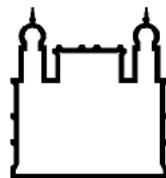


Communicating DU studies

Prepared by Brian Godman



Ministério da Saúde

FIOCRUZ
Fundação Oswaldo Cruz

1. Objective

2. Single country studies

3. CNC studies

4. Summary

Objective of DU studies allied with health policy

- If you do not measure pertinent current prescribing and expenditure patterns – how can you effectively plan future initiatives/ measures (personal philosophy)?
- This means drug utilisation researchers, health authority/ health insurance personal and hospital personnel (if pertinent) working together to analyse their findings and use these as a platform for future strategies (personal philosophy)
- Future strategies/ initiatives should subsequently be analysed to assess the need for further measures
- The nature of any drug utilisation study undertaken will depend on the level of sophistication of available data, e.g. aggregated data vs. patient identity data including data on effectiveness and safety of different treatment approaches

Comparative effectiveness/ safety studies of different treatment approaches

Increasing sophistication

Analytical drug utilisation studies using patient data

Patient data for descriptive drug utilisation studies

Patient identity data to determine ongoing incidence and prevalence of diseases

Aggregated drug utilisation statistics (volume and/ or expenditure)



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4. Summary

The 'Wise List' has been successfully developed in Stockholm to enhance the rational use of drugs

- The 'Wise List' was developed in Stockholm as a means to enhance the rational use of drugs, with the first version published in 2001. This followed a law in 1996 making it mandatory for each county to have at least one DTC
- The 'Wise List' typically contains approximately 200 drugs for treating common diseases, which are typically older (generic) products as they typically have the greatest evidence/ value
- Clear criteria for drug selection, coupled with trust among the physicians and public (with a separate 'Wise List' for patients), has enhanced adherence to this 'voluntary' list - reducing costs and improving the quality of care
- Adherence also enhanced by regular monitoring (DU90%), comprehensive communication programmes as well as prescribing indicators and financial incentives (more recent)

The 'Wise List' is solid, simple and consistent, updated each year with a separate version for physicians and patients

Basic & Clinical Pharmacology & Toxicology, 108, 224–233

Doi: 10.1111/j.1742-7843.2011.00682.

The 'Wise List' – A Comprehensive Concept to Select, Communicate and Achieve Adherence to Recommendations of Essential Drugs in Ambulatory Care in Stockholm

Lars L. Gustafsson^{1,2}, Björn Wettermark^{1,3}, Brian Godman¹, Eva Andersén-Karlsson^{3,4}, Ulf Bergman^{1,2}, Jan Hasselström⁵, Lars-Olof Hensjö⁶, Paul Hjemdahl^{2,7}, Ingrid Jägre³, Margaretha Julander³, Bo Ringertz⁸, Daniel Schmidt⁹, Susan Sjöberg³, Folke Sjöqvist¹, Carl-Olav Stiller^{2,7}, Elisabeth Törnqvist³, Rolf Tryselius³, Sigurd Vitols^{2,7} and Christer von Bahr¹⁰, for the Regional Drug Expert Consortium*



Strict EBM criteria used by Stockholm County Council when developing the annual 'Wise List'

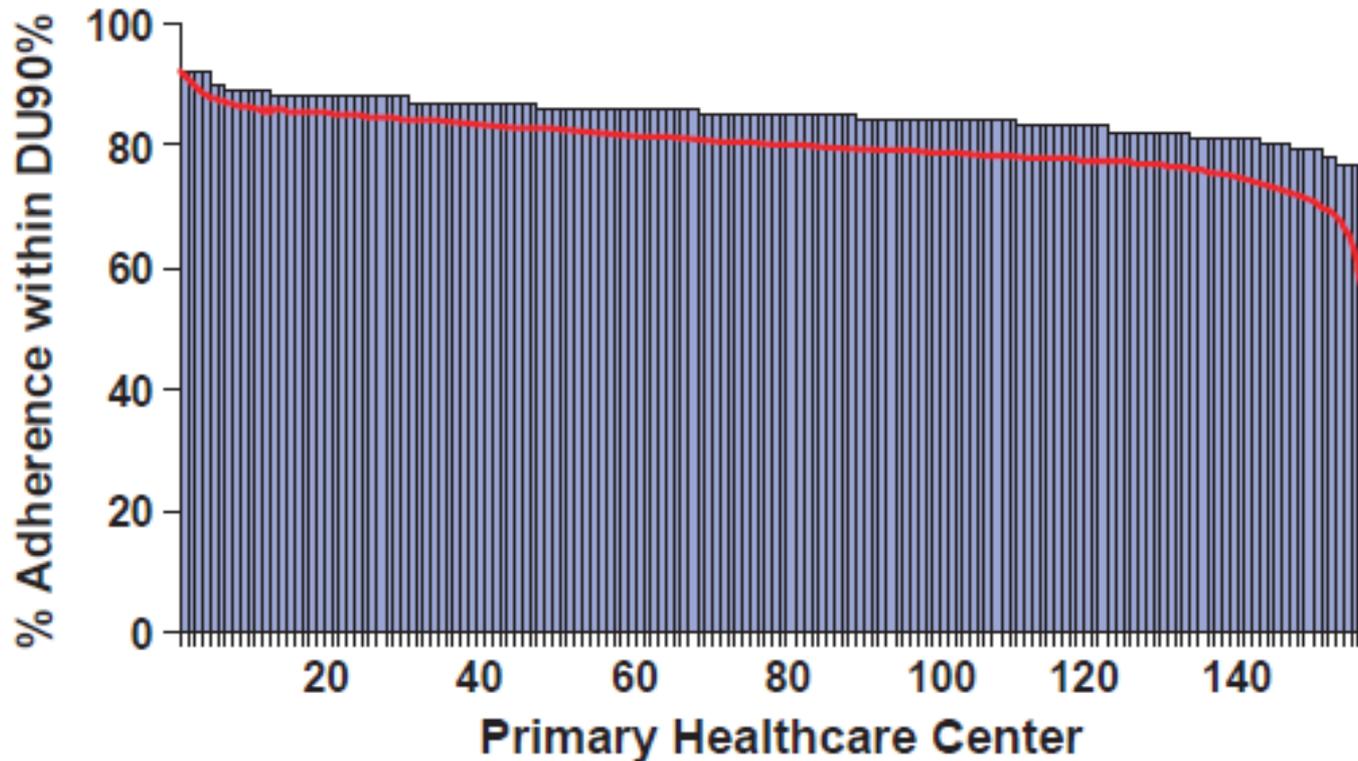
Five point criteria used by Stockholm for drug selection

- **Efficacy and safety** – based on evidence preferably from RCTs
- **Pharmaceutical suitability** – Formulations, strengths and pharmaceutical properties
- **Efficiency** – comparative reimbursed prices and overall budget impact versus current standards. Limited use of cost/QALYs in decision making unlike TLV (Reimbursement body)
- **Experience** – Mainly concerned with drug safety. Ideally, recommended drugs should have been available for at least two years. More recent drugs included depending on the extent of evidence provided (EBM regulations)
- **Environmental aspects** – growing concern reflected by Swedish government initiative from 2010 onwards

Guidance well accepted as seen by high adherence rates



Multiple activities enhances high adherence rates to this 'voluntary' prescribing guidance



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

Communication and other activities in Slovenia have reduced antibiotic utilisation in recent years

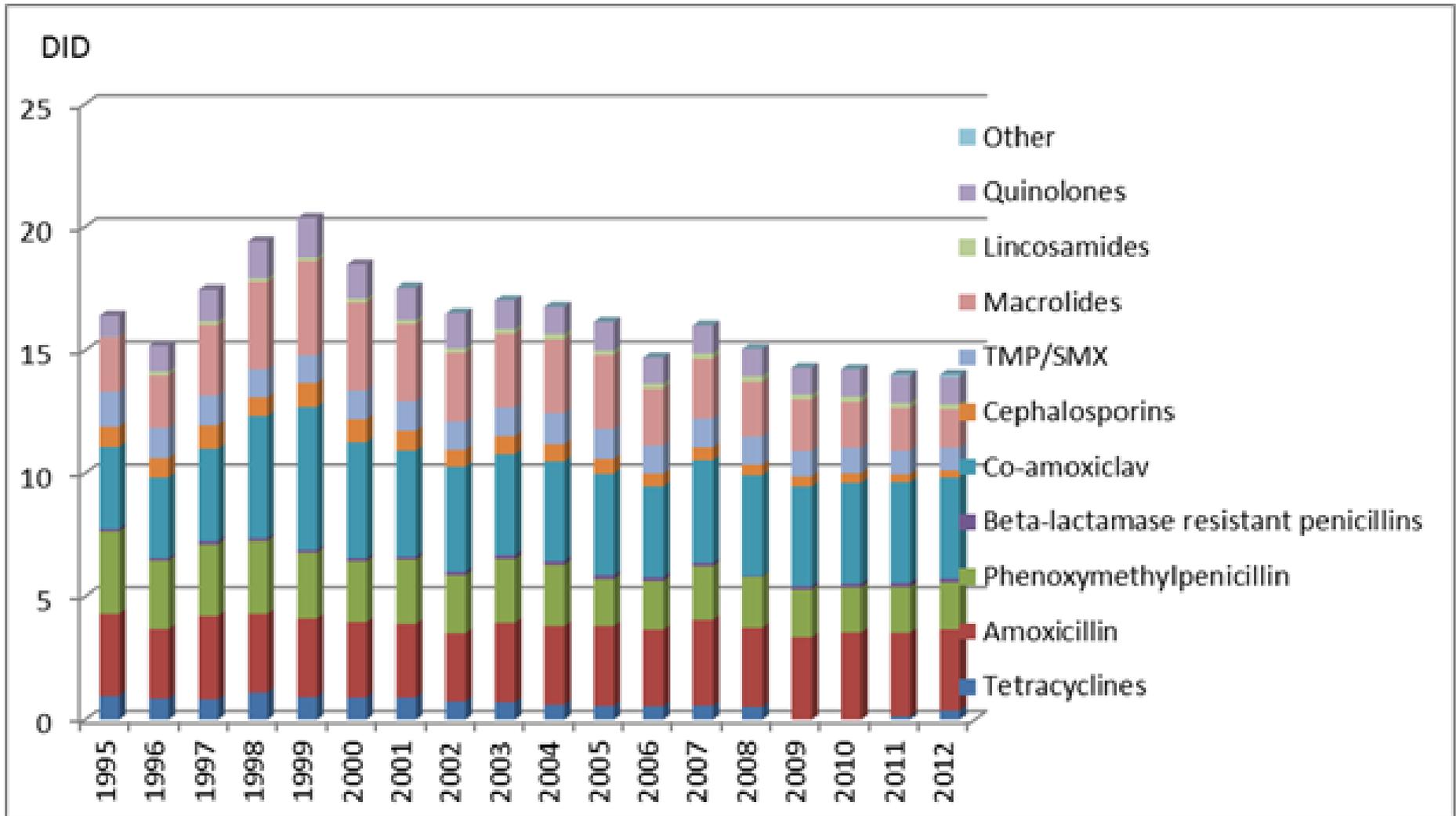
- Multifaceted interventions/ communication programmes were instigated in Slovenia in the late 90s to reduce antibiotic utilisation following a 24% increase
- These were undertaken by all key stakeholder groups including the Ministry of Health, national health insurance agency, physician groups, pharmacists and patients – with good communication between them
- From 1999 to 2012, antibiotic consumption decreased by 2-9% per year, with an overall decrease of 31% - greater for restricted than non-restricted antibiotics. Expenditures on antibiotics also decreased by 53% during the study period
- Future activities will include local pharmacotherapeutic groups with an emphasis on the quality of care to further reduce their use (already ongoing). The results of the current study act as a basis for future studies

Activity	Institution (organizer)	Targeted public	Introduction / frequency
2-day symposium on antibiotics once a year	Dept. of Infectious Diseases of the UMC Ljubljana	GPs	1995 every year
Prescribing restrictions for antibiotics	ZZZS	All physicians	Starting 2000/ permanent
Workshops in Primary health centres	Primary health centres, ZZZS	GPs	2001/ sporadically
Guidelines on treatment of infectious diseases	Medical professionals	GPs	2002
The drug Bulletin "Recept"	ZZZS	All physicians	2003/ twice a year
Workshop on rational prescribing of antibiotics	Faculty of Medicine University of Ljubljana	Specializing GPs	2004/ every year
Flyer "Safe use of drugs"	ZZZS, medical professionals	Lay public	2006/ always available
Booklet "My child has a fever"	ZZZS, medical professionals	Parents	2007/ always available
Workshop in a region with the highest use of antibiotics	National Committee for the Rational Use of Antimicrobials	GPs	2007/ once a year
Antibiotic Awareness Day	MoH and National Committee for the Rational Use of Antimicrobials	Lay public and GPs	2008/ every year
Workshop on rational prescribing of antibiotics	Slovenian society of chemotherapy	Young physicians	2010/ every year
Flyer "Get well without antibiotics" and "Interactions of drugs"	ZZZS, medical professionals	Lay public	2010/ always available
Quality indicators including antibiotics	ZZZS	GPs	2011

Multiple activities, groups and their frequency in Slovenia from the late 1990s onwards.

ZZZS = national health insurance group

The multiple measures led to a 31% decrease in antibiotic consumption in recent years in Slovenia



1. Objective

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4. Summary

Countries are learning from each other through cross national studies. This will continue

Learnings from cross national studies include:

- Achieving low cost generics – Sweden now has monthly auctions further lowering prices of generics (Netherlands - 3 monthly, Croatia and New Zealand yearly, etc.)
- Enhancing the prescribing of generics versus originators, i.e. increasingly instigating either INN prescribing (compulsory or voluntary) or reference pricing for the molecule – majority of EU countries (France, Ireland and Italy recently learning from others)
- Enhancing the prescribing of low cost generics versus patented products in a class:
 - ❑ Measures instigated over several years among EU countries for ACEIs/ ARBs, PPIs, statins as they learnt from each other
 - ❑ More recently with generic losartan – typically measures instigated around/ shortly after generic availability or not at all (conscious decision in some countries)

Countries are learning from high voluntary INN prescribing rates seen across product classes in the UK through education – reduces confusion associated with branded generics

Class	Molecule	Year	% Generic (DDD basis)
PPI	Omeprazole	2010	98
Statins	Simvastatin	2010	98
ACEIs	Enalapril	2007	99
	Lisinopril	2007	98
ARBs	Losartan	2011	99
SSRIs	Fluoxetine	2007	98
	Sertraline	2007	98
	Citalopram	2007	99
Atypical antipsychotics	Risperidone	2009	98

Assessment of demand-side measures to increase the prescribing of generic ACEIs, PPIs and statins typically involved multiple countries and stakeholders to enhance the robustness of the content - with findings communicated to provide future guidance

First study – influence of measures to limit the prescribing of patented ARBs vs. ACEIs (similar effectiveness and only limited number of patients experiencing coughing)

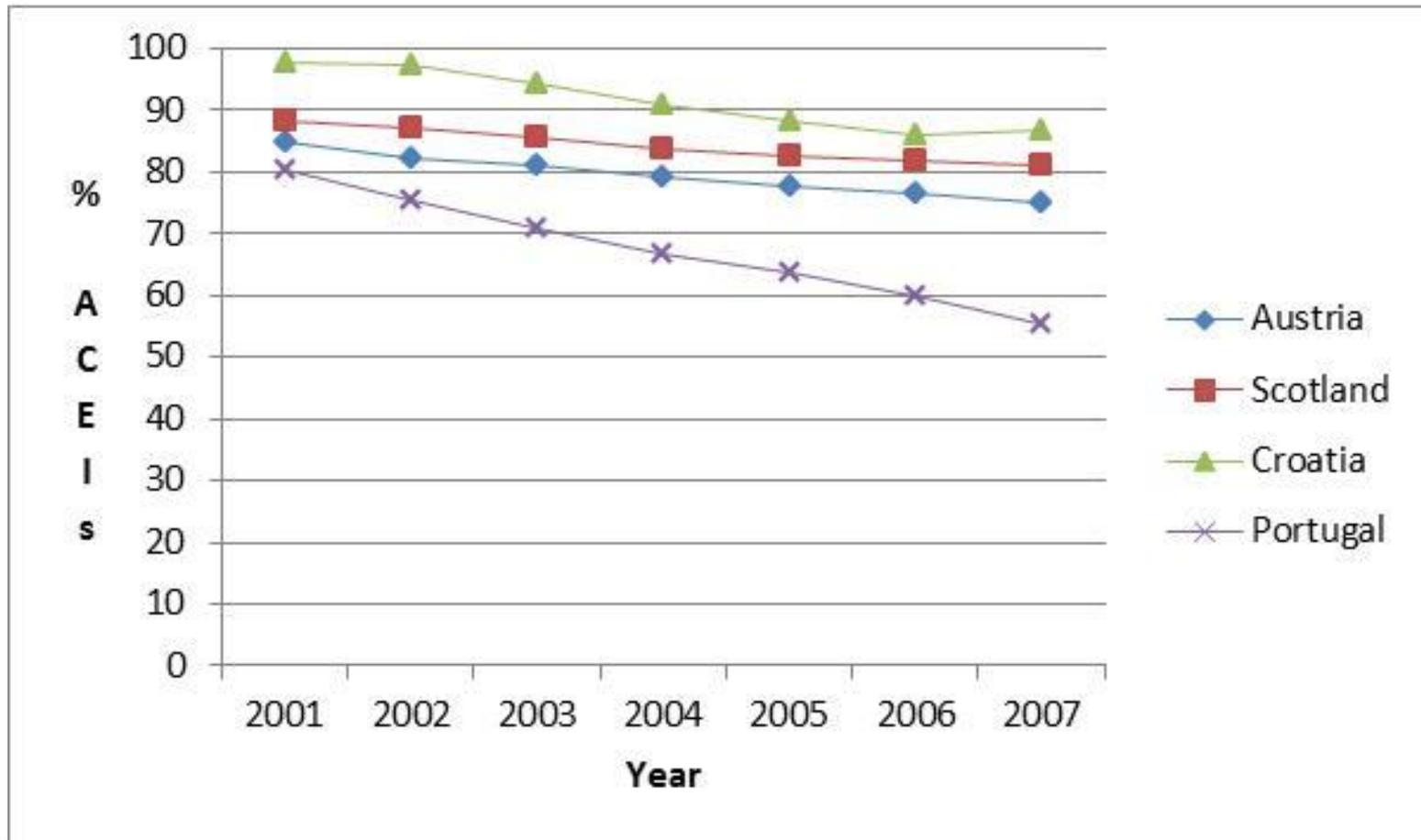
EXPERT
REVIEWS

Influence of demand-side measures to enhance renin–angiotensin prescribing efficiency in Europe: implications for the future

Expert Rev. Pharmacoeconomics Outcomes Res. 11(4), 469–479 (2011)

Luka Vončina¹,
Tihomir Strizrep¹,
Brian Godman^{†2,3},
Marion Bennie^{4,5},
Iain Bishop⁵,
Stephen Campbell⁶,
Vera Vlahović-
Palčevski⁷ and
Lars L Gustafsson²

Multiple demand-side measures limited ARB utilisation vs. generic ACEIs (Scotland) matching the influence of prescribing restrictions for ARBs in Austria and Croatia (ARBs second line – greater intensity of follow-up in Croatia vs. Austria) - y axis = % ACEIs vs. total renin-angiotensin inhibitors on a DDD basis



Principally health authority personnel from across Europe demonstrated multiple demand-side measures increased the prescribing of generic PPIs and statins. Findings communicated to provide future guidance

EXPERT
REVIEWS

Comparing policies to enhance prescribing efficiency in Europe through increasing generic utilization: changes seen and global implications

Expert Rev. Pharmacoeconomics Outcomes Res. 10(6), 707–722 (2010).

Brian Godman[†],
William Shrank,
Morten Andersen,
Christian Berg,
Iain Bishop,
Thomas Burkhardt,
Kristina Garuoliene,
Harald Herholz,
Roberta Joppi,
Marija Kalaba,
Ott Laius,
Diane McGinn,
Vita Samaluk,
Catherine Sermet,
Ulrich Schwabe,
Inês Teixeira,
Lesley Tilson,
F Cankat Tulunay,
Vera Vlahović-
Palčevski,
Kamila Wendykowska,
Björn Wettermark,
Corinne Zara and
Lars L Gustafsson

Appreciable differences in generic utilisation (PPIs and statins) leading 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

A retrospective drug utilisation study was undertaken documenting changes in utilisation patterns and costs before and after generic simvastatin as multiple measures introduced in most countries over time preventing time series analyses

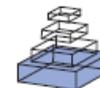
Demand-side measures can be collated under the 4 Es to compare their influence across countries

- Demand side initiatives can be collated under 4 'E's – well accepted by payers and endorsed in publications:
 - **Education** – e.g. Academic detailing, benchmarking, guidelines and formularies
 - **Economics** – e.g. financial incentives for physicians, pharmacists or patients
 - **Engineering** – e.g. prescribing targets - % of PPIs as generics, % of statins as generics, % of patients achieving agreed BP and lipid goals
 - **Enforcement** – e.g. prescribing restrictions, compulsory generic substitution

Typically multiple interventions over time making time series analyses difficult, e.g. UK PCT

Year	2004	2005	2006	2007
General				
Education - Regional	Practice based Pharmacists provided by PCTs to monitor prescribing and provide educational input to GPs			
Engineering - national				Better Care, Better Value Metric for statins and PPIs
Engineering - Regional	Generic switch programmes initiated by practice pharmacists to enhance prescribing and dispensing of generics			
			ScriptSwitch software installed	
Economics	Prescribing incentive scheme based on prescribing targets for PPIs and statins and PPI doses prescribed		Practice based commissioning	
PPIs				
Education - Regional	NICE Technology Appraisal PPIs including dose reduction, guidance on dyspepsia including PPIs first line and dropping to maintenance doses. MeReC Bulletins and drug information on esomeprazole			
Statins				
Education	Blackpool, Fylde and Wyre HEPAC Guidelines on lipids			
			NICE and MeReC guidance on statin prescribing encouraging generics	
Engineering				Information to practices on potential savings from prescribing generics
Engineering	QoF targets including clinical indicators CHD 8, Stroke 8, Diabetes 17			

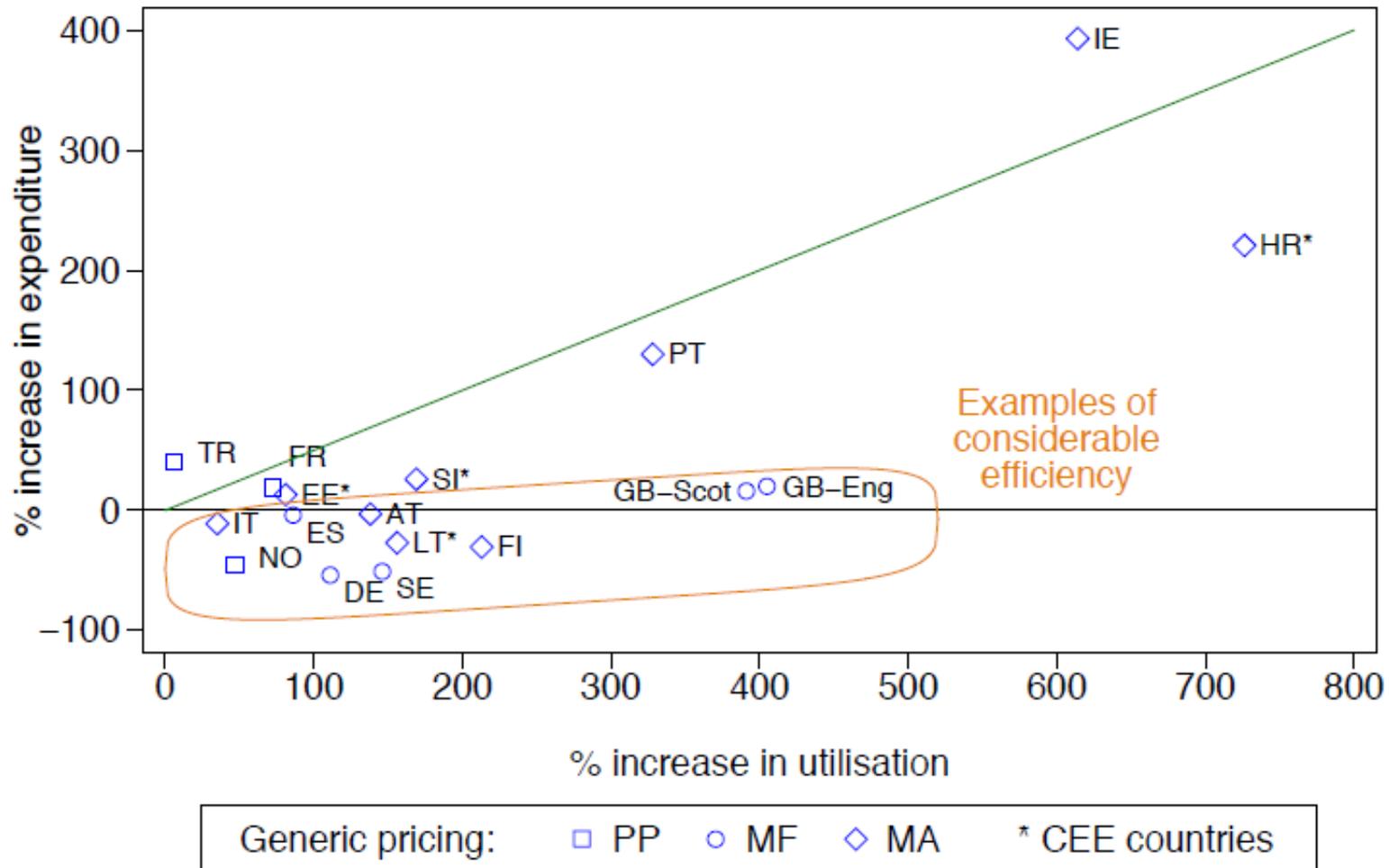
The second publication also involved central and eastern European (CEE) countries documenting changes in expenditure and utilisation of PPIs and statins over time (2007 vs. 2001)



Policies to enhance prescribing efficiency in Europe: findings and future implications

Brian Godman^{1,2,3}, William Shrank⁴, Morten Andersen⁵, Christian Berg⁶, Iain Bishop⁷, Thomas Burkhardt⁸, Kristina Garuoliene^{9,10}, Harald Herholz¹¹, Roberta Joppi^{1,12}, Marija Kalaba¹³, Ott Laius¹⁴, Julie Lonsdale¹⁵, Rickard E. Malmström¹⁶, Jaana E. Martikainen¹⁷, Vita Samaluk¹⁸, Catherine Sermet¹⁹, Ulrich Schwabe²⁰, Inês Teixeira²¹, Lesley Tilson²², F. Cankat Tulunay²³, Vera Vlahović-Palčevski²⁴, Kamila Wendykowska²⁵, Bjorn Wettermark^{3,5,26}, Corinne Zara²⁷ and Lars L. Gustafsson³*

The study again showed that multiple demand-side measures greater influence on statin prescribing of generics/ efficiency. Limited change in CEE countries as typically only generics reimbursed (2007 vs 2001)



Different activities were undertaken by health authorities in Western European countries in response to generic losartan (first generic ARB) – typically initially or not at all

Country	Generic losartan reimbursed	Activities
Austria	October 2008	Prescribing restrictions removed for losartan but not the other ARBs. Potential sanctions for abuse
Belgium	July 2010	Prescribing restrictions removed for losartan; prior authorisation for other ARBs (otherwise 100% co-payment). General co-payment 25%
Bury PCT	July 2010	No immediate measures. This changed in March 2011 with multiple measures including educational activities, switching programmes, prescribing targets and financial incentives
Denmark	April 2010	Delisting of all other ARBs from the reimbursed list apart from losartan
Ireland	March 2010	No specific activities were undertaken to enhance losartan utilisation
Scotland	July 2010	No specific activities as high INN prescribing rates, other priorities and the imminent launch of generics of other ARBs
Spain (Catalonia)	July 2006	No specific activities regarding losartan - apart from general activities enhancing the prescribing of generics
Sweden	March 2010	Multiple activities among the counties including educational programmes, switching programmes and financial incentives

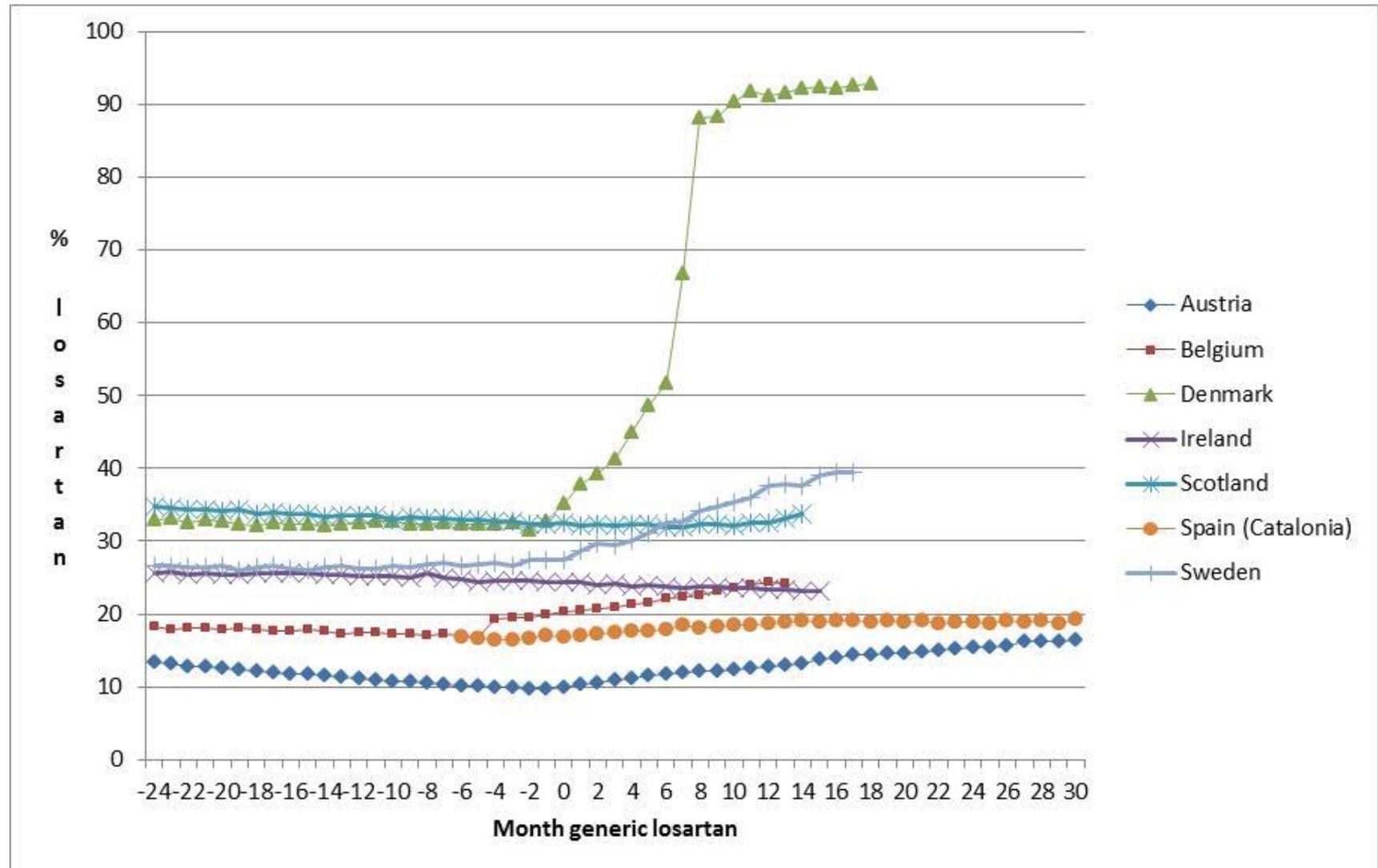
Again the study involved DU researchers, statisticians, physicians and health authority personnel from across Europe



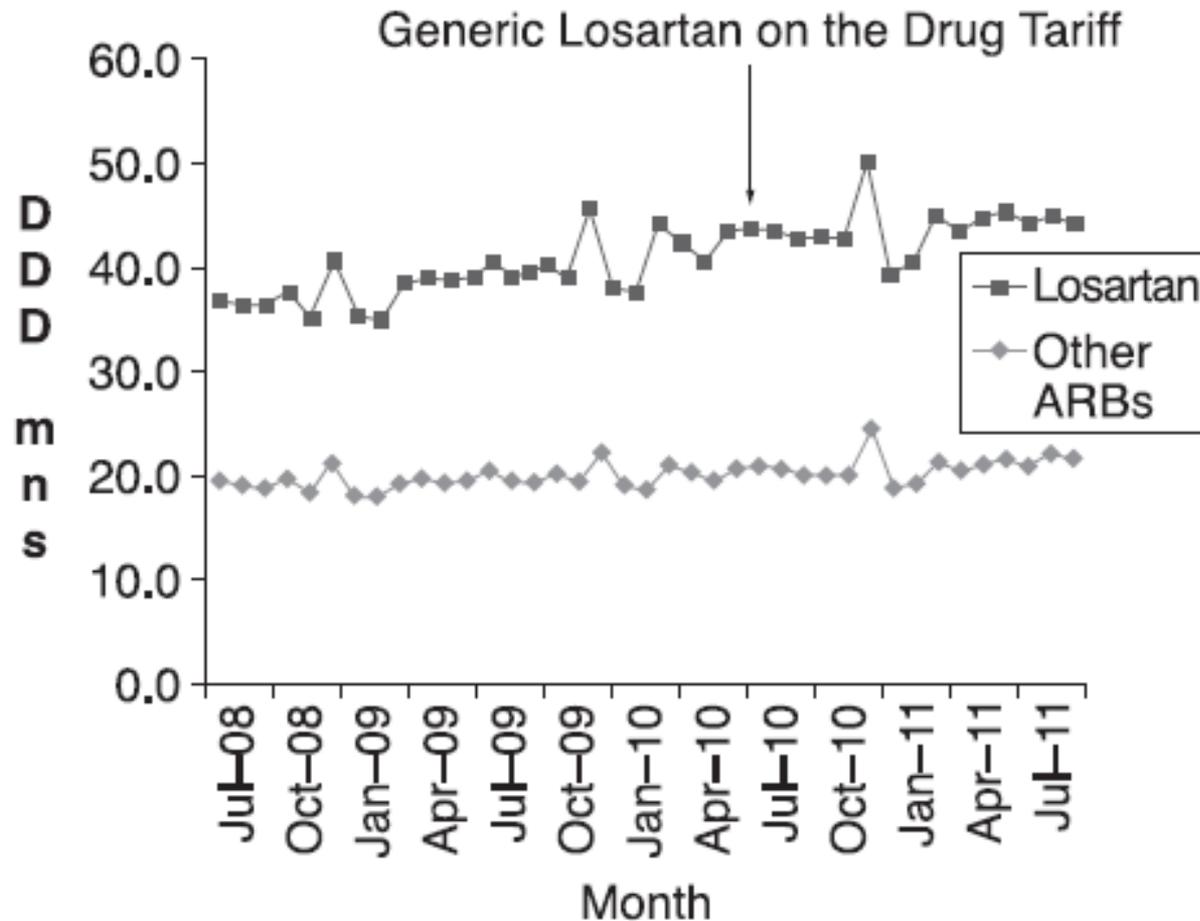
Different initiatives across Europe to enhance losartan utilization post generics: impact and implications

James C. Moon¹, Brian Godman^{2,2,4}, Max Petzold³, Samantha Alvarez-Madrado³, Kathleen Bennett⁵, Iain Bishop⁷, Anna Bucsic^{8,9}, Ulrik Hesse¹⁰, Andrew Martin¹¹, Steven Simoens¹², Corinne Zara¹³ and Rickard E. Malmström¹⁴*

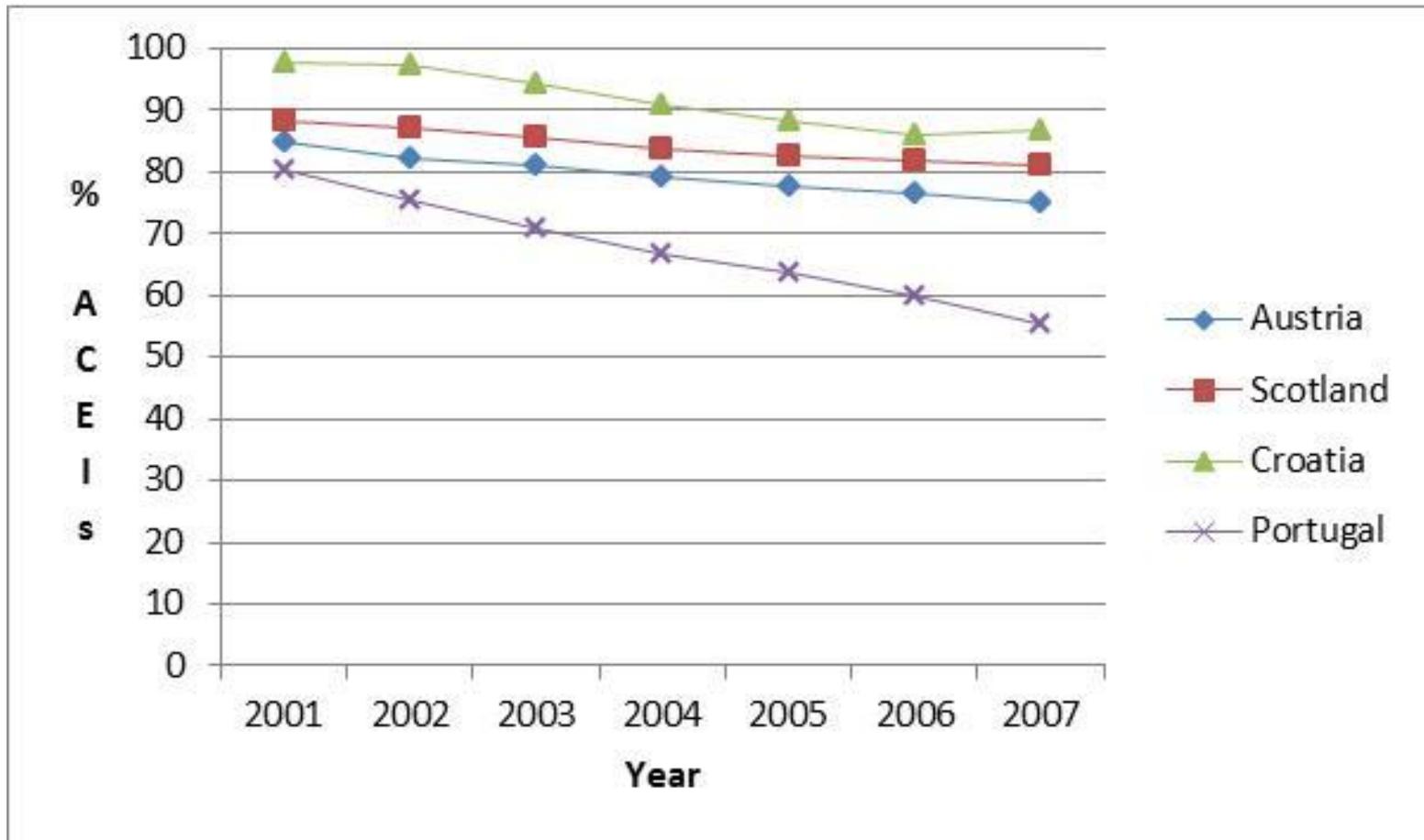
Multiple demand-side activities in Austria, Belgium, Denmark and Sweden increased losartan use once available as generics vs. Ireland, Scotland and Spain



No specific measures undertaken in Scotland (deliberate policy) leading to no change in the utilisation of losartan following generics in Scotland even with measures encouraging generic ACEIs (exacerbated by a more complex message) – suggests no 'spill over' effect



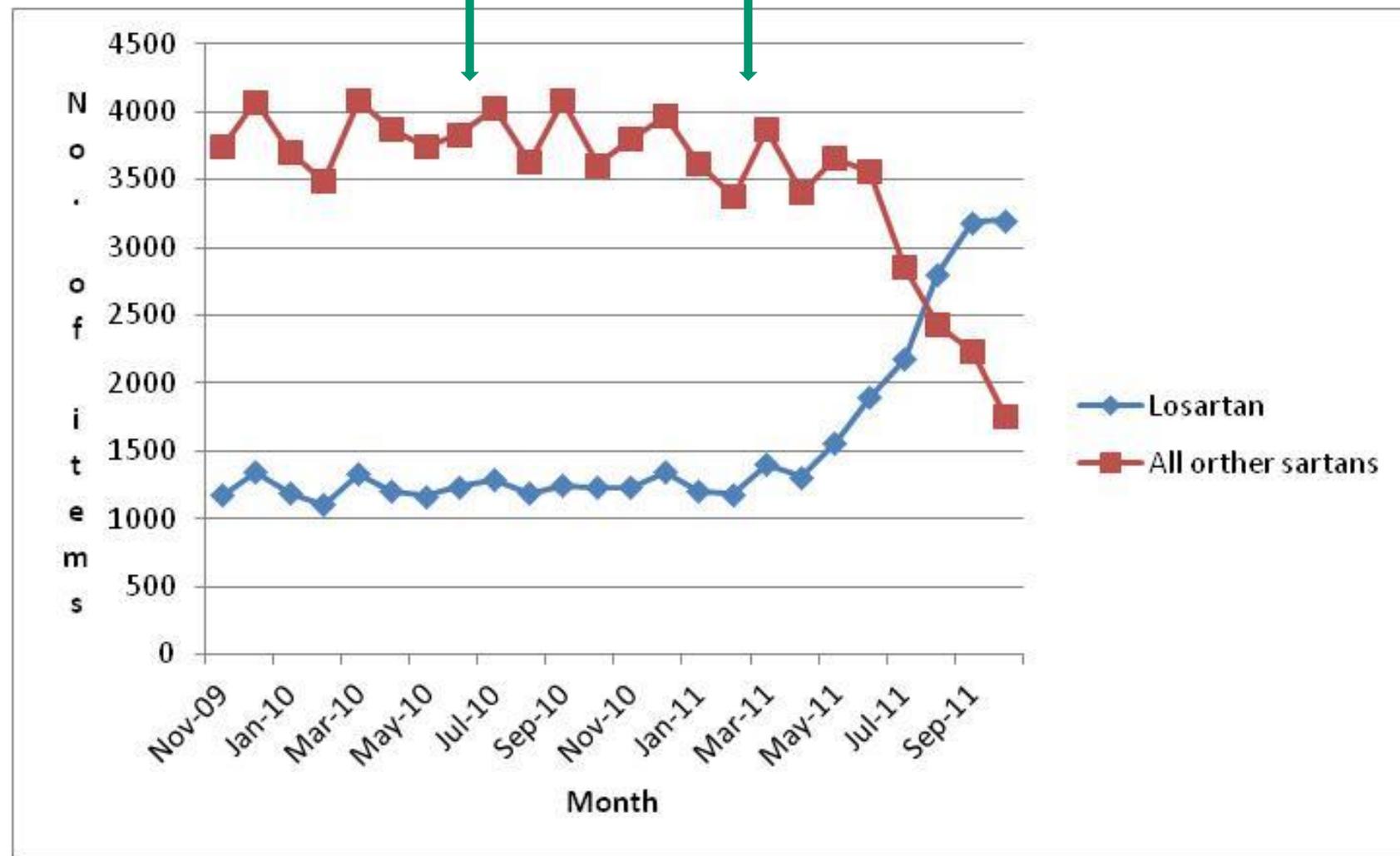
Multiple demand-side measures limited ARB utilisation vs. generic ACEIs in Scotland versus Portugal, matching the influence of prescribing restrictions for ARBs in Austria and Croatia (ARBs second line – greater intensity of follow-up in Croatia vs. Austria) - y axis = % ACEIs vs. total renin-angiotensin inhibitors on a DDD basis



These findings of no 'spill over' further endorsed by study in Bury PCT where initially no change in losartan utilisation post generics. This changed with multiple measures (similar to Sweden)

Generic losartan available

Multiple measures for losartan



1. Objective

2. Single country studies

3. CNC studies

4. Summary

What have we learnt?

Undertaking and communicating the findings from DU studies essential to enhance RUM

- Undertaking and communicating DU studies with all key stakeholder groups is essential to enhance the rational use of medicines within and across countries
- Examples include:
 - ❑ Successful measures to enhance the appropriate use of antibiotics
 - ❑ Understanding key initiatives to encourage the prescribing of good quality generics vs. originators
 - ❑ Acknowledging multiple measures necessary to enhance the prescribing of low cost high quality generics vs. patented products in a class (implemented quickly)
 - ❑ Demonstrating quality of prescribing enhanced by limiting choices to a selected group of well proven medicines
- The nature of any DU study undertaken will depend on the sophistication of available DU datasets

Thank You

Any Questions!

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