Does reference pricing drive out generic competition in pharmaceutical markets? Evidence from a policy reform

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Reference Pricing

- Pharmaceutical expenditures are to a large extent covered by (mandatory) health insurance in most countries.
- Insurance for prescription drugs usually includes demand-side cost sharing (copayments).
- Design of copayment scheme is key issue for policy makers in order to contain pharmaceutical expenditures.
- **Reference Pricing (RP)** defines a maximum reimbursement for a set of drugs with similar therapeutic effects.
- Consumers demanding higher priced drugs have to pay the price difference out of pocket.

Reference Pricing

For a given number of products in the market, moving from fixed-percentage reimbursement to RP has three effects:

1. Shifting costs from payer to consumer (reduced coverage).
2. Shifting demand from high-priced to low-priced drugs, typically generics.
3. Stimulate price competition.

Emprical evidence: for a given number of competitors in the market, RP lowers expenditures.

Research question

- **What is the effect of RP on the number of generics in pharmaceutical markets?**
- Is the effect on generic competition reinforcing or weakening its direct negative effect on prices and expenditures?
- If RP enhances price competition, it might also reduce the expected profit of generic entrants.
- Major policy implications: reduced entry may lead to higher prices (Brekke, Canta, Straume, 2016).
- We estimate the impact of RP on entry using Norwegian data.

Preview of results

- Theoretically, the effect of RP on generic competition is ambiguous.
  - For a fixed number of firms: **positive demand effect** for generics.
  - Branded drug producer has an incentive to reduce price to regain market shares: **negative price effect** for generics
  - The equilibrium effects of RP on generic competition and on pharmaceutical expenditures are an empirical question.
- Empirically, we find that the Norwegian RP reform implied:
  - more generic firms and higher generic market shares,
  - lower prices of both brand-name and generic drugs,
  - lower expenditures.

Empirical strategy: DiD

- Norway introduced RP in 2005 (on top of fixed-percentage reimbursement and price caps).
- We exploit the fact that some markets are never included in the RP scheme, and treated markets were not all included at the same time.
- Treatment group: 19 markets (=molecules).
  - Of the 19 markets in the treatment group, 14 get RP in 2005, the others up to 2013.
- Comparison group: 17 markets.

- Only markets with generic competition prior to the announcement of the RP reform (May 2004).
  $\Longrightarrow$ This allows us to exclude molecules potentially under patent protection.

Empirical strategy: DiD

Detailed data on all products sold in Norway 2003-2013.

Estimate the following fixed effect model (market i at month t)

$$N_{it} = \beta \mathbf{X}_{it} + \rho D_{it} + \delta_t + a_i + \epsilon_{it},$$

- N_{it} is the number of generic firms active on the market.
- D_{it} is dummy taking value 1 when market is subject to RP.
- $\mathbf{X}_{it}$ is a control vector.
- δ_t time dummies.
- a_i market fixed effects.

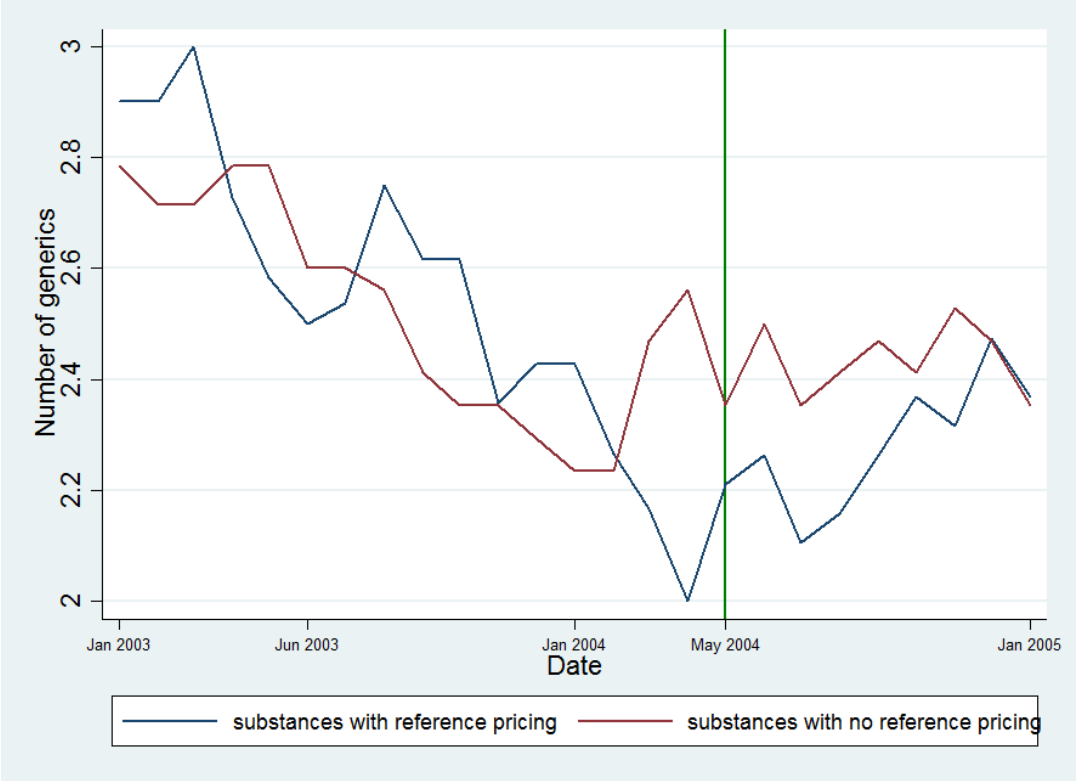
Data Description

VARIABLES	RP. Before	RP. During	No RP. Before 2005	No RP. After 2005
Number of generics	1.860 (1.863)	2.497 (1.269)	2.487 (2.032)	1.692 (1.699)
Brand-name Market Share	0.723 (0.285)	0.392 (0.210)	0.664 (0.356)	0.616 (0.410)
Number of markets	19	19	17	17
Number of Observations	694	1,719	386	1,772

- No. generics: +34% in treatment, - 47% in comparison group.
- Brand-name market shares: sharp decrease in treatment, stable in comparison group.
- Treated markets tend to be bigger and display higher prices.
- Validity issue: Selection of drugs into the RP scheme may not be random.
- Validity check: competition variables have similar trends prior the reform.

Pre-reform tests

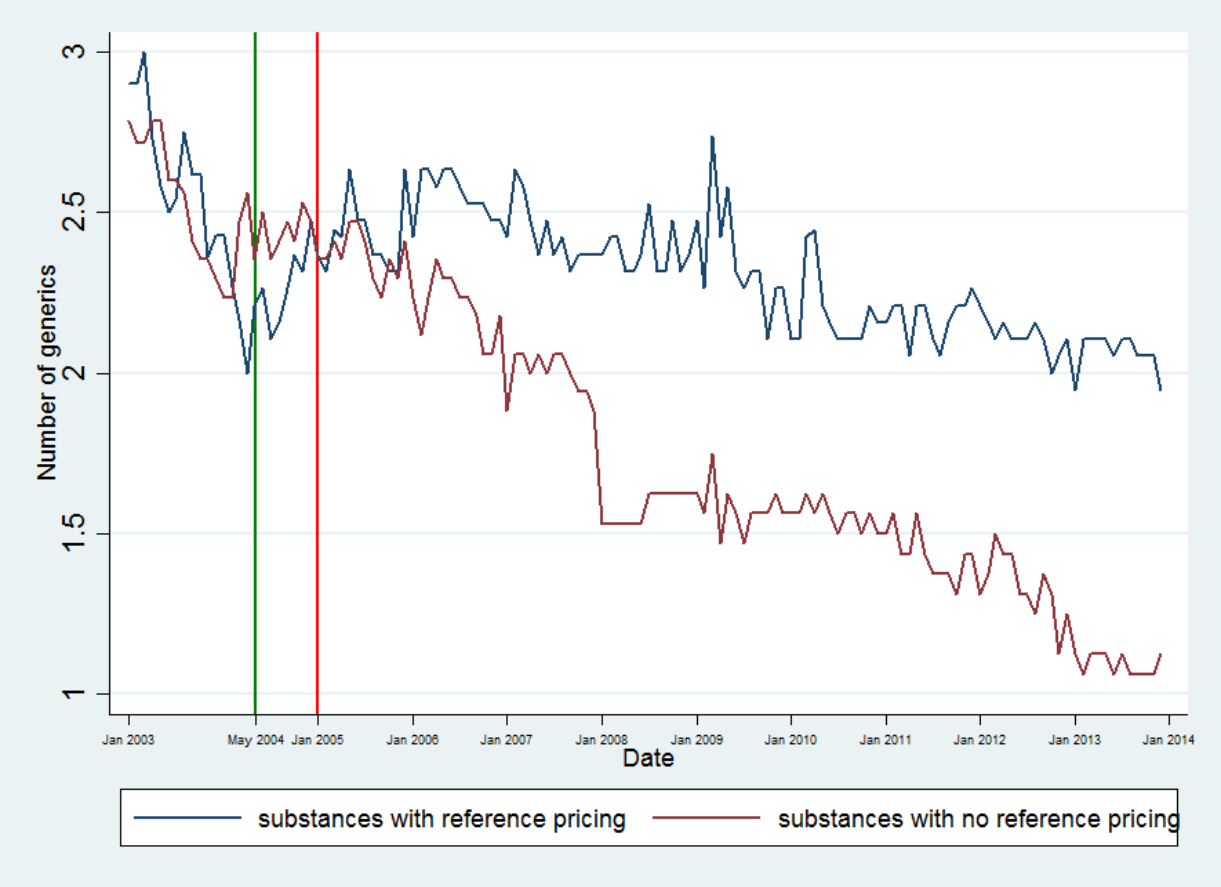
Figure: Average number of generics. Pre-reform development for markets subject to reference pricing (RP) and not subject to reference pricing (CR)



Parallel trends prior to the introduction of the reform.

Data Description

Figure: Average number of generics. markets subject to reference pricing (RP) and not subject to reference pricing (CR)



Results. Number of generics

Estimated effects of reference pricing on the **number of generics**.

Reference Pricing	1.243***	
	(0.429)	
Reference Pricing, 7 month lagged		1.330***
		(0.374)
Number of therapeutic substitutes	-0.218	-0.235
	(0.219)	(0.219)
LogRevenues	-0.00595	-0.0348
	(0.183)	(0.192)
Constant	4.425	4.954*
	(2.733)	(2.932)
Time dummies	Yes	Yes
Market dummies	Yes	Yes
Number of markets	36	36
Observations	4,571	4,571
R^2	0.175	0.176

Discussion

- We find evidence of both a RP effect and an announcement effect (7 month lag).
- Treatment group displays on average 1.25 generics more after the reform.
- Market shares of the originator 30 percentage points lower after the treatment. Shares
- **Reference pricing encouraged generic competition**.
- Countered downward trend.

Further results

- Prices drop by 30% for originators and 40% for generics after the reform. Prices
- The full picture: RP
  - Reduced prices for all products but
  - ...shifted demand towards generics.
  - Overall, the sales revenues of generics went up, and this may justify the increase in generic entry.

Policy implications

- Policy makers are mainly concerned with prices and expenditures, and not with generic competition per se...
- We find that RP led to a 25% decrease in expenditures, with respect to non-treated markets.
- Demand relatively stable shifted towards generics, and prices are lower for all kind of producers.

Results: Expenditures

Estimated effects of reference pricing on **expenditures** (logged).

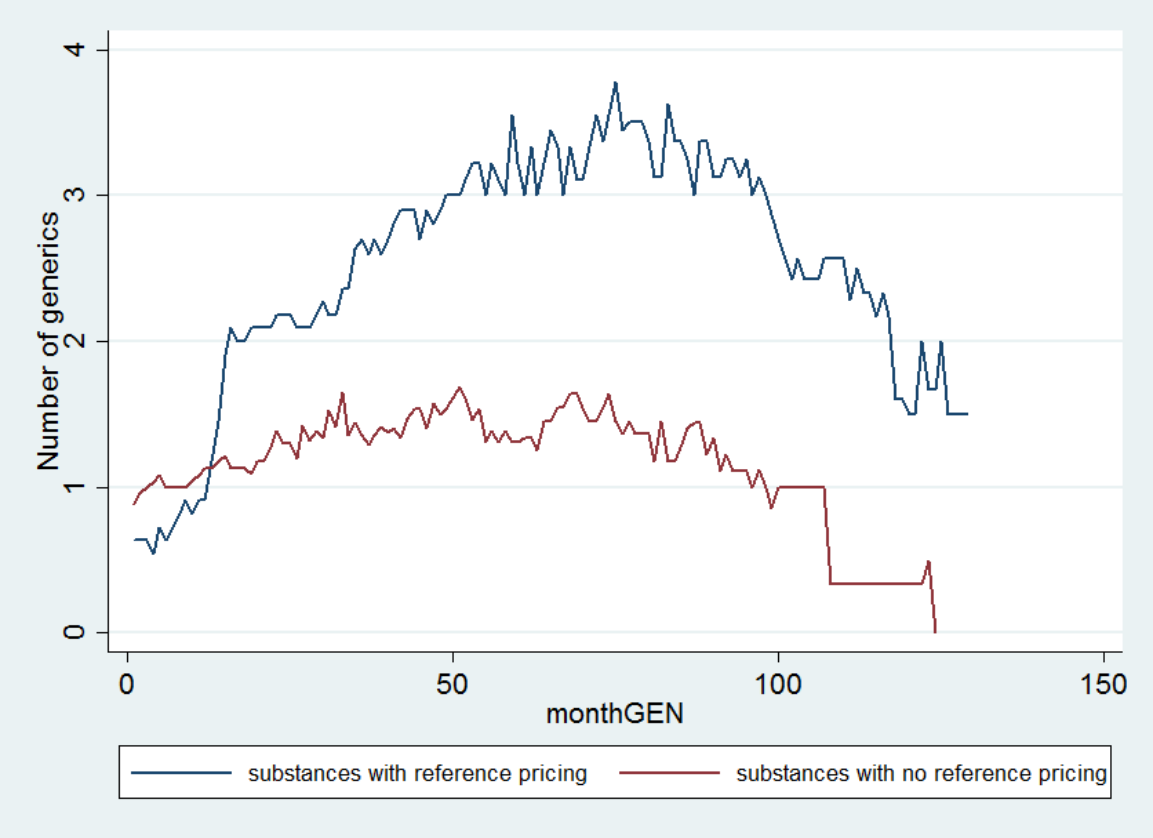
Reference Pricing	-0.242*	-0.240*		-0.236*	
	(0.142)	(0.136)		(0.131)	
Reference Pricing, 7 month lagged			-0.175		-0.163
			(0.122)		(0.117)
Number of therapeutic substitutes	0.0125	0.0122	0.0105	0.0146	0.0136
	(0.0630)	(0.0651)	(0.0664)	(0.0629)	(0.0645)
Number of generics		-0.00110	-0.00651	-0.000903	-0.00660
		(0.0337)	(0.0354)	(0.0332)	(0.0350)
Constant	14.15***	14.15***	14.18***	13.56***	13.55***
	(0.518)	(0.564)	(0.578)	(0.573)	(0.592)
Time dummies	Yes	Yes	Yes	No	No
Year and month dummies	No	No	No	Yes	Yes
Market dummies	Yes	Yes	Yes	Yes	Yes
Number of markets	36	36	36	36	36
Observations	4,571	4,571	4,571	4,571	4,571
R^2	0.325	0.325	0.318	0.314	0.308

Alternative DiD approach

- Include molecules from the date of first generic entry
- Exclude molecules with less than 6 month of generic competition or first generic less than 12 month before RP
- 36 molecules
  - Treatment group: get RP at some point (11 molecules).
  - Comparison group: never get (25 molecules)
- Of the 11 molecules in the treatment group, on average RP applied after 17 month from first generic entrant, but some variability
- Advantage: take into account products' life cycle.

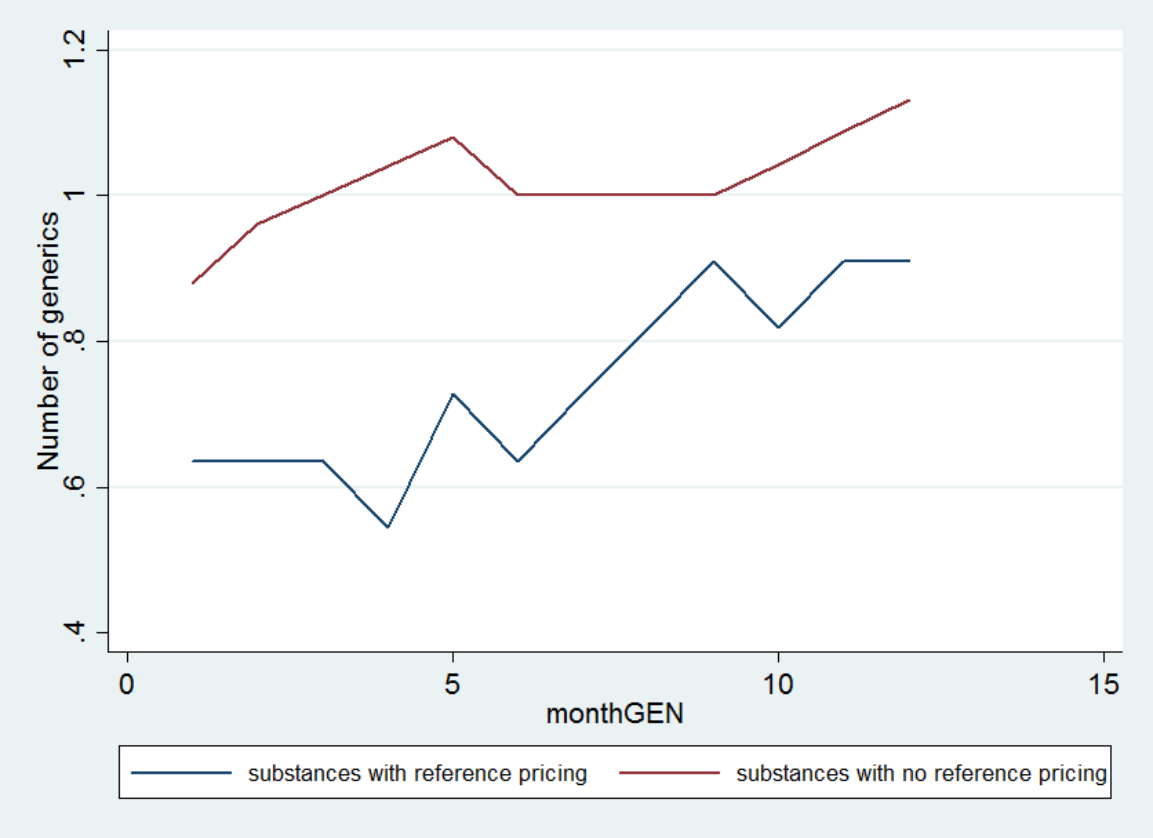
Data Description

Figure: Average number of generics. Substances subject to reference pricing (RP) and not subject to reference pricing (CR)



Prereform tests

Figure: Average number of generics. Pre-reform development for substances subject to reference pricing (RP) and not subject to reference pricing (CR)



Results. Number of generics

Number of generics, fixed effects model

	Full sample	3 years after GE.	2 years after GE
Reference Pricing	2.057***	0.875***	0.636***
	(0.469)	(0.180)	(0.222)
Number of ther. sub.	-0.00274	-0.808**	-0.689*
	(0.361)	(0.331)	(0.341)
Constant	4.410*	6.353**	5.523**
	(2.190)	(2.464)	(2.588)
Observations	2,718	1,170	824
R^2	0.357	0.539	0.523
Number of molecules	36	36	36
Month from GE dummies	Yes	Yes	Yes
Month dummies	Yes	Yes	Yes
Molecule dummies	Yes	Yes	Yes

Robust standard errors in parentheses
*** p<0.01, ** p<0.05, * p<0.1

Results. Market shares and prices

Fixed effects model, 3-year window after first generic entry

VARIABLES	Share orig	lnPrice orig	lnPrice gen
Reference Pricing	-0.243***	-0.212***	-0.593***
	(0.0644)	(0.0709)	(0.110)
Number of ther. sub.	0.207***	0.00193	-0.0356
	(0.0744)	(0.0475)	(0.0866)
Constant	-0.729	2.565***	2.587***
	(0.570)	(0.445)	(0.604)
Observations	1,170	1,148	923
R^2	0.636	0.484	0.614
Number of Molecules	36	36	34
Month from GE dummies	Yes	Yes	Yes
Month dummies	Yes	Yes	Yes
Molecule dummies	Yes	Yes	Yes

Robust standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

Conclusion

- In the Norwegian case, RP has lead to an increase in the number of generics, which may have reinforced the static effect on prices and expenditures.
- Brands responded to RP by cutting prices.
- However, response was not aggressive enough for the brands to maintain market shares.
- Overall, our results suggest that the profits of generic producers went up after RP.
- Price cap may be a key factor here (Brekke et al, 2016).

Results. Originator's market shares

Estimated effects of reference pricing on the **originator's market shares**.

Reference Pricing	-0.340***	
	(0.072)	
Reference Pricing, 7 month lagged		-0.325***
		(0.069)
Number of therapeutic substitutes	0.0270	0.0297
	(0.031)	(0.031)
LogRevenues	-0.004	0.006
	(0.048)	(0.051)
Constant	0.576	0.413
	(0.708)	(0.752)
Time dummies	Yes	Yes
Market dummies	Yes	Yes
Number of markets	36	36
Observations	4,571	4,571
R^2	0.390	0.356

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Results: Prices

Estimated effects of reference pricing on **prices** (logged).

	Brand	Brand	Brand	Gen.	Gen.	Gen.
RP	-0.323***	-0.307***		-0.427***	-0.423***	
	(0.065)	(0.072)		(0.074)	(0.074)	
RP, 7 month lagged			-0.235***			-0.328***
			(0.075)			(0.083)
Number of ther. subst.	0.019	0.017	0.015	0.054*	0.052	0.053
	(0.032)	(0.034)	(0.037)	(0.031)	(0.032)	(0.035)
Number of generics		-0.014	-0.020		-0.007	-0.013
		(0.018)	(0.022)		(0.014)	(0.016)
Constant	1.707***	1.761***	1.788***	1.278***	1.312***	1.318***
	(0.267)	(0.291)	(0.325)	(0.273)	(0.293)	(0.322)
Time dummies	Yes	Yes	Yes	Yes	Yes	Yes
Market dummies	Yes	Yes	Yes	Yes	Yes	Yes
Number of markets	36	36	36	36	36	36
Observations	4,369	4,369	4,369	3,845	3,845	3,845
R^2	0.518	0.521	0.480	0.556	0.556	0.492

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Results. Sales revenues

Estimated effects of reference pricing on **sales revenues** (logged).

	Brand	Brand	Generics	Generics
Reference Pricing	-0.870***		1.836*	
	(0.206)		(0.982)	
Reference Pricing, 7 month lagged		-0.757***		2.158*
		(0.190)		(1.139)
Number of therapeutic substitutes	0.058	0.058	-0.344	-0.380
	(0.126)	(0.125)	(0.290)	(0.305)
Number of generics	-0.096*	-0.106*	0.242***	0.244***
	(0.049)	(0.053)	(0.065)	(0.064)
Constant	13.73***	13.75***	14.35***	14.59***
	(1.126)	(1.118)	(2.547)	(2.674)
Time dummies	Yes	Yes	Yes	Yes
Market dummies	Yes	Yes	Yes	Yes
Number of markets	36	36	36	36
Observations	4,369	4,369	3,845	3,845
R^2	0.408	0.387	0.198	0.212