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Price regulation and parallel imports of pharmaceuticals☆

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ABSTRACT

This paper studies the effects of price regulation and parallel imports in the on-patent pharmaceutical market. In a theory model where the producer price is subject to bargaining between the brand-name producer and a distributor, we show that the effects of stricter price regulation crucially depend on whether the producer faces competition from parallel imports. While parallel imports improve the bargaining position of the distributor, price regulation counteracts this effect and may even be profitable for the producer. We test the implications of our model on a unique dataset with information on sales and prices at both producer and retail level for 165 substances over 4 years (2004–2007). We show that stricter price regulation reduces competition from parallel imports, and has no (strictly negative) effect on producer profits in the presence (absence) of parallel imports. Our results suggest that price regulation might improve static efficiency without being harmful for dynamic efficiency in the presence of parallel imports.

1. Introduction

Price regulation and parallel trade are essential features of pharmaceutical markets in Europe. Almost every European country use price control to curb the growth in pharmaceutical expenditures.[1] Parallel trade is generally encouraged in the EU through the principle of free movements of goods, which implies that pharmaceuticals can be legally traded without the consent from the original producer across national borders. In the US, price regulation and parallel imports (particularly from Canada) have been discussed as policy measures to better control increasing medical expenditures, but are so far not implemented due to concerns for innovation incentives.[2]

From an economic perspective, price regulation and parallel trade are controversial in pharmaceutical markets. On the one hand, these policy instruments may improve static efficiency. Price regulation curbs the market power of pharmaceutical companies and forces prices closer to marginal production costs. Parallel trade stimulates (intra-brand) competition in the importing (high-price) country, and induces price convergency across high- and low-income countries. On the other hand, price regulation and parallel trade are likely to be harmful for dynamic efficiency. Price regulation directly cuts pharmaceutical prices below profit-maximising levels, whereas parallel trade limits the scope for international price discrimination, reducing pharmaceutical companies' profits and thus incentives for innovation.[3]

There exists several papers that study either price regulation or parallel trade in pharmaceutical markets, but the literature on the interaction and joint impact of these policy instruments is very limited. Our paper contributes to filling this gap in the literature by studying the

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[1] See Carone et al. (2012) for a recent overview of pharmaceutical market regulation in the EU.

[2] See, for instance, Vernon and Golec (2008) for a presentation of the US debate and a comprehensive literature review on this topic.

[3] Danzon (1997) provides an excellent presentation and discussion of the efficiency arguments related to regulation in pharmaceutical markets.

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effects of price cap regulation on market outcomes depending on the presence of parallel import. Based on the discussion above, we expect price regulation and parallel trade to have negative effects on prices and profits, and that the combination of these two policy instruments are particularly bad for pharmaceutical companies. In this paper, we show that these conjectures are actually false, and that the interaction between price regulation and parallel imports significantly changes the expected effects. In particular, we show that stricter price regulation can be beneficial to pharmaceutical firms in the presence of parallel imports, though it is clearly negative in absence of parallel imports.

Our paper consists of both a theory and an empirical part. In the theory part, we consider a patent-protected brand-name drug that is sold in a domestic (high-price) country and a foreign (low-price) country. In the domestic country, the brand-name producer negotiates the producer price with a monopoly distributor that may or may not have access to a parallel-imported version from the foreign country. The distributor sets the retail prices on the original and parallel-imported drug versions in the domestic country subject to price cap regulation. We show that, in absence of parallel imports, stricter price cap regulation reduces the bargained producer price and the profits of both the producer and distributor. However, in presence of parallel imports, the effects of stricter price cap regulation are ambiguous and depend on relative bargaining power.

The reason for the different results is that competition from parallel imports changes the pricing incentives of both the producer and the distributor. If the producer pushes for higher prices, the distributor will shift demand towards the parallel-imported drug by reducing its retail price. This implies that the producer price is constrained not only by relative bargaining power, but also by the producer's incentive to restrain competition from parallel importers. Thus, the presence of parallel import shifts market power from the upstream to the downstream part of the industry. However, stricter price cap regulation weakens competition from parallel importers, shifting market power back towards the upstream part of the industry. The producer can take advantage of this and obtain a higher producer price and profits if relative bargaining power is sufficiently strong.

In the empirical part, we estimate the effects of price cap regulation on sales, prices, profits and expenditures in therapeutic markets depending on the existence of parallel imports. The empirical analysis exploits exogenous variation in the price caps over time for different substances to identify causal effects on the dependent variables. We make use of a unique administrative data set covering all prescription-bound sales in Norway with monthly information on prices and volumes per product at both producer and retail level. The data set also includes information about the retail price cap levels and whether the drug is original or parallel-imported. Our sample consists of 165 on-patent substances and covers a 4-year period from 2004 to 2007.

Using a regression model with product fixed effects, we find, as expected, that a reduction in the price cap weakens competition from parallel imports, resulting in higher market shares to the original product. A stricter price cap also reduces producer prices, but the effect is much weaker when the original producer faces competition from parallel imports, as predicted by our theoretical analysis. The effect on producer profit is clearly negative in absence of parallel import. However, in presence of parallel imports, a stricter price cap has no effect on producer profits. This is consistent with our theoretical results that suggest that price cap regulation is less harmful (and may potentially be beneficial) to the original producers when facing competition from parallel importers. Finally, we find that stricter price cap regulation reduces total expenditures, with the effect being stronger for substances with parallel imports than for substances without parallel imports. These results suggest that price regulation is less harmful to dynamic efficiency when original producers face competition from parallel importers, and that price regulation and parallel trade are policy complements rather than policy substitutes.

Our paper contributes to, and bridges, the two strands of literature on the effects of (i) parallel trade and (ii) price regulation of pharmaceuticals. To the best of our knowledge, this paper is the first to study price regulation and parallel imports in conjunction, taking explicitly into account the vertical structure of the pharmaceutical industry. The literature on *parallel trade of pharmaceuticals* consists of papers that are mainly concerned with the effects on prices, innovation and welfare. Ganslandt and Maskus (2004) study the effects of parallel trade using Swedish data, and find that competition from parallel imports reduced prices by 12-19%.[4] Using data from 30 countries, Kyle (2010) examines the effect of both potential and actual entry of parallel imports on prices of original drugs. She also finds that parallel import reduces prices, but the effects are weaker than those reported by Ganslandt and Maskus (2004). On the contrary, Kanavos and Costa-Font (2005) estimate the effect of the market share of parallel imports on price competition, but do not find statistically significant effects.

Even if parallel trade leads to lower prices, the welfare implications are far from clear-cut. Jelovac and Bordoy (2005) analyse the (static) welfare effects of parallel imports of pharmaceuticals using a theory model where a monopoly producer sells a drug in two countries. They find that permitting parallel imports improves welfare if countries only differ in patients' utility of drug treatment, while it reduces welfare if countries only differ in insurance coverage.[5] While the static welfare effects of parallel trade may be positive, a main concern is that it reduces the monopoly rent of the patent holder and may therefore have adverse effects on innovation. However, Grossman and Lai (2008) offer a theoretical argument to the contrary. In a North–South model with innovation in the North and price regulation in the South, they show that allowing for parallel trade may in fact increase innovation incentives under optimal price regulation. The key to this insight is that regulators will optimally set different prices depending on whether or not parallel trade is allowed. [6]

Our paper differs from the above-mentioned papers in two important aspects. First, neither of these studies take explicitly into account the vertical structure of the pharmaceutical industry when assessing the effects of parallel trade; more specifically, how parallel trade affects the relative bargaining position of a distributor vis-á-vis the patent-holding producer. Second, while the above-mentioned studies are concerned about the effects of parallel trade *per se*, we focus instead on how the presence of parallel trade affects the impact of price regulation.

Regarding studies on the impact of *price regulation of pharmaceuticals*, several papers find that such regulation is detrimental to innovation incentives (see, e.g., Giaccotto et al., 2005; Vernon, 2005; Golec and Vernon, 2006; Kyle, 2007). Another strand focuses on the impact of price regulation on competition, pricing and expenditures in the off-patent market. For example, Danzon and Chao (2000) argue that price regulation in pharmaceutical markets tends to drive out competition and present empirical evidence in support of this claim. Furthermore, recent papers by Brekke et al. (2009, 2011) show that the use of reference pricing may be more effective than price cap regulation in reducing pharmaceutical prices and expenditures.[7] We contribute to this particular strand of the literature by analysing how the presence of parallel trade affects the impact of price cap regulation.

The rest of the paper is organised as follows. In Section 2 we describe the Norwegian pharmaceutical market. In Section 3 we develop our

[4] Granlund and Köksal (2011) find that the Swedish mandatory substitution reform caused 15–17% fall in prices on drugs facing competition from parallel imports.

[5] There is also a more general literature on the welfare effects of allowing parallel imports (or, more generally, uniform pricing versus third degree price discrimination). In a seminal paper Malueg and Schwartz (1994) show that the welfare effects are generally ambiguous. Later contributions have considered extensions such as endogenous quality (Valletti and Szymanski, 2006) and strategic policy choices (Roy and Saggi, 2012).

[6] A related mechanism is present in the analysis by Pecorino (2002), who discusses whether the US should allow for parallel imports of prescription drugs from Canada.

[7] See also Brekke et al. (2013) for the effect of pharmacy margins on sales of brand-names and generics, and on prices and expenditures.