

The impact of *managed entry agreements* on pharmaceutical prices

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Disclosure of conflict of interest

We have nothing to declare for this study

Motivation

- ▶ **soaring costs** of innovation
- ▶ **trade-off** between access to innovation vs. incentives to produce innovation
- ▶ **efficacy vs. effectiveness**
- ▶ **strategies** deployed **by payers**:
 - ▶ ensuring *value for money* of innovation
 - ▶ (external) reference pricing
 - ▶ ...
 - ▶ **Managed entry agreements (MEA)**

Taxonomy of MEA

<i>Financial-based (FA)</i>	simple (confidential) discounts cost & volume cost-sharing expenditure cap ...
<i>Performance-based (PA)</i>	payment-by-result evidence related price adjustments ...
<i>Appropriateness (AA)</i>	registries

Issues

- ▶ a tool for manufacturers to reduce the impact of external reference pricing (Morgan et al., 2017; Espin et al., 2018)
- ▶ is it *risk-sharing* or *risk-shifting* (Towse and Garrison, 2010)
- ▶ what impact on R&D incentives? (Levaggi et al., 2017)
- ▶ monitoring costs for PA
- ▶ lack of transparency
- ▶ impact on gross (list) prices (Towse, 2010; Pita Barros, 2011)

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This paper: research questions

1. under **what conditions** would the manufacturer be able to raise list prices to reduce losses due to the wedge between list price and net price?
2. what the **implications** for the estimate of savings from MEA?
3. is there **evidence** of higher prices in the presence of a MEA?

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Outline

Introduction

Expected impact of MEA on prices

Empirical analysis

Conclusion

Two questions, several settings

- ▶ Our questions:
 1. should we expect higher list prices in the presence of a MEA?
 2. Could the common (naïve) way of estimating savings from MEA be biased?
- ▶ focus on simplest form of FA: *'simple discount'*
- ▶ Settings:

A1	<i>firm decides on MEA, prices exogenous</i>
A2	<i>firm decides on MEA, price determined through bargaining</i>
B1	<i>payer decides on MEA, prices exogenous</i>
B2	<i>payer decides on MEA, price determined through bargaining</i>
B3	<i>payer decides on MEA after the price is set, myopic firm</i>
B4	<i>payer decides on MEA after the price is set, forward looking firm</i>

Summary of expectations

case	Impact on list prices?	savings overestimated?
A1	No MEA	No MEA
A2	Yes	Yes
B1	No	No
B2	Yes	Yes
B3	No	No
B4	Yes	Yes

Table : Expected impact of *financial-based* agreement

► Main conclusions:

- similar results in the literature for *performance-based* agreements (Pita Barros, 2011)

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Table : Expected impact of *financial-based* agreement

► Main conclusions:

1. unless prices are exogenous or manufacturers myopic we may expect a positive impact of MEA on prices
 2. If the price with MEA is higher, then there exists a risk of overestimating financial saving
- similar results in the literature for *performance-based* agreements (Pita Barros, 2011)

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Data

- ▶ **countries:**
 - ▶ active: Belgium, England, Italy, Netherlands
 - ▶ control: Greece, Norway
- ▶ **reference date:** December 2016
- ▶ **products:**
 - ▶ include all those for which there is a MEA (broadest definition) in at least one country for at least one indication ([156 medicines](#))
 - ▶ select just one presentation per product (i.e. one combination pharmaceutical form, strength and pack size)
- ▶ **prices:** ex-factory prices (source: Pharma Price Information (PPI) of the Austrian Public Health Institute)
- ▶ **MEA:**
 - ▶ official administrative sources: INAMI, NICE, AIFA, Dutch Ministry of Health
 - ▶ minimum info available: class of agreement

MEA in the data

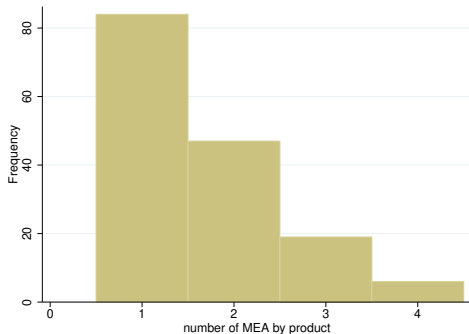


Figure : Number of MEA by product

Empirical specification

$$\ln[\text{price}_{pc}] = \alpha + \beta FA/PA_{pc} + \gamma AA_{pc} + \delta_p + \zeta_c + \varepsilon_{pc}$$

- ▶ price_{pc} : price per unit of product p in country c
- ▶ FA/PA : dummy for presence of either a *financial-based* or a *performance-based* agreement
- ▶ AA : dummy for agreement on appropriateness only
- ▶ δ_p : product fixed effect
- ▶ ζ_c : country fixed effect

Results: baseline

	(1)	(2)	(3)	(4)	(5)	(6)
	ln_price	ln_price	ln_price	ln_price	ln_price	ln_price
PA/FA	0.055** (0.016)	0.059** (0.019)			0.053* (0.025)	0.052* (0.025)
AA		0.031 (0.029)		0.029 (0.033)		0.039 (0.041)
Greece	-0.091*** (0.007)	-0.089*** (0.009)	-0.090*** (0.008)	-0.089*** (0.008)	-0.092*** (0.012)	-0.092*** (0.012)
Italy	0.061*** (0.003)	0.049*** (0.011)	0.065*** (0.007)	0.051** (0.017)	0.062*** (0.008)	0.038 (0.025)
Netherlands	0.064*** (0.007)	0.066*** (0.008)	0.065*** (0.008)	0.066*** (0.008)	0.061*** (0.013)	0.060*** (0.013)
Norway	-0.020* (0.009)	-0.018 (0.010)	-0.019* (0.009)	-0.018 (0.009)	-0.020 (0.013)	-0.021 (0.013)
England	-0.089*** (0.004)	-0.088*** (0.004)	-0.089*** (0.004)	-0.089*** (0.004)	-0.088*** (0.014)	-0.088*** (0.014)
PA			0.032 (0.021)	0.044 (0.033)		
FA			0.057** (0.018)	0.059** (0.019)		
PA/FA_Italy					-0.004 (0.011)	0.020 (0.028)
PA/FA_Netherlands					0.027 (0.034)	0.028 (0.035)
PA/FA_England					-0.001 (0.026)	-0.002 (0.027)
Product FE	YES	YES	YES	YES	YES	YES
N	892	892	892	892	892	892
R ²	0.995	0.995	0.995	0.995	0.995	0.995

Cluster standard errors (at the country level) in parentheses

* $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$

Results: restricted sample of MEA

	(1)	(2)	(3)
	ln_price	ln_price	ln_price
PA/FA	0.078*		0.083*
	(0.032)		(0.034)
Greece	-0.039*	-0.040*	-0.036*
	(0.016)	(0.016)	(0.018)
Italy	0.083***	0.088***	0.089***
	(0.001)	(0.009)	(0.016)
Netherlands	0.126***	0.126***	0.117***
	(0.015)	(0.015)	(0.019)
Norway	0.023	0.022	0.025
	(0.018)	(0.018)	(0.020)
England	-0.041***	-0.043***	-0.020
	(0.002)	(0.002)	(0.024)
PA		0.051	
		(0.032)	
FA		0.077*	
		(0.031)	
PA/FA _Italy			-0.010
			(0.032)
PA/FA _Netherlands			0.114
			(0.059)
PA/FA _England			-0.043
			(0.047)
Product FE	YES	YES	YES
<i>N</i>	518	518	518

Cluster standard errors (at the country level) in parentheses

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Table 4: Results for the sample of products covered by a FA or a PA

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1. unless prices are homogeneous or manufacturers myopic we would expect list prices to be higher in the presence of MEA
2. If there is an increase in list prices, the naïve computation of savings due to MEA may lead to an overestimate
3. Empirical evidence suggests that:
 - ▶ conservative estimate of increase in price with MEA of at least 5.9%
 - ▶ impact driven by financial-based agreements
 - ▶ limited heterogeneity across countries

THANK YOU!

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ADDITIONAL MATERIALS

	(1)	(2)	(3)	(4)	(5)	(6)
	ln_price	ln_price	ln_price	ln_price	ln_price	ln_price
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Netherlands	0.064*** (0.025)	0.066*** (0.025)	0.065*** (0.025)	0.066*** (0.025)	0.061** (0.030)	0.060** (0.030)
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