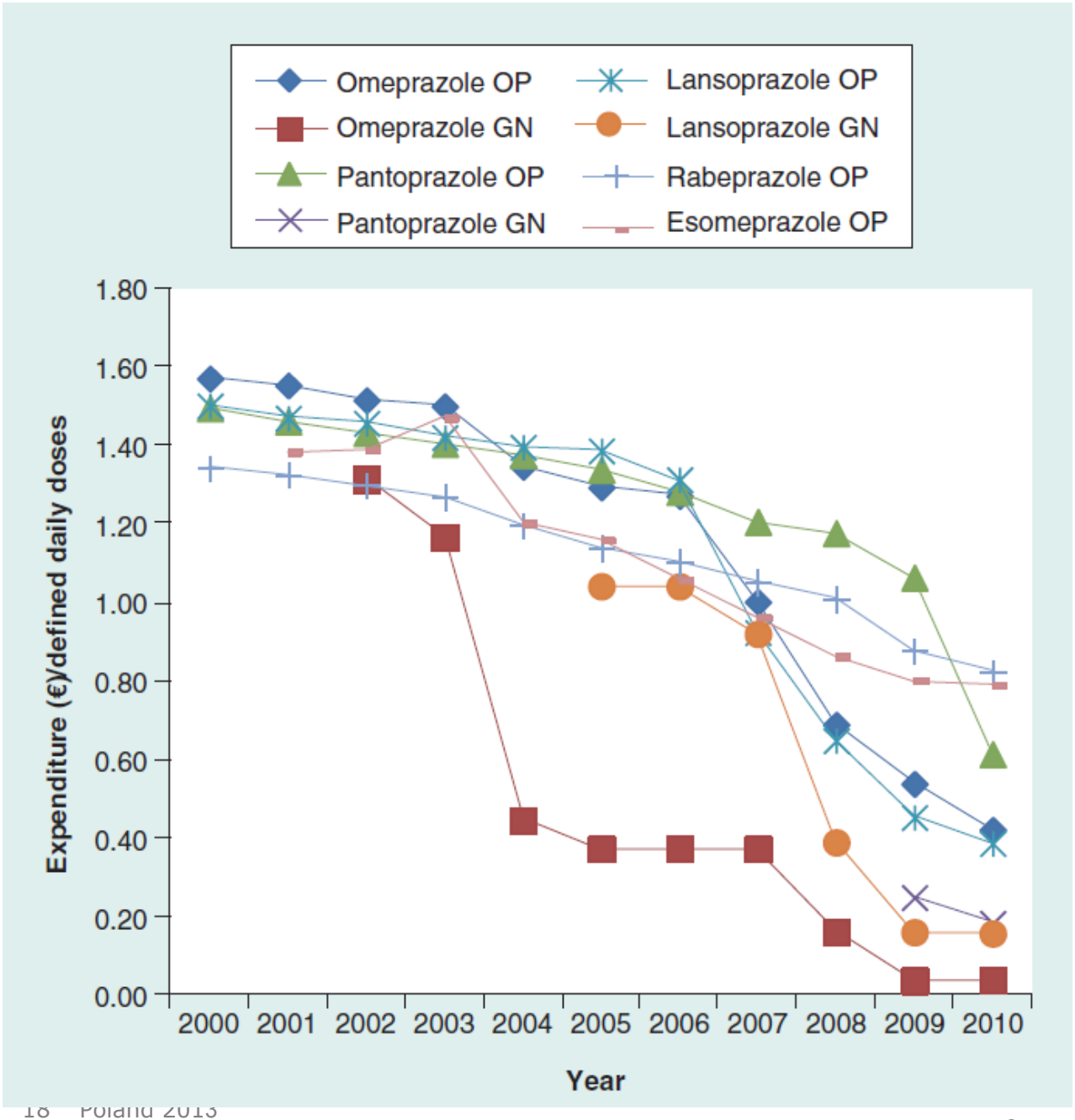
European countries have instigated measures to lower generic prices – now down to 2 – 4%

- All European countries have instigated measures to lower generic prices, some more successful than others. Successful measures include:
  - aggressive prescriptive pricing policies – Norway
  - enhancing volumes, e.g. compulsory or voluntary INN prescribing (Lithuania or UK), compulsory substitution (Sweden) or substitution targets (France). High INN prescribing pre-patent loss appreciably reduces patient confusion post loss (as seen with branded generics)
  - greater transparency in the pricing of generics including Preference Pricing Policies in the Netherlands, monthly auctions plus substitution in Sweden and 'M' and 'W' scheme in the UK has led to low prices for generics

- Myth that European countries with small populations cannot obtain low prices for generics, e.g. Lithuania and Srpska

Ref: Godman et al 2010; van Woerkom, Piepenbrink, Godman et al 2012; Garuoliene, Godman et al 2011



Preference pricing policies in the Netherlands led to low prices for generic omeprazole (similarly for generic simvastatin)

Ref: van Woerkom, Pipenbrink, Godman et al 2012

Typically European countries have introduced a range of different demand side measures, e.g. generic vs. patented PPIs and statins. However, their intensity varies leading to differences in efficiency

Country	Education	Engineering	Economics	Enforcement
AT	√		√	√
DE/ States	√	√	√	√
EE	√	√	√	√
ES/ regions	√	√	√	√
FR*	√	√	√	√
GB – En	√	√	√	
GB - Scot*	√	√	√	
IE	√			
IT/ Regions	√	√	√	√
LT	√	√	√	√
HR	√	√	√	√
NO	√			√
PO	√		√	√
PT	√	√	√	√
RS			√	Selected drugs
SE	√	√	√	√
SI	√		√	Selected drugs
TR	√			

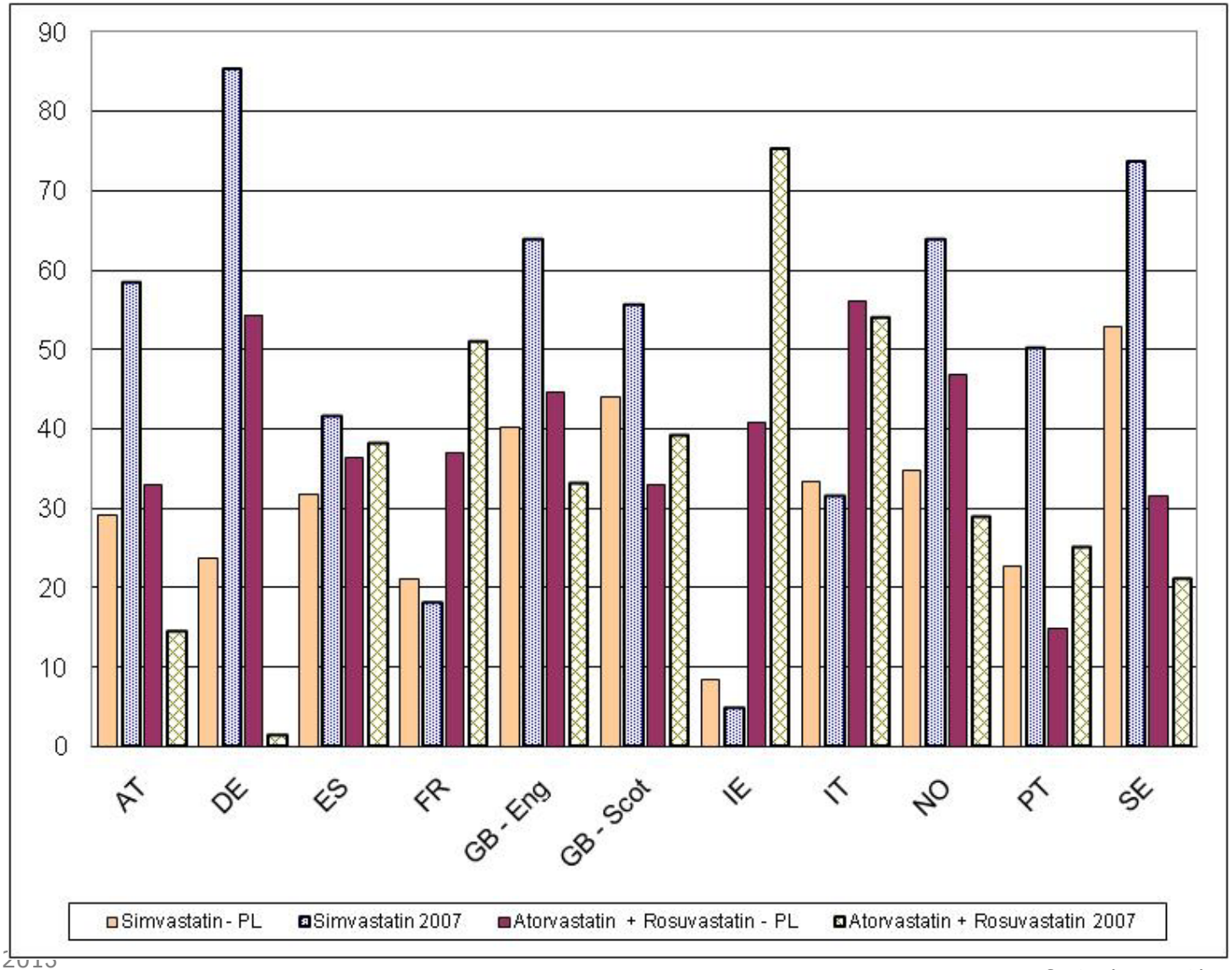
Ref: Godman, Shrank, Andersen et al 2011

Demand side measures are based on the 4 Es

- Demand side initiatives can be collated under 4 'E's – well accepted by payers and endorsed in publications:
  - **Education** – e.g. Academic detailing, benchmarking and formularies
  - **Economics** – e.g. financial incentives for physicians
  - **Engineering** – e.g. prescribing targets
  - **Enforcement** – e.g. prescribing restrictions
- Do see appreciable differences among European countries in their extent, nature and intensity leading to considerable difference in prescribing efficiency
- Some classes are challenging, e.g. antidepressants and atypical antipsychotics

Ref: Godman, Wettermark et al 2009; Wettermark, Godman et al 2009; Godman, Bennie et al 2012

The intensity and nature of the reforms impacts on utilisation, e.g. statins in Ireland and France vs. UK



Ref: Godman, Shrank et al 2010

Overall considerable differences in generic prices and their utilisation - leads to considerable differences in efficiency

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

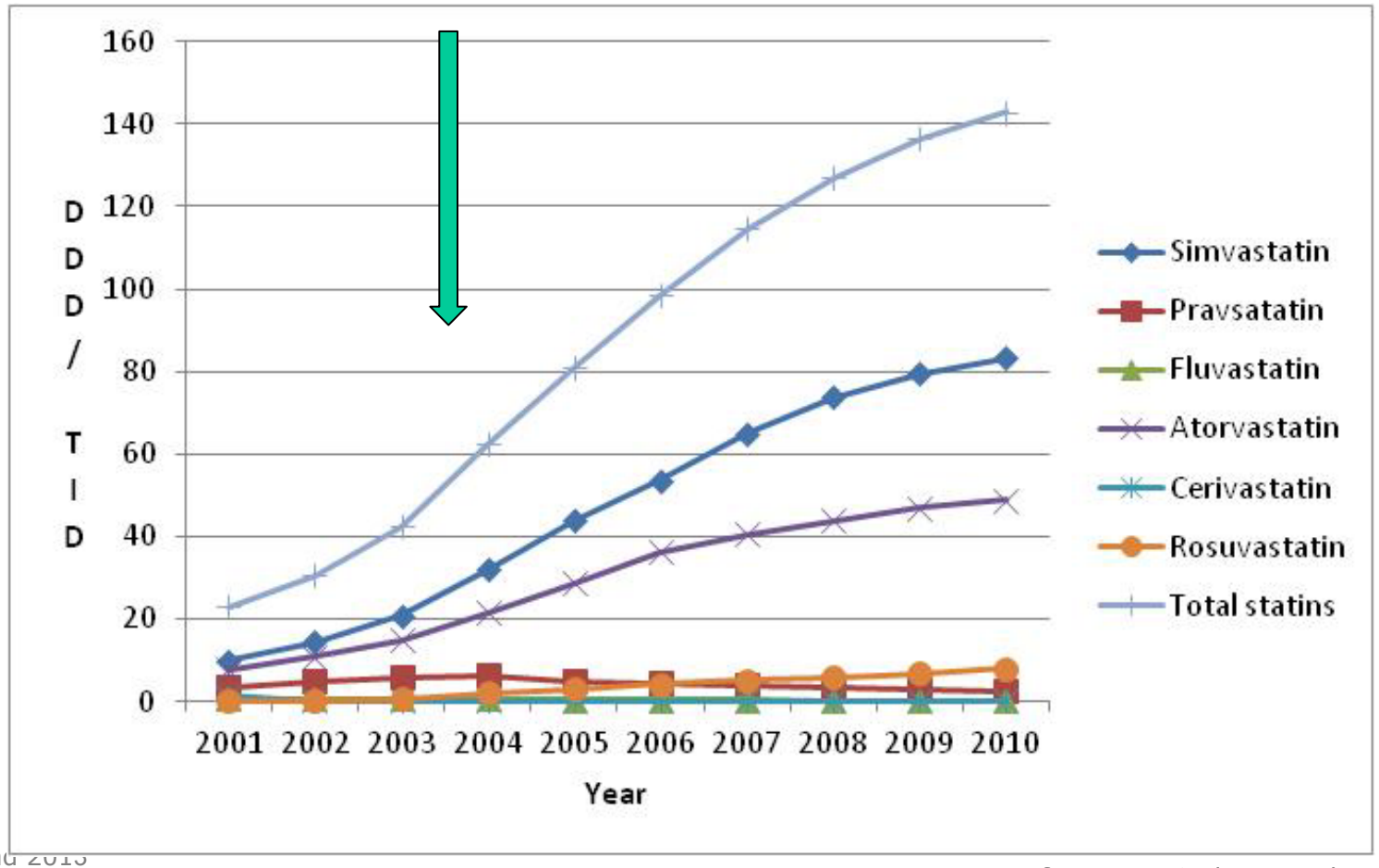
* In France co-pays up to 35% for each class

Sweden and the UK provided direction to other countries with their multiple supply and demand side measures

Ref: Godman, Shrank et al 2010

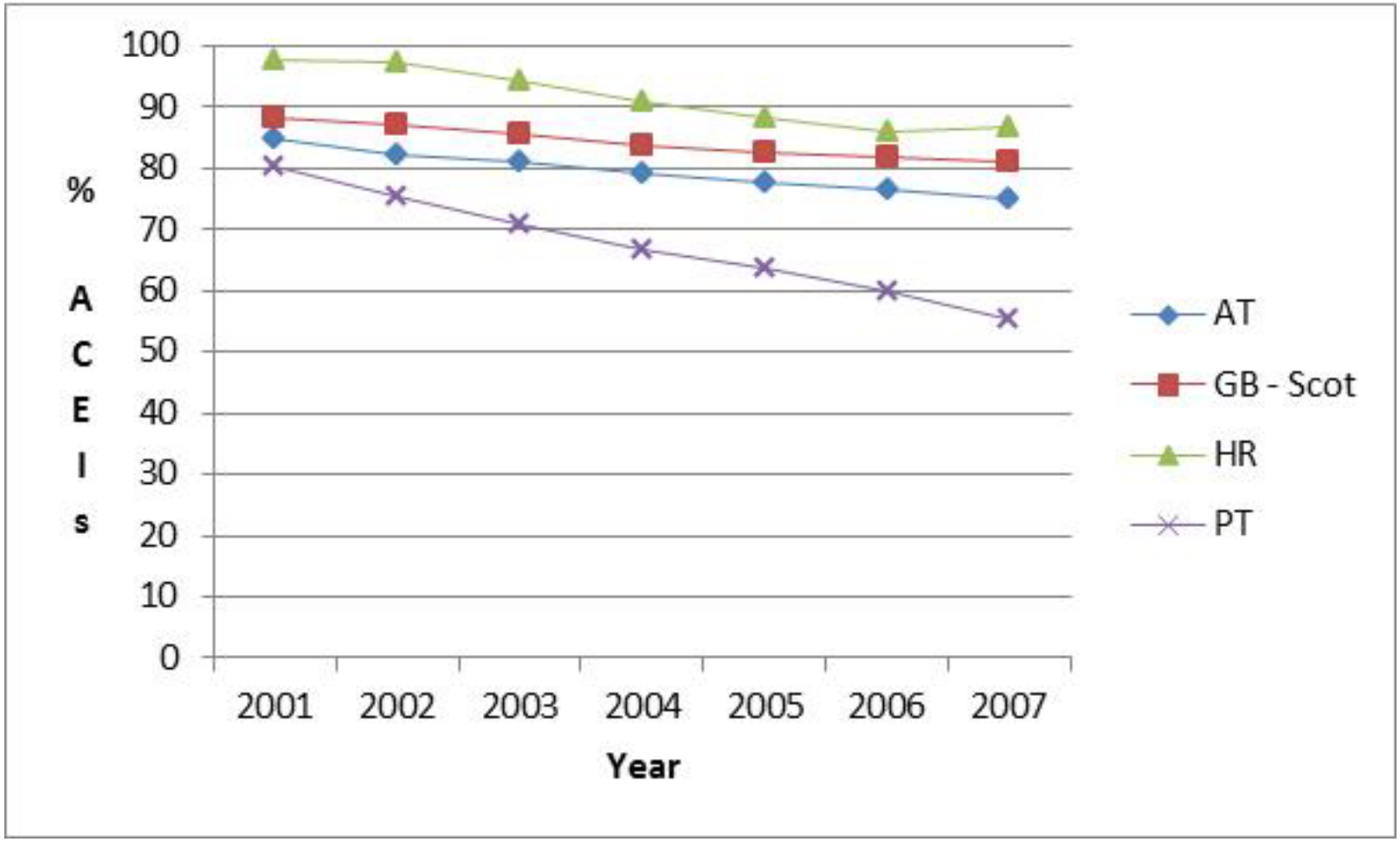
Multiple demand side measures continued to increase simvastatin utilisation in Scotland. Without these measures, statin expenditure would be GB£290m higher in 2010 (PPIs £159m) for a 5.2m population

Generic simvastatin reimbursed



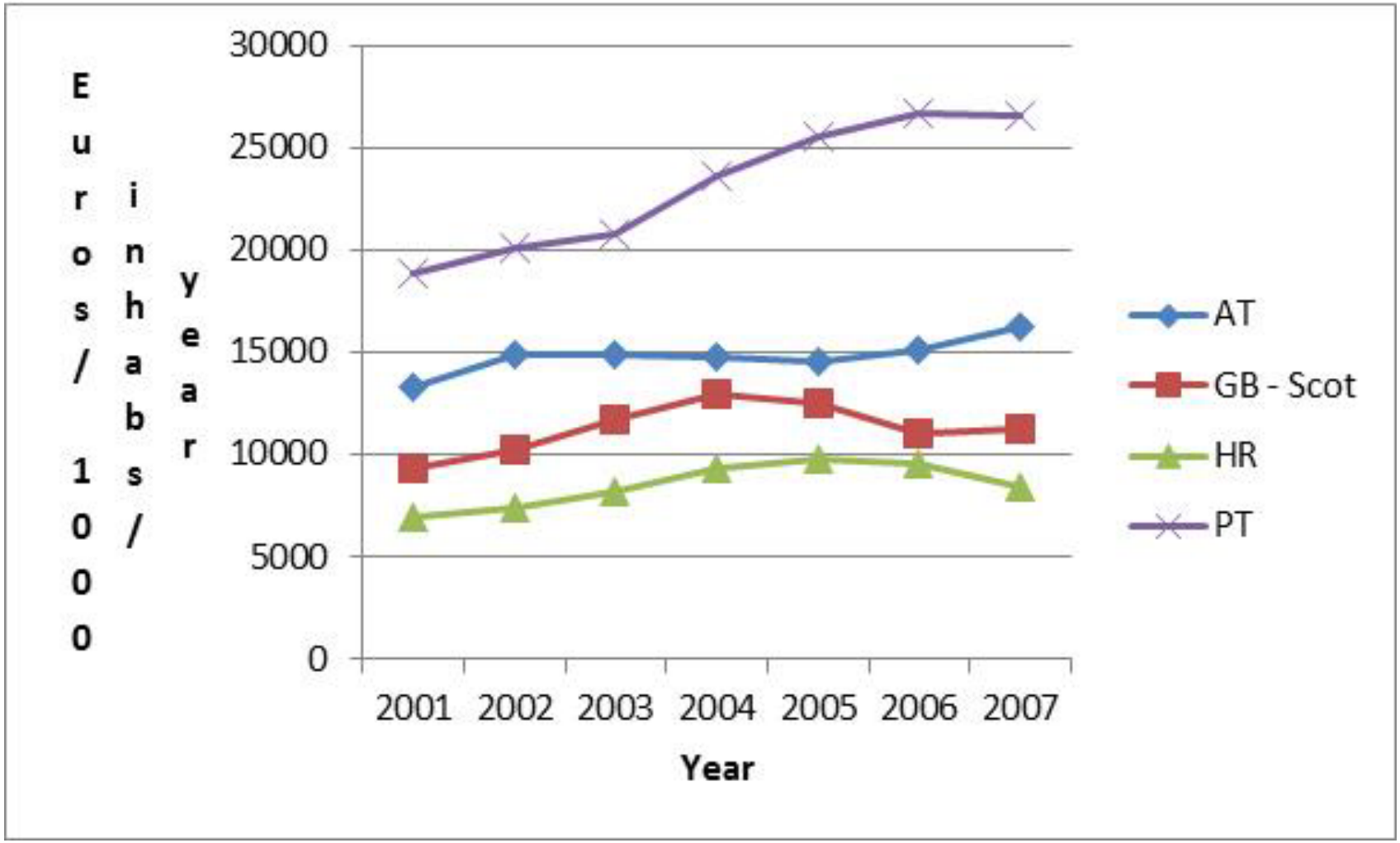
Ref: Bennie, Godman, Bishop et al 2012

Multiple demand-side measures limited ARB utilisation vs. generic ACEIs in Scotland versus Portugal, matching the influence of prescribing restrictions for ARBs in Austria and Croatia



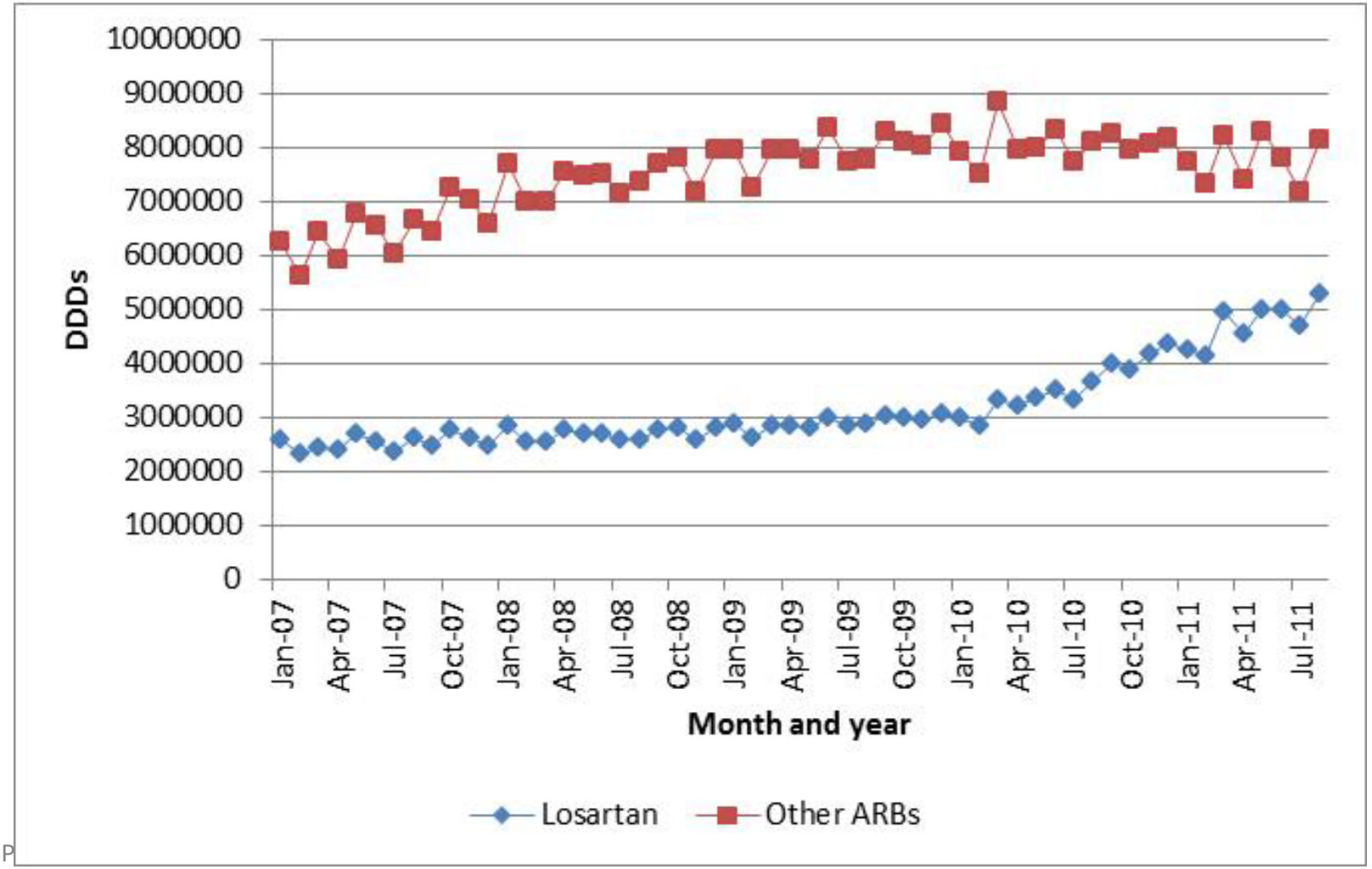
Ref: Adapted from Voncina, Strizrep et al 2011

As a result, limited increase in expenditure on renin-angiotensin inhibitor drugs in Scotland in recent years when adjusted for populations versus Portugal despite increased utilisation (159% Scotland, 72% Portugal)



Ref: Adapted from Voncina, Strizrep et al 2011

Multiple demand side measures among the Counties in Sweden including guidelines, prescribing targets, financial incentives and therapeutic switching significantly increased losartan utilisation post generics (March 2010) reducing costs (costs⬇ by 26%; utilisation⬆16%)



Ref: Godman, Wettermark, Miranda et al 2013

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Care needed when introducing prescribing restrictions as expectations may not be fully realised

- Differences in the nature and follow up of prescribing restrictions is important to effect change:
  - ❑ Differences in utilisation of patented statins versus generics in Austria, Finland and Norway following restrictions
  - ❑ Differences in utilisation rates of ARBs in Croatia vs Austria
  - ❑ Esomeprazole versus generic PPIs in Norway

- The disease area is also important. Prescribing restrictions introduced in Sweden for duloxetine had limited impact on its subsequent utilisation as complex disease area; however, significantly increased utilisation of venlafaxine

- Timing is also important – limited impact of prescribing restrictions for patented statins in Sweden some 6 years + after multiple measures among the Counties (Regions)

Ref: Godman, Sakshaug et al 2011; Voncina, Strizrep, Godman et al 2011; Godman, Persson et al 2013

European countries must continue learning from each other as resource pressures grow

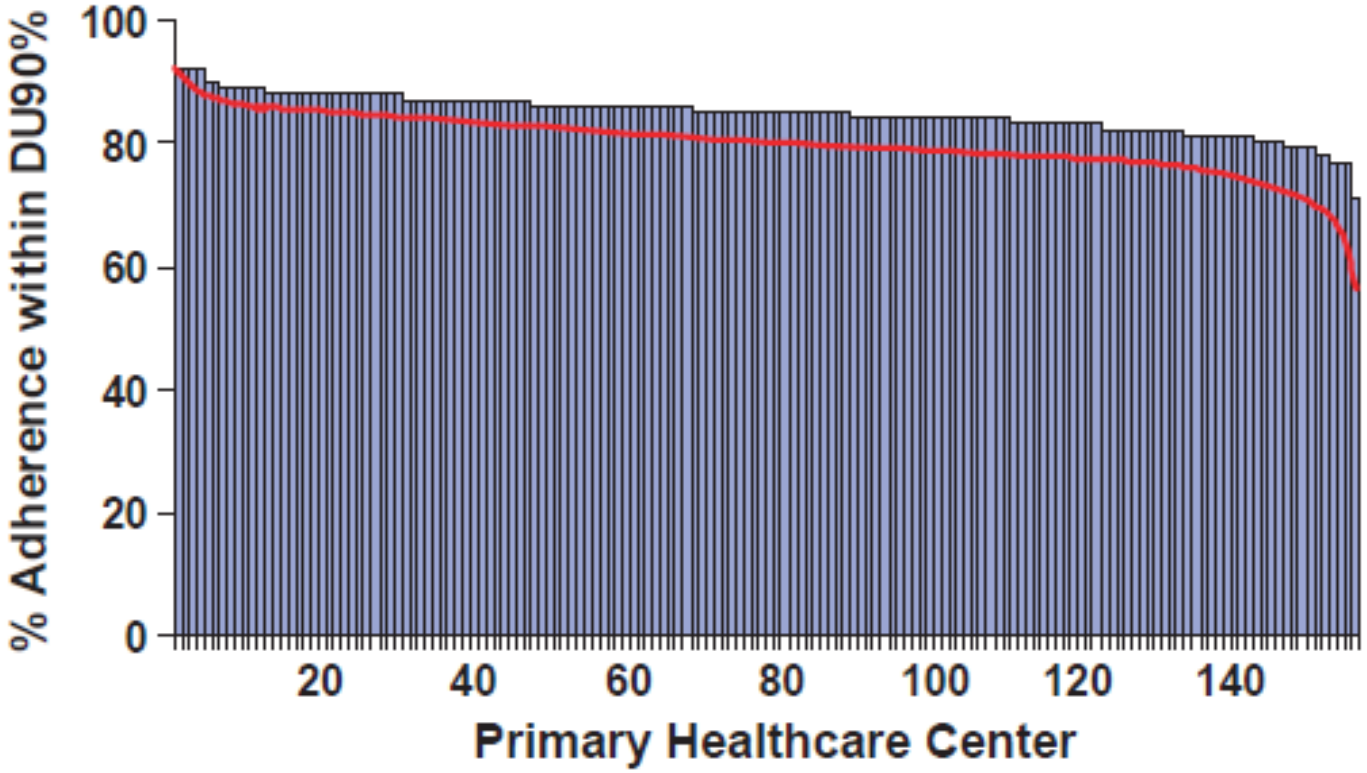
- Greater proactivity among payers will include:
  - ❑ Continued refinement of new models to optimise their managed entry with greater scrutiny on requested prices
  - ❑ Further measures to lower generic prices (where pertinent) and increase their utilisation versus originators and patented products in a class – recognising no 'spill over' effect even in related classes, e.g. losartan in Scotland
  - ❑ Further development of regional drug formularies to minimise ADRs building on the 'Wise List' in Stockholm

- There will also be greater care when instigating additional demand-side measures else there could be disappointment with the outcome

- Countries must continue learning from each other – otherwise continuing difficulties with providing equitable and comprehensive healthcare as resource pressures grow

Ref: Godman et al 2011; 2012, 2013; Gustafsson et al 2011; Malmstrom, Godman et al 2013

Multiple activities enhances high adherence rates to this 'voluntary' prescribing guidance improving the quality of care efficiently



- Red line refers to adherence among the 156 PHCs in 2003
- Trust, academic detailing, regular monitoring, prescribing targets and financial incentives key to high adherence rates

Ref: Gustafsson, Wettermark, Godman et al 2011

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Any Questions!

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