

Introduction of generic substitution and reference pricing in Ireland:

Early effects on state pharmaceutical expenditure and generic penetration, and associated success factors.

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Conflict of Interest Disclosure

No conflict of interest to disclose.



Study objectives

- Synthesise and present policy story of generic substitution and reference pricing in Ireland
- Examine policy effects
- Consider success factors and potential next steps

Presentation outline

- Pharmaceutical reimbursement in Ireland
- Background to introduction of policy
- Policy processes
- Analysis and results of policy effects
- Future directions



STATE FUNDING OF PHARMACEUTICALS

Community sector pharmaceuticals

- Non-prescription medicines
- Privately funded prescription medicines

- State-provided or state-subsidised prescription medicines
 - Health Service Executive (HSE):
 - 4 main access schemes
 - 1,800 pharmacies contracted



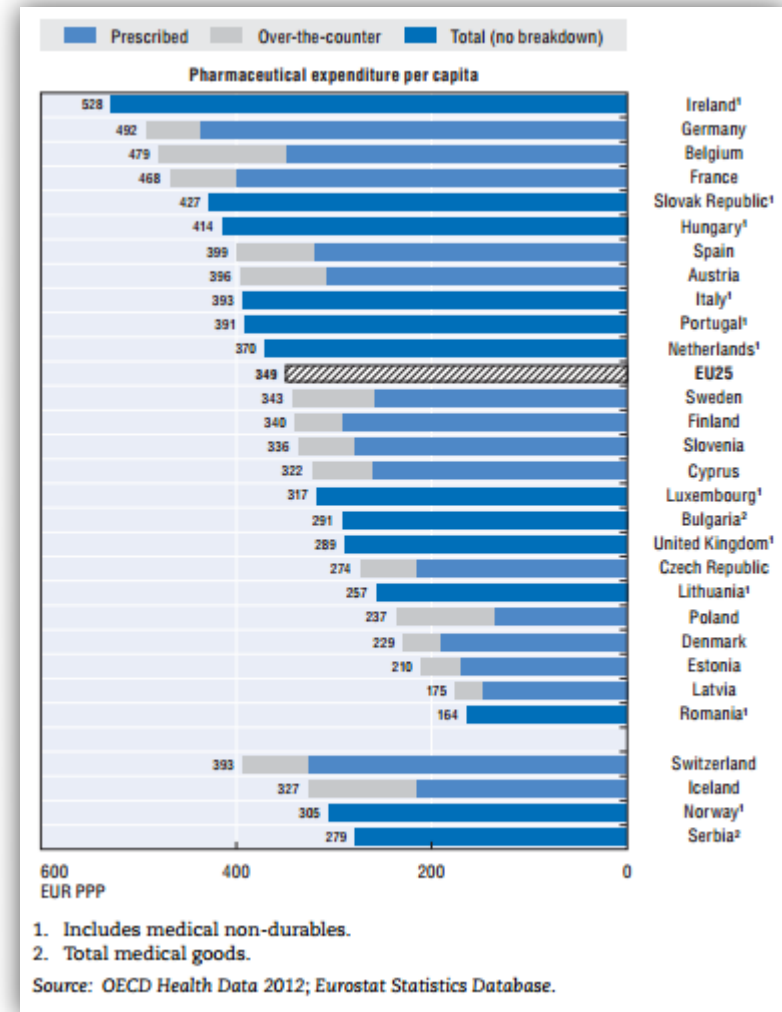
Pharmacy reimbursement schemes

■ Four main schemes:

- General Medical Services (GMS) scheme
 - ‘Medical card’ patients (means testing). €2.50 co-payment per item.
- Drugs Payment (DP) scheme
 - Threshold for claims: €144 per individual/family unit per month
- Long-term illness (LTI) scheme
 - 16 conditions covered: CF, MS, Epilepsy, Diabetes, parkinsonism...
- High Tech Drugs (HTD) arrangements
 - Hospital-initiated drugs supplied through community pharmacies

State expenditure on medicines

- 2000s: **Rapid rise in expenditure** in Ireland (2010: ranked 3rd out of 25 OECD countries after US, Canada, Greece. 2000: ranked 20th of 27).¹ **Spend per capita (€528)** above the EU average by 50%.²
- High prices** of generic pharmaceuticals (relative to comparable EU states). Low usage of generics.¹
- Advent of **financial crisis**: EC/IMF/ECB adjustment programme e.g. **→ generic usage targets**



1 Brick A, Gorecki PK, Nolan A. Ireland: Pharmaceutical Prices, Prescribing Practices and Usage of Generics in a Comparative Context. ESRI Research Series 32. June 2013.

2 OECD (2012), Health at a Glance: Europe 2012, OECD Publishing. <http://dx.doi.org/10.1787/9789264183896-en>



POLICY MEASURES INTRODUCED

2010-2012

- Price reductions (industry agreements).
- Pharmacy and wholesale mark-up reductions.
- Prescription charges (co-payments) introduced for GMS, raised for DPS.
- Delisting of some items.
- Pharmacoeconomic evaluation of all new medicines.

Table 6 Policy measures influencing pharmaceutical sales in eight European countries, 2008–2011

Policy measure	No. of measures implemented between 2008 and 2011 ^a								Total
	Economically stable countries ^b			Economically less stable countries ^b					
	Austria	Estonia	Finland	Greece	Ireland	Portugal	Slovakia	Spain	
Pricing									
Price cuts	0	0	0	2	2	3	0	4	11
External price referencing	0	0	0	3	0	2	2	1	8
Distribution remuneration	0	1	0	3	3	3	0	3	13
VAT on medicines	1	1	0	1	1	1	0	1	6
Extraordinary price review	0	0	0	2	2	1	1	1	7
Reimbursement									
Internal reference pricing	0	1	1	1	0	2	2	1	8
Out-of-pocket payments	4	1	0	0	1	5	3	2	16
Delisting	0	0	1	2	0	1	0	1	5
Generics									
INN prescribing	0	1	0	0	0	1	1	1	4
Generic substitution	0	0	0	0	0	0	0	0	0
Public campaigns and other generic policies	1	2	0	0	1	3	1	2	10
Total	6	7	2	14	10	22	10	17	88

INN: international nonproprietary name; VAT: value-added tax.

^a The number of measures implemented in each year was: 4 in 2008; 11 in 2009; 33 in 2010; and 40 in 2011.

^b The three economically stable countries implemented 15 measures during 2008–2011 compared with 73 in the five economically less stable countries.

2013+

- Industry agreements continue
- Medicines Management Programme
 - Promotion of generic usage
 - Promotion of a 'preferred' drug within a therapeutic class (e.g. lansoprazole = 'preferred PPI')
- Health Act 2013





The Health (Pricing and Supply of Medical Goods) Act 2013

- *Establish list of groups of interchangeable medicines which can be substituted for each other. Aim: enable savings to be made for patients, the State, or both, where the lower priced medicines are supplied. ***I.e. generic substitution.****
- *To ***establish a list of drugs, medicines*** and medical and surgical appliances which can be supplied.*
- *To establish mechanisms to set the prices of such drugs, medicines and medical and surgical appliances where they are so supplied. ***I.e. reference pricing.****

Generic Substitution



- Establishes, publishes, maintains list of interchangeable medicines:
 - Same active ingredient
 - Same strength
 - Same pharmaceutical form
 - Same route of administration

	Atorvastatin	10mg	Film-coated Tablets	Interchangeable List Code: IC0001-002-003 Products on List: 23 Show products Date of Last Publication: 16/09/2015
	Atorvastatin	20mg	Film-coated Tablets	Interchangeable List Code: IC0001-003-003 Products on List: 23 Show products Date of Last Publication: 16/09/2015
	Atorvastatin	40mg	Film-coated Tablets	Interchangeable List Code: IC0001-004-003 Products on List: 23 Show products Date of Last Publication: 16/09/2015
	Atorvastatin	80mg	Film-coated Tablets	Interchangeable List Code: IC0001-005-003 Products on List: 21 Show products Date of Last Publication: 16/09/2015

Reference pricing



Atorvastatin Reference Prices

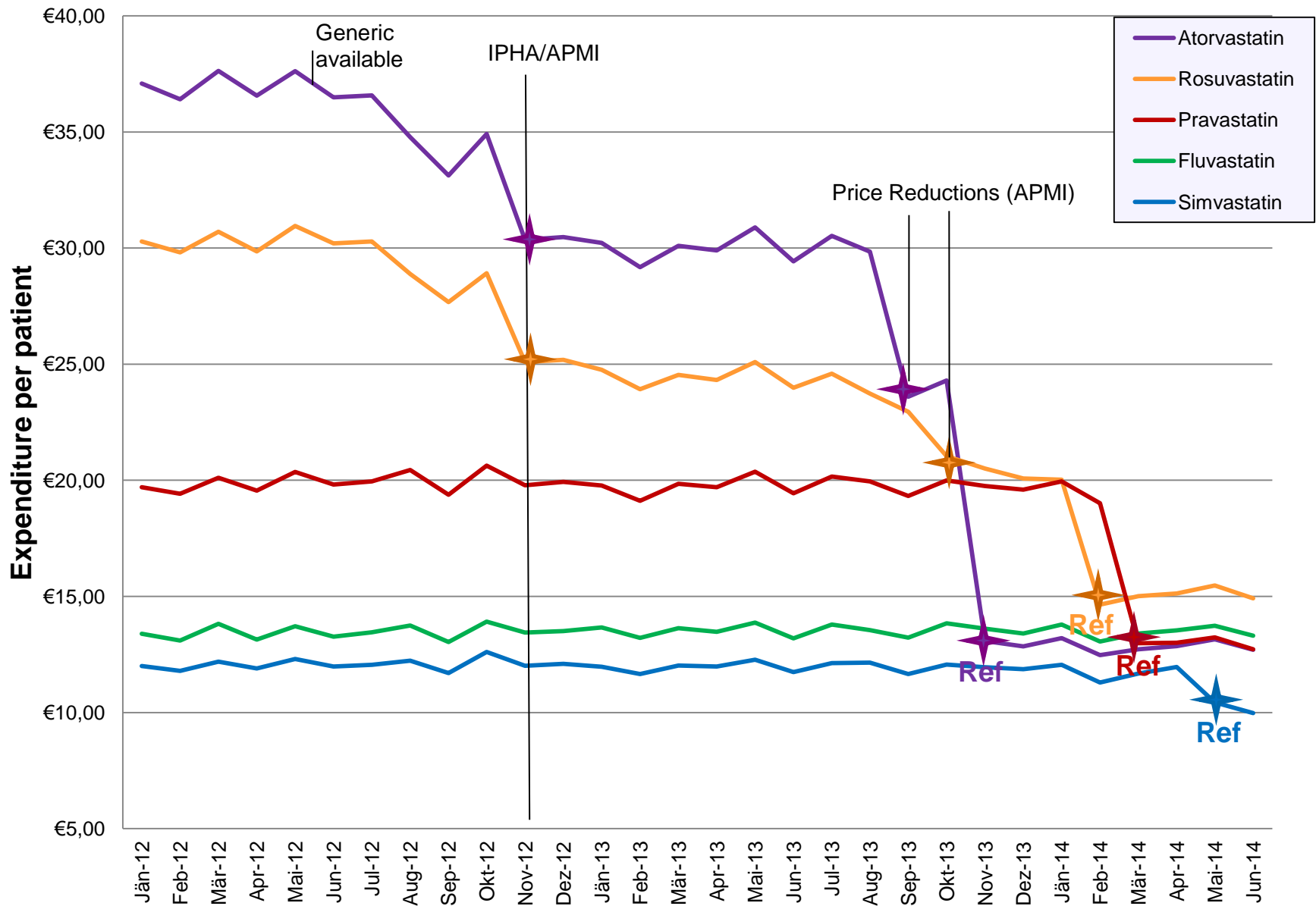
The HSE pays pharmacists a set price, or reference price, for atorvastatin products. If you take atorvastatin, a medicine for high cholesterol, you may be offered a different version of your medicine that is priced at or below this set reference price.

Atorvastatin - 10mg Dosage
Reference Price per 28 tablets: €2.52
Atorvastatin - 20mg Dosage
Reference Price per 28 tablets: €3.64
Atorvastatin - 40mg Dosage
Reference Price per 28 tablets: €5.32
Atorvastatin - 80mg Dosage
Reference Price per 28 tablets: €7.84

Prices Updated May 1, 2015.



Total expenditure on statins per patient (GMS +DP/LTI)



Aims and objectives

- Examine effects of generic substitution and reference pricing introduction.
 - Expenditure and 'savings'
 - Generic usage
 - Adherence to policy



ANALYSIS METHODS

Data source

- HSE Primary Care Reimbursement Service
 - Pharmacy claims data
 - 3 month delay due to manual pharmacy claims submission and other required processing
 - As of analysis date (June 2015), data available up to October 2014.

- Scope of analysis:
 - GMS scheme
 - Difficult to accurately estimate savings achieved from DP/LTI schemes

Statistics

(Conducted using SAS v9.3)

For each interchangeable group:

- Identify all pharmacy claims for that category in each month.
- Identify number of prescriptions in each generic usage category (patent/off-patent/generic) in order to examine trends.

- 'Look-back' at 6 months prior to GS introduction
 - Calculate 'cost per 28 units' for each claim
 - Calculate mean 'cost per 28 units' across claims = 'pre-price'
- Apply 'pre-price' to claims for each of 6 months of data following introduction of reference pricing (i.e. x quantity dispensed) = 'expected cost' if no GS/RP occurred.
- Calculate difference between 'expected cost' and real cost. = 'savings'
- Savings summed across 6 months and across drugs.

Information sources

■ Dates and timeline:

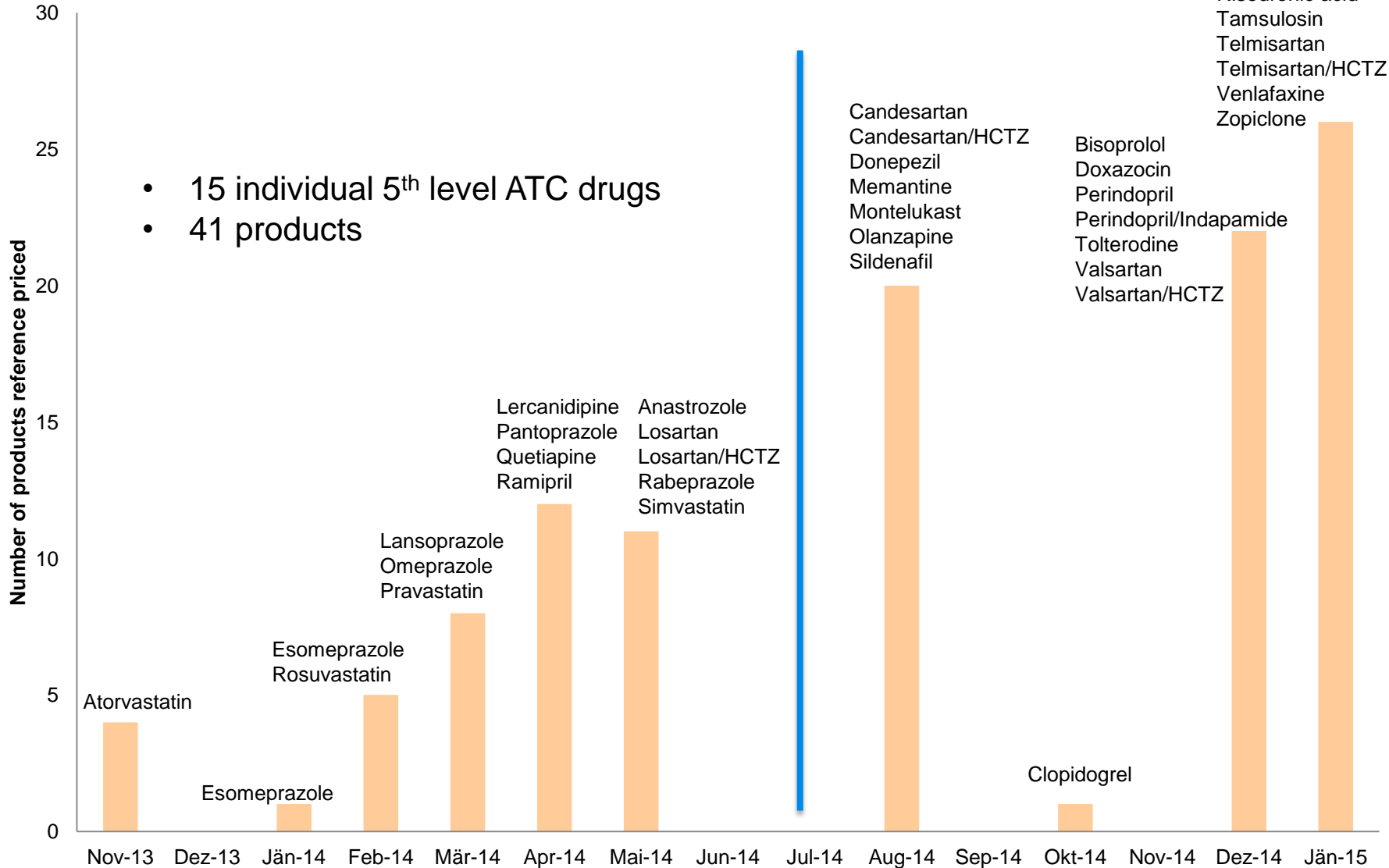
- HPRA pharmaceutical assessment team
 - Dates of initial publication of interchangeability
- HSE Statement to Joint Committee on Health: Press Release, 12th March 2015
 - Dates of reference pricing

■ Pricing information

- <http://www.hse.ie/referenceprice/>

Reference Pricing Timeline

- 15 individual 5th level ATC drugs
- 41 products



Generic Sub / Ref Pricing timeline

2013													2014								
Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct
1	Atorvastatin						GS			RP											
2	Rosuvastatin							GS						RP							
3	Pravastatin								GS					RP							
4	Simvastatin											GS				RP					
5	Esomeprazole 20mg							GS						RP (20mg)							
	Esomeprazole 40mg							GS						RP (40mg)							
6	Lansoprazole									GS				RP							
7	Omeprazole								GS					RP							
8	Pantoprazole										GS				RP						
9	Rabeprazole												GS			RP					
10	Ramipril									GS	GS				RP						
11	Lercanidipine										GS				RP						
12	Losartan											GS				RP					
13	Losartan/HCTZ											GS				RP					
14	Quetiapine IR									GS					RP						
15	Anastrozole													GS		RP					

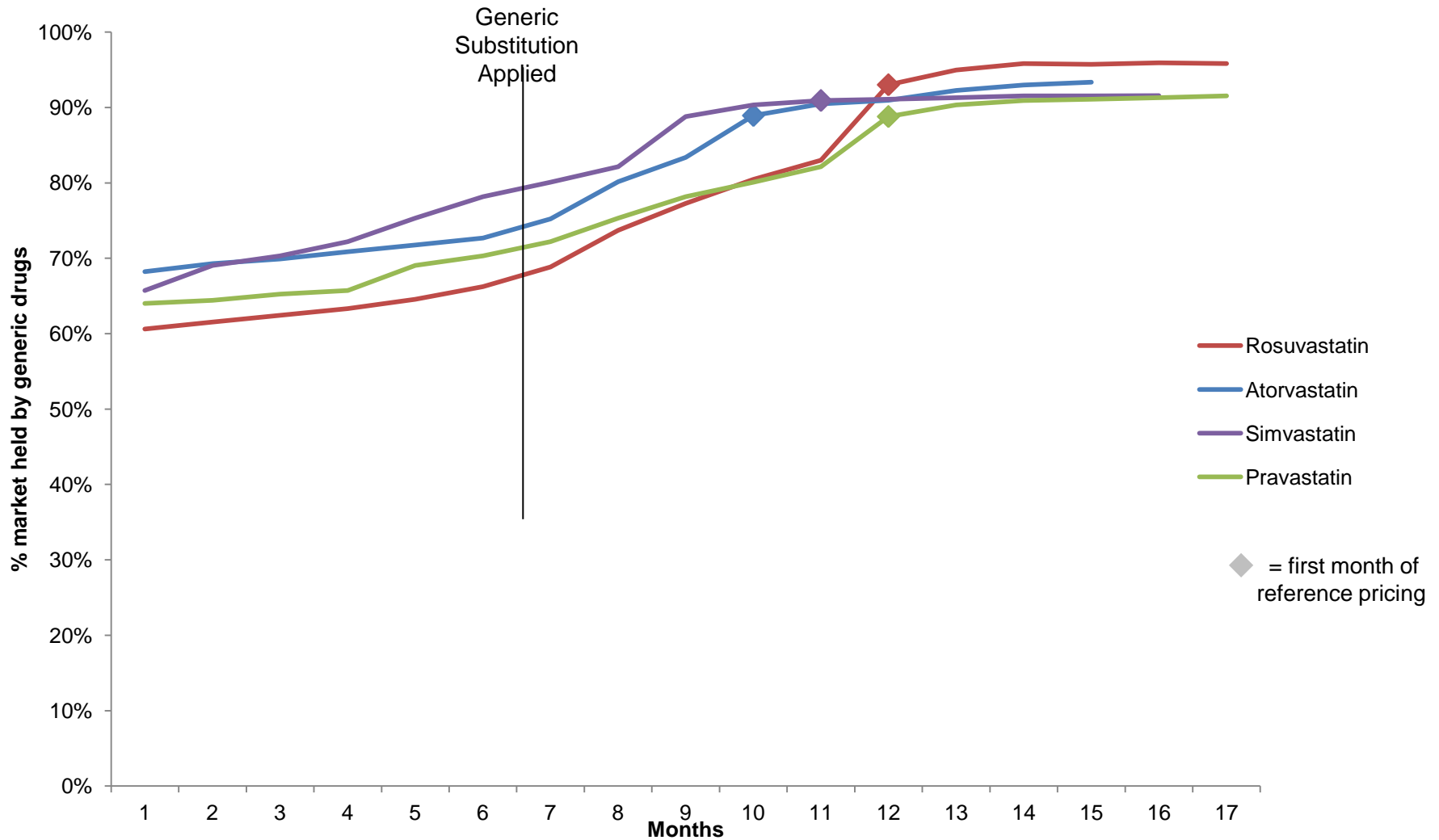
RESULTS

Expenditure and 'savings' within GMS scheme: First six months* following assignment of reference price

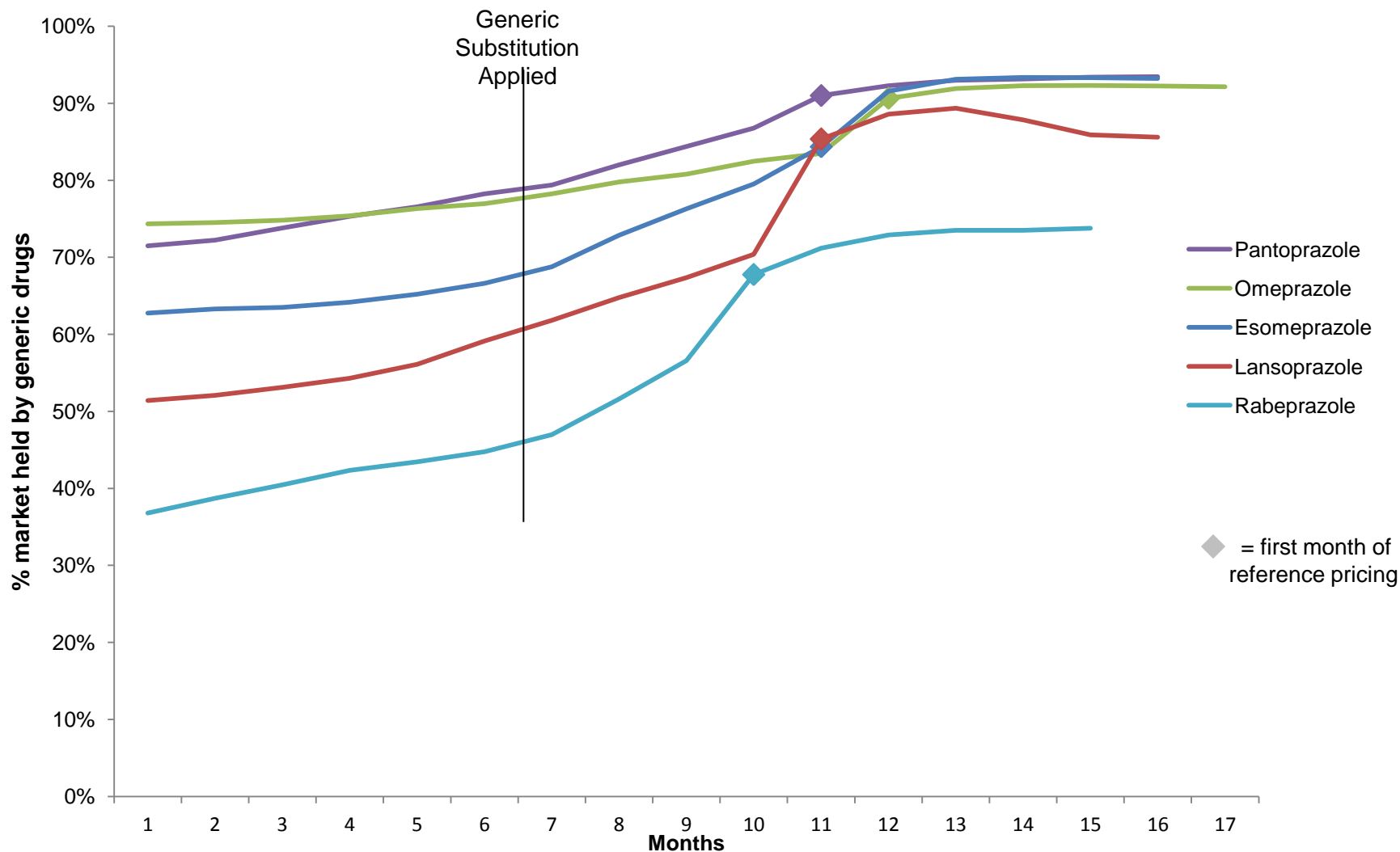
	'Expected' cost (if no GS/RP)	Actual cost	Savings	% expend reduction	% price reduction
Atorvastatin	€20,236,648	€5,924,770	€14,311,879	71%	73%
Rosuvastatin	€6,486,564	€3,427,976	€3,058,588	47%	58%
Pravastatin	€2,221,477	€1,121,028	€1,100,449	50%	50%
Simvastatin	€620,727	€435,988	€184,740	30%	28%
Esomeprazole	€12,318,557	€4,912,431	€7,406,126	60%	68%
Omeprazole	€6,402,618	€3,994,042	€2,408,576	38%	35%
Lansoprazole	€5,298,320	€3,364,761	€1,933,559	36%	39%
Pantoprazole	€4,089,801	€2,529,990	€1,559,811	38%	39%
Rabeprazole	€654,368	€347,412	€306,956	47%	56%
Lercanidipine	€1,503,712	€943,293	€560,420	37%	45%
Losartan	€972,142	€472,638	€499,504	51%	58%
Ramipril	€1,904,948	€1,454,929	€450,019	24%	23%
Losartan/HCTZ	€596,283	€308,707	€287,576	48%	
Quetiapine IR	€2,532,078	€1,431,536	€1,100,542	43%	50%
Anastrozole	€786,767	€459,838	€326,929	42%	51%
Total*	€66,625,012	€31,129,338	€35,495,675	53%	

* 'First six months': Sequence of individual months differs by drug due to phased introduction of reference pricing.

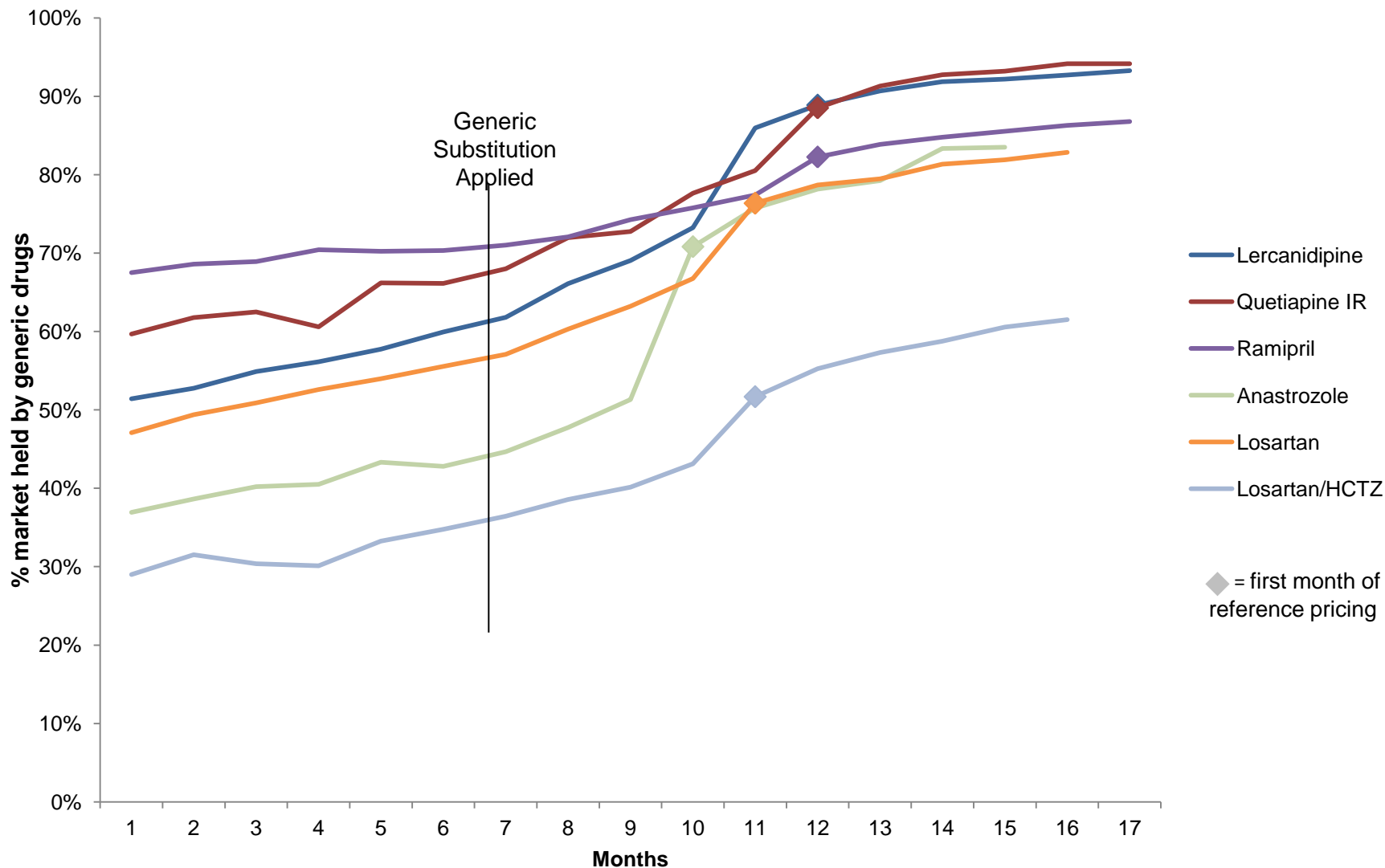
Generic trends - statins



Generic trends – PPIs



Generic trends – other drugs



DISCUSSION

Analysis review

Strengths

- Modelling using actual usage data
- Savings modelled for each of 41 interchangeable groups in order to optimise accuracy
- Allows comparison between price reductions and actual savings achieved
 - Monitoring of compliance with policy in cases of off-patent not meeting reference price

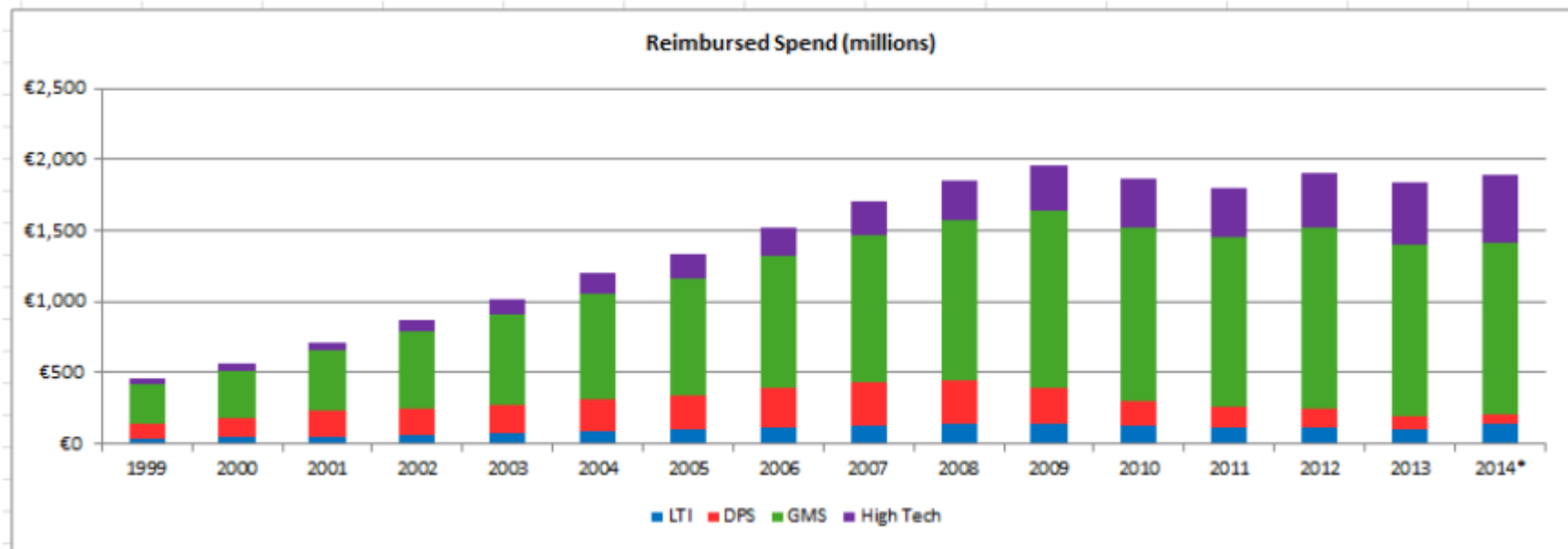
Limitations

- Does not include savings occurring post GS and prior RP.
 - Figures therefore likely to underestimate true savings.
- November 2013 generic price cuts (IPHA agreement)
 - As only average pre-price is applied post RP, may overestimate savings for some products where savings are due to industry agreement.

Conclusions

- Generic substitution & RP have greatly increased the proportion of the off-patent market held by INN/branded generics.
- Reference pricing has led to significant reductions in total expenditure within high volume drug classes.
- Success factors:
 - Health Act 2013
 - Phased basis
 - 5th level ATC substitution

Stable expenditure since 2009



Note: 2014 figures relate to Dec 2013 to Nov 2014;

GMS,DPS and LTI include pharmacy fees

Further initiatives?

- Further roll-out of reference pricing in 2015/2016
- Introduction of prescribing incentives within drug classes?
- New IPHA agreement 2015
- Compulsory INN prescribing
 - Medicinal Products (Prescription and Control of Supply) (Amendment No.2) Regulations 2014 : Compulsory INN prescribing as part of cross-border directive
- Challenges:
 - Inpatient prescribing
 - High-tech drugs – introduction of highly expensive new medicines and increased use of existing medicines:
 - 2009: €315m 2014: €485m

Thank you!



References

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- (2006-2015): HSE Statement to Joint Committee on Health, 12th March 2015
 - Appendix including summary of interventions
 - <http://www.hse.ie/eng/services/news/media/pressrel/statemarch15.html>
- Cost of Medicines Paper: Correspondence of John Hennessy, National Director of Primary Care Division, Health Service Executive, from Meeting May 2015