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Parallel Trade, Reference Pricing and Competition in the Pharmaceutical Market: Theory and Evidence

Miyase Yesim Köksal-Ayhan

UNIVERSITY OF GOTHENBURG

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To My Parents,

Meriç and Nabi

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Miyase Yesim Köksal-Ayhan

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Abstract

Paper I. Reference Pricing: Making Parallel Trade in Pharmaceuticals Work

This paper shows that parallel trade makes pharmaceutical manufacturers reduce their prices in the home (importing) country more when it is combined with the healthcare reimbursement policy of reference pricing, requiring consumers to pay the full extra cost if they don't buy cheaper parallel imported drugs. On the other hand, contrary to intuition, reference pricing leaves price unchanged in the foreign (exporting) country. By and large, a change from coinsurance to reference pricing results in a pure transfer of wealth from the pharmaceutical manufacturers to the insurance providers without affecting consumers' pharmaceutical consumption or their out-of-pocket costs.

Paper II. Compassion and Cost: The Dual Role of Reference Pricing

Providing health insurance involves a trade-off between the benefits from risk spreading and the costs due to moral hazard. Focusing on pharmaceuticals consumption, this paper examines theoretically whether reference pricing, requiring individuals to pay the price difference if, in this case, they don't buy the cheaper parallel imported drug, can ease this trade-off – an issue which has not previously been pointed out in the debate on health insurance. The results indicate that, if individuals are extremely risk-averse, a policy shift from coinsurance to reference pricing would do this by providing more insurance while decreasing moral hazard.

Paper III. Parallel Imports and Mandatory Substitution Reform: A Kick or A Muff for Price Competition in Pharmaceuticals (with David Granlund)

What has been the effect of competition from parallel imports on prices of locally-sourced on-patent drugs? Did the 2002 Swedish mandatory substitution reform increase this competition? To answer these questions, we carried out difference-in-differences estimation on monthly data for a panel of all on-patent prescription drugs sold in Sweden during the 40 months from January 2001 through April 2004. On average, facing competition from parallel imports caused a 15-17% fall in price. While the reform increased the effect of competition from parallel imports, it was only by 0.9%. The reform, however, did increase the effect of therapeutic competition by 1.6%.

Paper IV. EU Enlargement, Parallel Trade and Price Competition in Pharmaceuticals: What's to Blame? Derogation or Perception? (with David Granlund)

Given the cost of trade and availability of pharmaceuticals, the driving force for parallel trade is the price difference between the source (exporting) and the destination (importing) country. An increase in the price difference or in the availability of pharmaceuticals for parallel trade should increase price competition in the destination country. Using 2003-2007 data from Sweden we investigated whether EU enlargement in 2004, when new countries with low pharmaceutical prices joined the EU, increased competition from parallel imports. Drugs facing competition from parallel imports are found to have on average 17% to 21% lower prices than they would have had if they had never faced such competition. But, contrary to expectation, EU enlargement is not found to have increased this effect, which might be explained by derogations and changes in consumer perceptions of parallel imports.

Introduction

Public expenditures on pharmaceuticals have exploded since the late 1980s, fuelled both by an aging population and new expensive drugs. The average annual real growth in pharmaceutical spending – 60% of which is covered by the public purse – has exceeded that in overall health spending in the EU. Spending on pharmaceuticals averaged 4.7% growth per year, while overall health spending grew 4% (OECD, 2010). Cost of drugs within the Swedish Pharmaceuticals Benefit Scheme increased 8-15 % annually during the 90s and early 2000s (Andersson, 2006).

New drugs are protected by strong patents for on average 20 years. During the patent life drugs face limited competition which is partly responsible for high prices. The largest part of pharmaceutical spending, about 50%, is for on-patent locally-sourced drugs, i.e. drugs that are supplied directly from the manufacturer by authorized wholesalers. Unless parallel trade is allowed, these drugs are only subject to competition from therapeutic alternatives – with different active ingredients but similar therapeutic effects – until the patent expires and generics enter the market

Policy makers try to contain the costs by promoting generic drugs and parallel import of on-patent drugs from low price countries. The mere existence of the cheaper alternatives may not help much, however. People are reluctant to switch medicines, even when they are therapeutically identical (Frank and Salkaver, 1997; Grabowski and Vernon, 1992). This price insensitivity may in part be the result of public or private insurance. To encourage switching, policy makers have therefore introduced policies such as reference pricing. With reference pricing, drugs are clustered according to chemical, pharmacological, or therapeutic equivalence, and a reference price is defined for each cluster. The insurance covers a large share of the cost up to the reference price. Consumers choosing more expensive drugs have to pay the extra cost.

For instance, Sweden introduced such a system of reference pricing in 1993. The system was later tightened by the mandatory substitution reform in 2002. Before the reform, the reference price system only covered off-patent drugs and their generics with the reference price set at 110% of the price of the cheapest available substitute. The reform, however, required substitution not only between off-patent drugs and their generics but also between on-patent drugs and their parallel imported versions, and set the reference price at 100% of the price of

the cheapest available substitute. The reform also made it mandatory for pharmacists – who otherwise have no incentive for substitution – to dispense the cheapest available substitute.

Have these reforms been successful? In particular, has competition from parallel imports increased? The papers in this thesis attempt to provide answers to this question both theoretically and empirically.

The ***first paper*** shows that reference pricing – a healthcare reimbursement policy introduced mainly in some European countries as a demand-side cost-containment policy – could be a solution to increase effectiveness of parallel trade for price competition.[1] This paper merges and extends the two strands of literature, on reference pricing and on parallel trade, by studying the implications of parallel trade for prices and welfare when combined with reference pricing. In order to fulfil this objective, reference pricing is introduced into Jelovac and Bordoy's (2005) two-country model of parallel trade so that insurance only covers a percentage of the cost of the cheapest alternative, the parallel imported drug, while consumers pay the full extra cost if they instead buy the locally sourced drug.[2]

It is assumed that a monopoly manufacturer holds the patent and supplies both countries with a certain drug. The two countries differ in their consumers' valuations of the drug, as well as in the share of the price (coinsurance rate) their consumers pay directly, and thus the manufacturer prices the drug differently in the two countries. Public insurance in each country is assumed to refund consumers' pharmaceutical consumption given the rule of reimbursement (coinsurance or reference pricing). In a perfectly competitive market with no costs of trade, parallel traders buy the drug in the low-price (exporting or source) foreign country and resell it in the high-price (importing or destination) home country. Although there are no real differences, parallel imported drug is assumed to be perceived by consumers as an imperfect (inferior) substitute for the locally sourced one, since it is repackaged or relabelled.[3]

Given these assumptions, parallel trade causes greater price reductions in the home country under reference pricing than under coinsurance while, contrary to intuition, leaving price unchanged in the foreign country. By and large, a change from coinsurance to reference

[1] The EU countries currently using reference pricing are, in historical order, Germany, Netherlands, Denmark, Sweden, Spain, Belgium, Italy, Poland and Slovenia; also Canada (British Colombia), New Zealand, and Australia outside the EU.

[2] Although reference pricing policies differ significantly from country to country (Lopez-Casasnovas and Puig-Junoy, 2000, reviews reference pricing extensively), it is assumed here that drugs with the same active substance are clustered together, with the reference price set equal to that of the cheapest drug in the cluster, as is currently the case in Denmark and Sweden.

[3] Kanavos and Holmes (2005) discuss detailed evidence on consumer perceptions of parallel imports.

pricing results in a pure transfer of wealth from the pharmaceutical manufacturer to the public insurance without affecting consumers' pharmaceutical consumption or their out-of-pocket costs.

The ***second paper*** complements the first paper by examining whether reference pricing provides more insurance while decreasing moral hazard. By covering part of the cost, insurance enables individuals to buy and consume drugs prescribed by their doctors, while reducing variations in real income between sick and healthy people. The drawback is moral hazard. With insurance, people become less price-sensitive and may choose more expensive drugs over cheaper but therapeutically equivalent alternatives. For example, people may continue to buy brand name or locally sourced drugs over generics or parallel imports. As a result, pharmaceutical companies have little reason to compete in prices, leading to higher costs for society. Thus, insurers must trade off the benefits from more generous insurance - primarily the reduction in risk it affords – against the costs of more generous insurance - primarily moral hazard (Cutler and Zeckhauser, 1999). This paper demonstrates that reference pricing can ease this trade-off – something that has not previously been pointed out in the debate.

As in the first paper a two country model of price differentiation is developed where different from the first paper (i) each individual faces the risk of getting sick with a certain probability; (ii)there are two types of individuals, high type (H-type), and low type (L-type) in the home country; and depending on their type, they have higher or lower severity of the disease; (iii) sick individuals choose either the parallel-imported or the locally-sourced drug, given their prices and the coinsurance rate (the percentage of price paid out-of-pocket); the home country is a small open economy such that it has no influence on the world prices and hence the price in the foreign country stays the same when parallel trade is allowed.

The model is solved as a three stage game under two alternative healthcare reimbursement policies (i) coinsurance, and (ii) reference pricing. As in the first paper, it is assumed that drugs with the same active ingredient are clustered together, and reference price is set equal to the price of the cheapest drug in the cluster. The timing of the game is as follows. First, the home-country government sets socially optimal coinsurance rate. Second, the manufacturer sets profit maximizing prices in the home and foreign countries. Third, individuals in the home-country choose which drug to consume, locally sourced or parallel import. The main contribution of the paper is to point out, and to demonstrate, that reference pricing eases the

trade-off between proper incentives and the demand for insurance. With reference pricing, the price of locally sourced drugs will be lower and the optimal amount of medical insurance will be higher.

Showing theoretically that reference pricing increases the price-effect of parallel imports, the **third paper** in this thesis investigates empirically to what extent a reference pricing policy as described in the theoretical papers affect the competition from parallel imports. The main questions this paper attempts to answer are: What has been the effect of competition from parallel imports on prices of locally-sourced on-patent drugs? Did the 2002 Swedish mandatory substitution reform increase this competition?

Sweden introduced a mandatory substitution reform in October 2002, requiring pharmacists to dispense, with the consent of the consumer, the cheapest available generic or parallel-imported drug, unless the prescribing physician opposed substitution for medical reasons. The reform brought in a special form of "reference pricing", whereby drugs with the same active substance – e.g., an off-patent drug and its generics, or an on-patent drug and its parallel imported versions – are grouped together and the price of the cheapest drug in each group is set as the reference price for reimbursement. Maximum reimbursement is fixed at a percentage of that price, but the amount consumers actually pay depends on which drug they buy. Consumers who choose a drug with the reference price pay only a certain "deductible", while consumers who choose a drug with a higher price still pay that deductible but, in addition, also pay the full price difference.

The analyses were carried out using a product level panel dataset covering all on-patent prescription drugs sold in Sweden during January 2001 through April 2004. To identify the effects of competition from parallel imports and how these effects were influenced by the mandatory substitution reform, following Pavcnik (2002) and Brekke et al. (2009), we used difference-in-differences estimation. Following Ganslandt and Maskus (2004), we also used instrumental variable estimation to address potential endogeneity in the entry decisions of parallel traders.

The empirical literature about the effects of competition from parallel imports is limited to Ganslandt and Maskus (2004), Kanavos and Costa-Font (2005), and Kyle (2011), none of which addressed reference pricing or substitution reforms in general. This study adds to the limited knowledge of competition from parallel imports by analyzing how the price effects of competition from parallel imports is affected by a mandatory substitution reform as well as

how it depends on the length of time the parallel imports have been available in the market. The dataset also allowed us to control for competition from therapeutic alternatives – drugs with different active ingredients but similar therapeutic effects in treating a particular disease – including indirect generic competition from off-patent therapeutic alternatives themselves facing generic competition.

We found that facing competition from parallel imports caused prices of locally-sourced drugs to fall on average with 15-17%. The mandatory substitution reform increased this effect causing prices to fall further, but only by one percentage point. The full effect of competition from parallel imports was not realized immediately, but instead prices kept decreasing over time.

Our analysis has implications for the effect of reform on therapeutic competition as well. We found that the prices of drugs facing therapeutic competition would have been 1.5% less on average than if they had not faced such competition. The mandatory substitution reform increased the effect of therapeutic competition by 1.6 percentage points. The effect of therapeutic competition depended on whether the therapeutic alternatives were subject to generic competition. Facing therapeutic competition led to a statistically significant fall in prices if the therapeutic alternatives were themselves subject to generic competition. The mandatory substitution reform increased this fall, indicating that the reform increased the effects of generic competition.

The ***fourth paper*** also examines means to increase competition from parallel imports focusing on the 2004 EU enlargement by which new countries with low pharmaceutical prices joined the EU. The analysis is motivated by the result in the first paper that the price difference between the source and destination countries should increase the intensity of competition from parallel imports. By the enlargement, Cyprus, Malta, and the Central and Eastern European countries – the Czech Republic, Hungary, Latvia, Lithuania, Estonia, Poland, Slovakia, and Slovenia – joined the EU on May 1, 2004. The prices of pharmaceuticals especially in the Central and Eastern European Countries were much lower than in the rest of the EU. Retail pharmaceutical price level was 71% of the OECD average in the Czech Republic in 2005; 70% in Slovakia , and 68% in Poland, while it is 73% in Greece and 77% in Spain, the two major source countries (OECD, 2008). Hence, enlargement increased price differences between EU countries with a twofold effect: causing some not previously subject to competition from parallel imports to face it and increasing competition for those previously

subject to it. That is, intra-EU price differences might have become sufficiently large for parallel traders to start importing drugs not previously subject to parallel trade, while the increased price difference and the increased availability of drugs for parallel trade might have increased competition for others. We here explore whether EU enlargement increased intensity of competition from parallel imports focusing on drugs already subject to it.

However, EU enlargement might not lead to any substantial increase in parallel imports, due to the "derogation" covering all accession countries except Cyprus and Malta. This provision was part of the Accession Treaty because the patent laws in the eight Central and Eastern European accession countries were not in line with those in the existing EU members.[4] The derogation restrains parallel trade by allowing the patent holder of a drug to prevent parallel trade of the drug if the intellectual property rights (IPRs) in the accession country were not comparable with those in the existing members at the time of the product's launch. Despite the derogation, a substantial number, about 6%, of the drugs facing competition from parallel imports, in Sweden had been granted approval for parallel import from the new EU members.

Using the difference-in-differences approach and data from Sweden from January 2003 through October 2007, this paper examines whether EU enlargement in 2004, despite the derogation, increased competition from parallel imports. We estimated the effects of facing competition from parallel imports on prices of on-patent locally-sourced prescription drugs, and how these effects changed with the EU enlargement. Drugs facing competition from parallel imports are found to have on average 17% to 21% lower prices than they would have had if they had never faced such competition. But, contrary to expectation, EU enlargement is not found to have increased this effect. For drugs always facing competition from parallel imports before and after the enlargement, there was no statistically significant effect of the enlargement.

[4] All of the accession countries except for Cyprus and Malta have only had EU compliant patent laws and provided patent protection for pharmaceuticals since the early 1990s (see Tobin and Turner, 2003; von Uexkull, 2004). Patent laws in Cyprus and Malta had been comparable to those in the EU for longer, so they were exempted from the derogation.

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Paper I

REFERENCE PRICING
Making Parallel Trade in Pharmaceuticals Work

Miyase Yesim Köksal [*]

Abstract

This paper shows that parallel trade makes pharmaceutical manufacturers reduce their prices in the home (importing) country more when it is combined with the healthcare reimbursement policy of reference pricing, requiring consumers to pay the full extra cost if they don't buy cheaper parallel imported drugs. On the other hand, contrary to intuition, reference pricing leaves price unchanged in the foreign (exporting) country. By and large, a change from coinsurance to reference pricing results in a pure transfer of wealth from the pharmaceutical manufacturers to the insurance providers without affecting consumers' pharmaceutical consumption or their out-of-pocket costs.

JEL Code: F13, L12, I10
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[*] University of Gothenburg, Department of Economics, Vasagatan 1, P. O. Box 640, SE 405 30 Göteborg, Sweden, e-mail: Miyase.Yesim@economics.gu.se
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Introduction

"There are no miracles from miracle drugs that people cannot afford."

- U.S. Senator Byron Dorgan, Democrat of North Dakota

Pfizer's top selling cholesterol-lowering medication, Lipitor, is sold for $320 in the U.S., but for only $164 in Canada; U.S. consumers thus pay almost twice the price for the same drug.[1] High pharmaceutical prices also increase costs for the U.S. health insurers, making them charge consumers higher premiums. At the same time, many U.S. consumers do not fill their prescriptions, reportedly because they could not afford to do so.[2] Cutting back on prescribed medicines can cause treatable conditions to escalate into severe medical problems with greater suffering, and the public cost of healthcare may then increase as well.

U.S. consumers and health insurers will probably continue to pay more for Lipitor until the patent expires in 2011 and generics enter the market. But a much-debated alternative would be to open the border for parallel trade, allowing intermediaries to buy Lipitor in Canada for resale in the U.S. [3] Such arbitrage, which has been legally practiced in the EU for three decades as a part of the general rules on free movement of goods, is the primary instrument for creating competition for any medicine during the life of its patent.[4]

An important concern, however, is that prices might not be lowered much in the home (high-price, importing) country, since many consumers might be price insensitive because their costs are largely covered by public or private insurance.[5] If consumers continue to buy the more expensive locally sourced drugs -those placed on the market directly from the

[1] A study by the U.S. Congressional Budget Office confirms this pattern: Drug prices are 35% to 55% higher in the U.S. than in Canada (Dorgan, 2007).

[2] An April 2008 study by the Kaiser Family Foundation found that 45% of uninsured and 22% of insured non-elderly adults (aged 18-64) had not filled a prescription because of cost; also see Saul (2008).

[3] U.S. lawmakers have recently proposed several bills to allow parallel trade: the Medicine Equity and Drug Safety Act of 2000; the Pharmaceutical Market Access Act of 2003; and the Pharmaceutical Market Access and Drug Safety Act of 2007 and 2009. The first two passed and allow parallel trade conditional on the Secretary of Health and Human Services' safety approval, which, however, has not been given to date. For the recent legislative history see www.cptech.org/ip/fsd/health-pi-us.html .

[4] The so called me-too drugs, with chemically related active substances that are pharmacologically equivalent, create competition as well, but not as much as do parallel imported drugs with the same active substances, which are virtually identical substitutes.

[5] Another important concern is the effect of parallel trade on the profits from and thus incentives for R&D. Pharmaceutical companies claim that parallel trade erodes profits and thereby decreases investment in R&D. This issue has been much debated (Danzon, 1998; Pecorino, 2002; Schlaepfer, 2008; Grossman and Lai, 2008; Bardey et al., 2009), but I do not consider it further here.

manufacturer by licensed wholesalers- there is little reason for manufacturers to reduce prices. Most of the gain then accrues to the parallel traders.

This paper shows that reference pricing – a healthcare reimbursement policy introduced mainly in some European countries as a demand-side cost-containment policy – could be a solution.[6] With reference pricing, drugs are clustered according to chemical, pharmacological, or therapeutic equivalence, and a reference price is defined for each cluster. If the price of the drug consumers buy is less than or equal to the reference price, consumers pay only a percentage of it. But if it is more, they pay a percentage of the reference price plus the difference between it and the drug price. Compared to the common provision of coinsurance – in which consumers pay a percentage of the price of the drug they choose, and the rest is borne by the insurer – reference pricing increases consumers' price sensitivity, rectifying the distortion created by insurance.

The impact of reference pricing on pharmaceutical companies' pricing strategies has been addressed both theoretically (Mestre-Ferrandiz, 2003; Brekke et al., 2007; Miraldo, 2009) and empirically (Aronsson, Bergman, and Rudholm, 2001; Pavcnik, 2002; Bergman and Rudholm, 2003; Brekke et al., 2008). However, this strand of research has mainly focused on generic competition, without considering competition exerted by parallel imports.

On the other hand, although there are quite a few studies on parallel trade, so far no one has investigated the implications of reference pricing in this context. Instead, previous theoretical research has examined the effects of parallel trade on pricing and welfare, accounting for cross-country demand dispersion (Malueg and Schwartz, 1994), vertical price control (Maskus and Chen, 2004; Chen and Maskus, 2005), pharmaceutical price regulations (Pecorino, 2002; Ganslandt and Maskus, 2004), supply limits (Ganslandt and Maskus, 2004), and cross-country differences in both coinsurance rates and valuation of pharmaceuticals (Jelovac and Bordoy, 2005).

This paper merges and extends the two strands of literature, on reference pricing and on parallel trade, by studying the implications of parallel trade for prices and welfare when

[6] The EU countries currently using reference pricing are, in historical order, Germany, Netherlands, Denmark, Sweden, Spain, Belgium, Italy, Poland and Slovenia; also Canada (British Colombia), New Zealand, and Australia outside the EU.

combined with reference pricing. In order to fulfil this objective, reference pricing is introduced into Jelovac and Bordoy's (2005) two-country model of parallel trade so that insurance only covers a percentage of the cost of the cheapest alternative, the parallel imported drug, while consumers pay the full extra cost if they instead buy the locally sourced drug.[7]

It is assumed that a monopoly manufacturer holds the patent and supplies both countries with a certain drug. The two countries differ in their consumers' valuations of the drug, as well as in the share of the price (coinsurance rate) their consumers pay directly, and thus the manufacturer prices the drug differently in the two countries. Public insurance in each country is assumed to refund consumers' pharmaceutical consumption given the rule of reimbursement (coinsurance or reference pricing). In a perfectly competitive market with no costs of trade, parallel traders buy the drug in the low-price foreign country and resell it in the high-price home country.[8] Although there are no real differences, parallel imported drug is assumed to be perceived by consumers as an imperfect (inferior) substitute for the locally sourced one, since it is repackaged or relabelled.[9]

Given these assumptions, parallel trade causes greater price reductions in the home country under reference pricing than under coinsurance while, contrary to intuition, leaving price unchanged in the foreign country. By and large, a change from coinsurance to reference pricing results in a pure transfer of wealth from the pharmaceutical manufacturer to the public insurance without affecting consumers' pharmaceutical consumption or their out-of-pocket costs.

Benefits of Reference Pricing compared to Coinsurance in the Context of Parallel Trade

The model shows that parallel trade, when combined with reference pricing, increases competition, and hence reduces prices in the home country more than it does under

[7] Although reference pricing policies differ significantly from country to country (Lopez-Casasnovas and Puig-Junoy, 2000, reviews reference pricing extensively), it is assumed here that drugs with the same active substance are clustered together, with the reference price set equal to that of the cheapest drug in the cluster, as is currently the case in Denmark and Sweden.

[8] The assumption of perfect competition is consistent with observed market structure, since for example, in a 2006 report by a biopharma market-research company, Spectra Intelligence, the UK is reported to have 70 parallel importers.

[9] Kanavos and Holmes (2005) report confusion and concerns about parallel imports among epilepsy patients.

coinsurance. What about the effect in the foreign country? One public concern is that manufacturers might reduce supply and increase prices in the foreign country in an attempt to deter parallel trade. Two of the big pharmaceutical manufacturers, GlaxoSmithKline and AstraZeneca, announced that they would cut shipments to Canada if their products were resold to Americans (Harris, 2003). As a result Canadians might not fill all their prescriptions. Even now Greeks cannot get some vital medicines because they are re-exported in such large quantities to other countries in Europe (Morgan, 2008). On the other hand, afraid of similar problems in Canada, the Canadian health minister announced that they would place restrictions on bulk export of drugs to the U.S. countering a move in the U.S. Congress to legalize the import of Canadian drugs (Struck, 2005).

Given this possible strategic response of pharmaceutical manufacturers to raise prices, wouldn't reference pricing in the home country make it worse for the foreign country? Not so! Although reference pricing reduces price in the home country, price in the foreign country remains the same. The manufacturer does have a strategic incentive to increase price in the foreign country to reduce competition in the home country, but there is a counteracting effect. All else equal, when price in the home country is reduced as a result of more intense competition, the manufacturer has an incentive to lower price in the foreign country as well, since reduced home price causes the demand for parallel import to fall.

Several implications follow from the result that price in the foreign country remains constant. As a direct consequence, the price of parallel imported drugs in the home country remains the same. Since marginal consumers buy parallel imports, whose price is constant, there will then be no decline in the share of prescriptions filled.

Introducing reference pricing would not even change the volume of parallel imports, because (i) the home-country consumer who is indifferent between the parallel imported drug and not consuming at all remains unaffected, as price in the foreign country (and thus price of the parallel import) stays the same, and (ii) the home-country consumer who is indifferent between the parallel imported and the locally-sourced drug also remains unaffected. Since the price of the locally sourced drug has fallen, one might have guessed that some consumers who had preferred the parallel import under coinsurance would now switch to the locally sourced drug. But it remains more expensive than the parallel import, and since consumers

are now paying the entire price difference out of their own pockets, there is a counteracting effect, and the two effects cancel each other out.

That the volume of parallel imports does not change with reference pricing has two implications: Further price reduction, in addition to that achieved under coinsurance, is achieved without using any additional resources for transportation, and the social cost incurred by the consumption of parallel imports does not rise. This cost accrues from the perception of parallel imports by some as inferior to locally sourced drugs because of their different packaging or labelling, even though they are therapeutically equivalent.

As a direct consequence of the results that price in the foreign country remains constant and that the volume of parallel imports does not change, foreign consumers are left unaffected by the policy change. So, contrary to intuition, parallel trade when combined with reference pricing – compared to coinsurance – need not harm foreign consumers. Thus reference pricing does not add to the beggar-thy-neighbour quality which parallel trade itself admittedly has even under coinsurance.

As the home-country consumer who is indifferent between the parallel imported and the locally sourced drug remains unaffected, the volume of locally sourced drugs consumed in the home country also does not change. This result, combined with the change in price, has implications for welfare. Although, everything else equal, the price of the locally sourced drugs has fallen, consumer surplus is unchanged, because the individuals who consume the locally sourced drug gain by paying a share of the price of the cheaper parallel import, but also lose by paying the full price difference. These two counteracting effects happen to be equal and offset each other. On the other hand, the monopolist incurs a profit loss due to the fall in the price of the locally sourced drug in the home country, which accrues as a gain to the public insurance, though aggregate welfare is unchanged in both the home and foreign country.

The next section presents the model in detail and solves for equilibrium conditions both under coinsurance and under reference pricing. The following section carries out a welfare analysis. The section after that performs robustness checks of the main results, followed by a section discussing price convergence and its components. Finally, the last section derives policy implications and conclusions.

The Model

I use Jelovac and Bordoy's (2005) two-country model with a price discriminating monopolist to analyze the effects of combining reference pricing with parallel trade. It is assumed that a pharmaceutical manufacturer supplies a certain patented drug, which is used in the treatment of a certain disease, in both home and foreign countries. Demand differs between the two countries due to (i) differing valuations due to different population characteristics and pervasiveness of the disease, and (ii) differing healthcare reimbursement policies. The monopolist manufacturer, therefore, price discriminates, selling the drug in the home and foreign countries at prices p and p^*. However, when parallel trade is legal, wholesalers in a perfectly competitive market can buy the drug in the low price country and sell it in the high price country. We assume that the parallel traders incur no other costs (e.g., transport costs). The marginal cost of production is assumed to be zero.

Individuals in each country can also differ in their valuation of the drug (v and v^*) depending on the severity of the disease and whether or not they have had the disease before.[10,11] We assume that the differing valuations among individuals in each country are distributed uniformly on the interval $[\underline{v}, \overline{v}]$ and $[\underline{v}^*, \overline{v}^*]$ where for simplicity $\overline{v} - \underline{v} = \overline{v}^* - \underline{v}^* = 1$.

As noted earlier, although there are no real differences between a parallel import and a locally-sourced drug – except that the parallel import is repackaged or relabelled – the parallel import is not considered to be a perfect substitute by consumers, and hence is valued less. The elderly, who may be used to one type of packaging, might even perceive them as inferior simply because they get confused by the differences in packaging. Evidence suggests that people are reluctant to switch medicines, even when they are therapeutically identical (Grabowski and Vernon, 1992; Frank and Salkaver, 1997). Consumers may also perceive parallel imports as inferior simply due to their lower price.[12] Thus we assume that consumers' gross valuations are deflated by a factor $\gamma \in (0,1)$ if they consume parallel imports, so that the

[10] Following common notation in the international trade literature, variables pertaining to the foreign country are denoted by a superscript asterisk (*).

[11] Gaither et al. (2001) discuss surveys providing evidence on the influence of severity of a medical condition on the valuation of a drug.

[12] Medicines are credence goods, the utility of which is difficult for the consumer to ascertain. Consumers, then, tend to use price as an indicator of quality, considering the less expensive drug to be of poorer quality.

perceived quality difference between the parallel import and the locally-sourced drug is $(1-\gamma)$.

Individual drug expenditures are assumed to be subsidized by public insurance in each country. Basically, individuals pay a percentage (r) of the price in the home country and a percentage (r^*) of the price in the foreign country, where $r, r^* \in (0,1)$ and the rest $(1-r)$ and $(1-r^*)$ is paid by the public insurance in each country. In order to investigate the effects of parallel trade under differing healthcare reimbursement policies, we will analyze: unconditional reimbursement in the form of *coinsurance* versus conditional reimbursement in the form of *reference pricing*. The basic difference between the two policies is whether cost sharing is independent of the choice of drug. In coinsurance, consumers pay the same percentage of the price regardless of whether the more expensive locally-sourced drug or the parallel import is chosen. In reference pricing, on the other hand, consumers pay a percentage of the price of the cheaper parallel import (the reference drug), plus the price difference if they choose the more expensive locally-sourced drug.

Individuals in each country are assumed to have additively-separable utility in the consumption of a numeraire composite good and the drug. Each has an income y to buy the composite good and the drug. In autarky, when parallel trade is illegal, individuals in each country maximize utility by choosing either to consume one unit of the drug or none. When parallel trade is legal, however, consumers in the home country choose whether to consume one unit of the more expensive locally-sourced drug, or one unit of the cheaper parallel import, or none. For simplicity, the population of each country is normalized to 1.

We will analyse the implications of parallel trade under different reimbursement policies by studying strategic interactions among the pharmaceutical manufacturer, parallel traders, and consumers in a three-stage game. In the first stage, the manufacturer, acting as Stackelberg leader, sets the price in each country. In the second stage, parallel traders buy in the low-price foreign country and re-sell it in the high-price home country. In the third stage, individuals in the home country choose to consume either one unit of the locally-sourced drug, one unit of the parallel-imported drug, or nothing, and individuals in the foreign country choose to consume either one unit of locally-sourced drug, or nothing. The game is solved using backward induction.

We will start with investigating the benchmark case of autarky. Then we will analyze parallel trade (i) under coinsurance and (ii) under reference pricing.

Autarky – Parallel Trade Illegal

When parallel trade is illegal, the three-stage game, described above, boils down to a two-stage game. In the second stage, individuals in each country choose to consume one unit of the drug or nothing. Individuals are indifferent if the utility from consuming one unit of the drug, $\tilde{U}_l = \tilde{v} - rp$, is equal to the utility from not consuming at all, $U_0 = 0$, so that individuals with valuation $\tilde{v} \geq rp$ consume one unit of the drug. Home demand D is then

$$D = \begin{cases} 1 & if \quad p \leq \frac{\underline{v}}{r} \\ \bar{v} - r\,p & if \quad p \in \left]\frac{\underline{v}}{r}, \frac{\bar{v}}{r}\right[\\ 0 & if \quad p \geq \frac{\bar{v}}{r} \end{cases} \qquad \text{(Figure 1a)} \qquad \text{(Eq. 1)}$$

while foreign demand D^* is

$$D^* = \begin{cases} 1 & if \quad p^* \leq \frac{\underline{v}^*}{r^*} \\ \bar{v}^* - r^*\,p^* & if \quad p^* \in \left]\frac{\underline{v}^*}{r^*}, \frac{\bar{v}^*}{r^*}\right[\\ 0 & if \quad p^* \geq \frac{\bar{v}^*}{r^*} \end{cases} \qquad \text{(Figure 1b)} \qquad \text{(Eq. 2)}$$

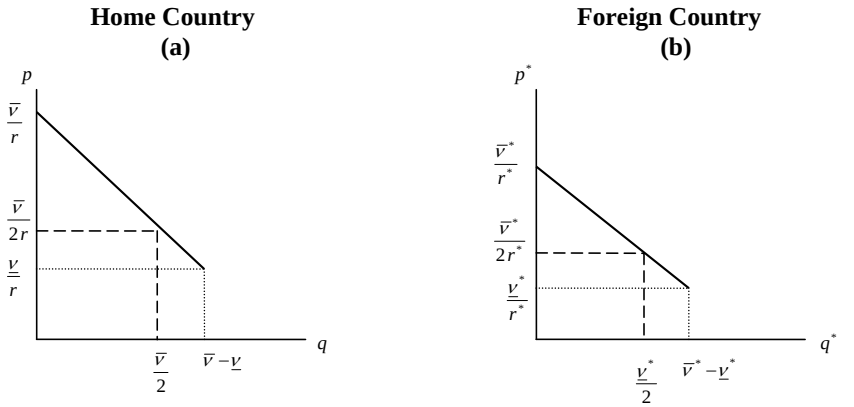

Figure 1: Demand schedules in home and foreign countries

Although a three-tier demand structure is defined, the analysis focuses on the second case where the market is partially covered, and the other two cases are ruled out. This is because the manufacturer won't charge prices lower than $\frac{v}{r}$ in the home country (Figure 1a) and $\frac{v^*}{r}$ in the foreign country (Figure 1b), since those would not be profit maximizing prices. Moreover, while there is evidence that demand for pharmaceuticals is inelastic, it is not perfectly inelastic (Ellison et al., 1997), so we can rule out the case where the monopolist charges a price equal to or less than $\frac{v}{r}$ and $\frac{v^*}{r}$. Hence, to get interior equilibrium solutions, we restrict the upper bounds $\bar{v}$ and $\bar{v}^*$ to vary within the range $[0, 2]$.

Given home and foreign demand, the manufacturer thus sets the price in each country that maximizes total profit

$$\Pi = p\,D + p^*\,D^* \qquad \text{(Eq. 3)}$$

Equilibrium prices are then

$$p = \frac{\bar{v}}{2r} \qquad \text{(Eq. 4)}$$

and

$$p^* = \frac{\bar{v}^*}{2r^*} \qquad \text{(Eq. 5)}$$

which are functions of the highest willingness to pay, and the coinsurance rate, in each country. At equilibrium, the more the consumers value the drug and the lower the coinsurance rate, the higher is the price the manufacturer charges. The coinsurance rate matters because, the less the consumers pay, the less price sensitive they are, and the less price elastic demand is.

Free Trade – Parallel Trade Legal

When parallel trade is legal, imports will flow from the low-price to the high-price country. We assume now (for the rest of the paper) that the two countries differ in such a way that the inequality $\frac{\bar{v}}{r} > \frac{\bar{v}^*}{r^*}$ holds. Given this assumption, the equilibrium price in the home country

in autarky is higher than that in the foreign country. Parallel imports, therefore, will flow from the foreign country to the home country. In the third stage of the game, then, individuals in the home country choose to consume either one unit of locally-sourced drug, one unit of parallel import, or nothing. Individuals are indifferent between consuming one unit of parallel import or not consuming at all if the utility from consuming, $\tilde{U}_p = \gamma \tilde{v} - r\,p$, is equal to the utility from not consuming, $U_0 = 0$, such that

$$\tilde{v} = \frac{r\,p^*}{\gamma}$$

Similarly, individuals are indifferent between consuming one unit of locally-sourced drug or one unit of parallel import if the utility from the locally-sourced drug, $\hat{U}_l = \hat{v} - r\,p$, is equal to the utility from the parallel import, $\tilde{U}_p = \gamma \tilde{v} - r\,p$, such that

$$\hat{v} = \frac{r\left(p - p^*\right)}{\left(1-\gamma\right)}$$

The choices of individuals with different valuations are described by the frequency function illustrated in Figure 2.

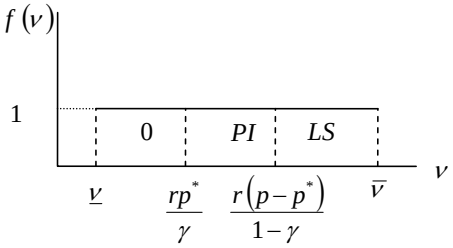

Figure 2: Frequency of valuations in the home country under coinsurance

Those with valuations higher than $\tilde{v} = \frac{r\,p^*}{\gamma}$ and lower than $\hat{v} = \frac{r\left(p - p^*\right)}{\left(1-\gamma\right)}$ choose the parallel import, making its demand

$$D_{PI} = \begin{cases} 0 & if \quad p^* \geq \gamma\, p \\ \dfrac{r\left(\gamma\, p - p^*\right)}{\gamma\left(1-\gamma\right)} & if \quad p^* < \gamma\, p \end{cases} \qquad \text{(Eq. 6)}$$

while those with higher valuations than $\hat{v} = \dfrac{r\left(p - p^*\right)}{\left(1-\gamma\right)}$ choose the locally-sourced drug, making its demand

$$D = \begin{cases} \bar{v} - r\, p & if \quad p^* \geq \gamma\, p \\ \bar{v} - \dfrac{r\left(p - p^*\right)}{1-\gamma} & if \quad p^* < \gamma\, p \end{cases} \qquad \text{(Eq. 7)}$$

Foreign-country individuals choose either consuming one unit of the drug or nothing. Demand in the foreign country is then

$$D^* = \bar{v}^* - r^* p^* \qquad \text{(Eq. 8)}$$

Given these demands, the manufacturer sets the price in each country to maximize total profit

$$\Pi = \left(\bar{v}^* - r^* p^*\right) p^* + \frac{r\left(\gamma\, p - p^*\right)}{\gamma\left(1-\gamma\right)} p^* + \left(\bar{v} - \frac{r\left(p - p^*\right)}{1-\gamma}\right) p \qquad \text{(Eq. 9)}$$

where the first term is revenue from sales for consumption in the foreign country; the second is revenue from sales in the foreign country for exports to the home country; and the third is revenue from sales of locally-sourced drug in the home country. Equilibrium prices are then

$$p = \frac{\left(\gamma\left(1-\gamma\right) r^* + r\right)\bar{v} + \gamma\, r\, \bar{v}^*}{2r\left(\gamma\, r^* + r\right)} = \frac{\bar{v}}{2r} - \frac{\gamma\, r^*}{\gamma\, r^* + r}\left(\gamma \frac{\bar{v}}{2r} - \frac{\bar{v}^*}{2r^*}\right) \qquad \text{(Eq. 10)}$$

and

$$p^* = \frac{\gamma\left(\bar{v}+\bar{v}^*\right)}{2\left(\gamma r^*+r\right)} = \frac{\bar{v}^*}{2r^*} + \frac{r}{\gamma r^*+r}\left(\gamma\frac{\bar{v}}{2r} - \frac{\bar{v}^*}{2r^*}\right) \quad \text{(Eq. 11)}$$

where $p = p^* + \frac{(1-\gamma)\bar{v}}{2r}$.

Because of the competition induced by parallel trade, price in the home country is lower than price in autarky, while price in the foreign country is higher (see Appendix A). This result confirms the common intuition, and the finding in the literature, that parallel trade leads to price convergence.

If (i) there are no trade costs; (ii) there is perfect competition among the parallel traders; and (iii) the parallel imported drugs are perceived as perfect substitutes for locally sourced drugs so that $\gamma=1$, then parallel trade leads to price equalisation across countries, $p = p^* = \frac{\bar{v}+\bar{v}^*}{2\left(r^*+r\right)}$.

So far we have assumed that the manufacturer accommodates parallel trade because the two countries are not too different, such that $\lambda < \gamma$ where $\lambda = \frac{\bar{v}^* r}{\bar{v} r^*}$ is the measure of difference between them. However, the manufacturer wouldn't supply the foreign country, and thus deter parallel trade, if the two countries were quite different, such that $\lambda < \gamma \frac{1}{1+\sqrt{1+\frac{\gamma r^*}{r}}}$. The manufacturer would then instead charge the autarky price in the home country, and would earn more profit.

Policy Change – Reference Pricing

Now let's consider a change in home-country healthcare reimbursement policy from *coinsurance* to *reference pricing*, under which drugs with the same active substance are grouped, and the price of the cheapest in each group is the reference which determines the level of reimbursement. The amount consumers pay, however, depends on which drug they buy. If they buy a parallel import they pay the coinsurance amount, and the rest is covered by

the public insurance. But if they buy the more expensive locally-sourced drug, they pay the same coinsurance amount plus the full price difference between the locally sourced-drug and the parallel import. We incorporate such conditional reimbursement into the model as follows:

If $\bar{p}$ is the reference price, then the co-payment c is

$$c = \begin{cases} r\,p & if \quad p \le \bar{p} \\ r\,\bar{p} + (p - \bar{p}) & if \quad p > \bar{p} \end{cases}$$

Only individuals with valuation

$$v \in \left[\frac{r\,p^*}{\gamma}; \frac{p - p^*}{1-\gamma} \right]$$

will consume the parallel import (Figure 3).

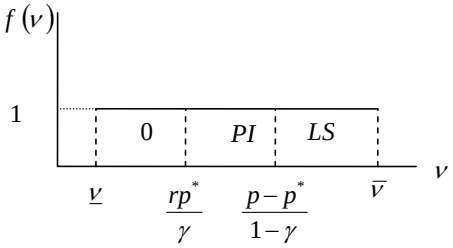

Figure 3: Frequency of valuations in the home country under reference pricing

Therefore demand for the parallel import in the home country is

$$D_{PI} = \begin{cases} 0 & if \quad p^* > \dfrac{\gamma}{r(1-\gamma)+\gamma}\,p \\ \dfrac{\gamma(p - p^*) - (1-\gamma)(r\,p^*)}{\gamma(1-\gamma)} & if \quad p^* \le \dfrac{\gamma}{r(1-\gamma)+\gamma}\,p \end{cases} \qquad \text{(Eq. 12)}$$

The condition for parallel imports to be available in the home country is now less restrictive than under coinsurance (cf. Eq. 6) since

$$\frac{\gamma}{r(1-\gamma)+\gamma} > \gamma \,. \qquad \text{(Eq. 13)}$$

This is why reference pricing promotes the use of parallel imports.

Home-country demand for the locally sourced drug is then

$$D = \begin{cases} \overline{v} - r\,p & \text{if} \quad p^* > \dfrac{\gamma}{r(1-\gamma)+\gamma}\,p \\ \\ \overline{v} - \dfrac{p - p^*}{1-\gamma} & \text{if} \quad p^* \le \dfrac{\gamma}{r(1-\gamma)+\gamma}\,p \end{cases} \qquad \text{(Eq. 14)}$$

while demand in the foreign country is

$$D^* = \overline{v}^* - r^*\,p^* \qquad \text{(Eq. 15)}$$

Given these demands, the manufacturer sets price in each country to maximize total profits

$$\begin{aligned} \prod_m &= \left(D^* + D_{PI}\right)p^* + D\,p \\ &= \left(\overline{v}^* - r^*\,p^* + \frac{\gamma\,p - \left[\gamma + (1-\gamma)r\right]p^*}{\gamma(1-\gamma)}\right)p^* + \left(\overline{v} - \frac{p - p^*}{1-\gamma}\right)p \end{aligned} \qquad \text{(Eq. 16)}$$

Subject to the condition in Eq. 13, equilibrium prices are then

$$p = \frac{\gamma\overline{v}^* + \left[(1-\gamma)\left(\gamma r^* + r\right) + \gamma\right]\overline{v}}{2\left(\gamma r^* + r\right)} = \Phi\frac{\overline{v}}{2r} - \frac{\gamma r^*}{\gamma r^* + r}\left(\gamma\frac{\overline{v}}{2r} - \frac{\overline{v}^*}{2r^*}\right) \qquad \text{(Eq. 17)}$$

where $\Phi = 1 - (1-\gamma)(1-r)r$

and

$$p^* = \frac{\gamma\left(\bar{v}^* + \bar{v}\right)}{2\left(\gamma r^* + r\right)} = \frac{\bar{v}^*}{2r^*} + \frac{r}{\gamma r^* + r}\left(\gamma\frac{\bar{v}}{2r} - \frac{\bar{v}^*}{2r^*}\right)$$

which is same as Eq. 11, indicating that changing from coinsurance to reference pricing in the home country has not changed the price in the foreign country. However, because of increased competition induced by reference pricing, price in the home country is lower than under coinsurance.

Lemma I. For $v \sim U\left[\bar{v}, \underline{v}\right]$ and $v^* \sim U\left[\bar{v}^*, \underline{v}^*\right]$

such that $\bar{v} - \underline{v} = \bar{v}^* - \underline{v}^* = 1; \quad 0 \le \bar{v} \le 2; \quad 0 \le \bar{v}^* \le 2; \quad 0 \le \gamma \le \frac{p^*}{p}; \quad 0 \le r \le 1; \quad 0 \le r^* \le 1:$

$$p_{CI}{}^* = p_{RP}{}^* = \frac{\gamma\left(\bar{v}^* + \bar{v}\right)}{2\left(\gamma r^* + r\right)}$$

That is, price in the exporting country does not change.

This effect of changing from coinsurance to reference pricing in the home country is not in line with intuition. Since reference pricing is described as a policy promoting use of parallel imports, it might be expected intuitively that prices would converge more, rising in the foreign country due to increased demand while falling in the home country due to increased competition. A change to reference pricing in the home country does promote consumption of parallel import and thereby encourages parallel trade. As a result, demand in the foreign country increases, which is an incentive for the manufacturer to raise price. The manufacturer might even have another strategic motive to raise price in the foreign country, to increase the parallel traders' costs and thus reduce their sales.

The manufacturer, while increasing price in the foreign country strategically to deter parallel trade, correspondingly reduces price in the home country to compete with the cheaper parallel imported drugs. As a result, locally sourced drugs become relatively cheaper, while parallel imported drugs become relatively more expensive, which leads to a decrease in demand for parallel imports in the home country. The monopolist, then, would like to reduce the price in the foreign country.

So the change in price in the foreign country is the sum of attempts to deter parallel trade by increasing price, *the strategic effect*, and attempts to secure profits in the foreign country by decreasing price, *the competition effect*. These two effects are equal in absolute terms but opposite in sign, hence they cancel out each other and price in the foreign country stays the same.

Proposition I. Parallel trade under reference pricing, compared to under simple coinsurance – while leaving price in the foreign country unchanged since the strategic and competition effects cancel each other – causes price to fall in the home country.

Figure 4 shows these effects in terms of price reaction functions derived from conventional first-order profit maximization conditions. Each of the price reaction functions – represented by thin solid lines under coinsurance and by thick solid lines under reference pricing – defines the manufacturer's profit maximizing price in one country as a function of price in the other country under the alternative reimbursement systems. The reaction functions under coinsurance are

$$p_{CI}^{*}(p_{CI}) = \frac{\gamma(1-\gamma)\bar{v}^{*} + 2\gamma r\, p_{CI}}{2\left[\gamma(1-\gamma)r^{*} + r\right]} \qquad \text{(Eq. 18)}$$

and

$$p_{CI}\left(p_{CI}^{*}\right) = \frac{(1-\gamma)\bar{v}}{2r} + p_{CI}^{*} \qquad \text{(Eq. 19)}$$

while under reference pricing they are

$$p_{RP}^{*}(p_{RP}) = \frac{\gamma(1-\gamma)\bar{v}^{*} + 2\gamma\, p_{RP}}{2\left[(1-\gamma)(\gamma r^{*} + r) + \gamma\right]} \qquad \text{(Eq. 20)}$$

and

$$p_{RP}\left(p_{RP}^{*}\right) = \frac{(1-\gamma)\bar{v}}{2} + p_{RP}^{*} \qquad \text{(Eq. 21)}$$

As equations 18-19 and 20-21 indicate, under each of the alternative policies optimal price in one country is an increasing function of price in the other. The reaction function $p_{CI}^{*}(p_{CI})$ is

upward sloping because the monopolist charges a higher foreign price as the home price increases, to keep the price difference. Everything else equal, when the home price increases, the price difference becomes larger, making parallel trade more profitable, and driving increased imports to penetrate the home market more. As a result, price in the home country would fall even more, reducing the manufacturer's profit. Acting strategically, the manufacturer then raises the foreign price as well, as home price rises.

The reaction function $p_{RP}\left(p_{RP}^{*}\right)$ is also upward sloping because, the manufacturer charges a higher home price as the foreign price rises. A foreign price rise makes parallel imports more expensive in the home country, reducing demand for them, but increasing demand for locally-sourced drugs, which in turn induces the manufacturer to charge a higher price in the home country.

The reaction function $p_{CI}\left(p_{CI}^{*}\right)$ representing home price as a function of foreign price under coinsurance has the same slope as $p_{RP}\left(p_{RP}^{*}\right)$ under reference pricing and hence they are parallel to each other. On the other hand, the reaction function $p_{RP}^{*}\left(p_{RP}\right)$, representing foreign price as a function of home price under reference pricing, is not as steep as $p_{CI}^{*}\left(p_{CI}\right)$ under coinsurance (Appendix B.1 compares the slopes).

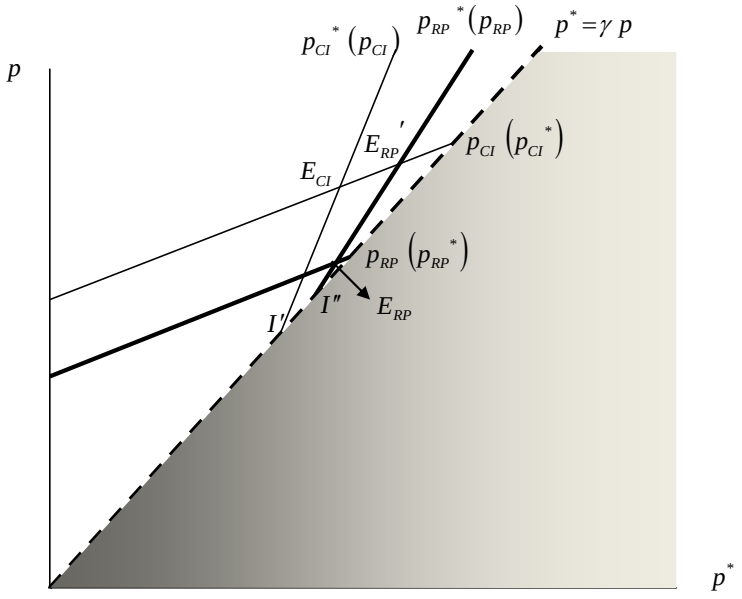

Figure 4: Strategic interaction and equilibrium prices after policy change from *coinsurance* to *reference pricing*

The line $p^{*}=\gamma p$, with intercept at the origin and lying above the 45^{0} degree line – which represents equal home and foreign pricing – is the condition for parallel trade, where the price difference equals the amount by which consumers discount the parallel imported drug. Since parallel trade takes place when $p^{*}<\gamma p$, the relevant region for our analysis is left of the line. Equilibria under coinsurance and under reference pricing should occur in that region. Given the positions of the reaction curves, γ must be large enough that the line $p^{*}=\gamma p$ intersects $p_{CI}^{*}(p_{CI})$ at the point I' in the graph, below the point I'' where $p^{*}=\gamma p$ intersects $p_{RP}^{*}(p_{RP})$ (as shown in Appendix B.2). This is because – given the home-country price – the foreign price is higher under reference pricing than under coinsurance.

Equilibrium under coinsurance occurs at point E_{CI} where $p_{CI}^{*}(p_{CI})$ and $p_{CI}(p_{CI}^{*})$ intersect. After the change from coinsurance to reference pricing, demand for parallel imports increases. The manufacturer then, acting strategically attempts to deter parallel trade by

increasing the foreign price. As a result $p_{CI}^{*}\left(p_{CI}\right)$ shifts to the right under reference pricing to $p_{RP}^{*}\left(p_{RP}\right)$, yielding the *strategic effect* represented by the move from E_{CI} to the new "equilibrium" at point E_{RP}'.

On the other hand, the greater availability of parallel imports in the home country triggers price competition, forcing the manufacturer to reduce the price of the locally sourced drug. As a result, $p_{RP}\left(p_{RP}^{*}\right)$ shifts downward to $p_{CI}\left(p_{CI}^{*}\right)$, resulting in a lower home country price for a given foreign price. As the locally-sourced drug becomes cheaper while the parallel import becomes more expensive, demand for the parallel import falls, forcing the manufacturer to reduce the foreign price. This yields the *competition effect* represented by the move from E_{RP}' to the true equilibrium under reference pricing at point E_{RP}.

In sum, the manufacturer first strategically increases foreign price to deter trade, then reduces home price due to increased competition, which reduces demand for the parallel import and forces the foreign price to fall. The impact of reference pricing on the equilibrium price in the foreign country is thus the sum of (i) the strategic effect and (ii) the competition effect, which are equal in absolute value but differ in sign, and hence cancel out each other. As a result, the foreign price under reference pricing is the same as under coinsurance. It follows straightforwardly that

Proposition II. Parallel trade under reference pricing – compared to coinsurance – does not reduce the share of prescriptions filled.

Foreign price under reference pricing – and hence the price of parallel import – is the same as under coinsurance. The price for marginal consumers – who buy parallel imports in the home-country – is thus constant, so there is no change in the prescriptions filled.

Given the equilibrium prices, equilibrium quantities of parallel imports under reference pricing are also the same as under coinsurance.

Lemma II. For $v \sim U\left[\overline{v}, \underline{v}\right]$ and $v^* \sim U\left[\overline{v}^*, \underline{v}^*\right]$

such that $\overline{v} - \underline{v} = \overline{v}^* - \underline{v}^* = 1; \quad 0 \le \overline{v} \le 2; \quad 0 \le \overline{v}^* < 2; \quad 0 \le \gamma \le \frac{p^*}{p}; \quad 0 \le r \le 1; \quad 0 \le r^* \le 1:$

$$q_{CI} = q_{RP} = \frac{\gamma r^* \overline{v} - r\overline{v}^*}{2\left(\gamma r^* + r\right)}$$

That is, equilibrium quantities of parallel imports do not change.

It is then straightforward that

Proposition III. A change from coinsurance to reference pricing does not lead to any change in the social cost incurred because of the perceived quality differences between parallel imports and locally-sourced drugs.

Proof. Demand for the parallel import is $D_i = \hat{v}_i - c$ where $i = CI, RP$; $\hat{v}_i$ represents the valuation of an individual who is indifferent between the parallel import and the locally-sourced drug; and $c = \frac{r}{\gamma} p_i^*$ represents the valuation of a marginal individuals who are indifferent between consuming the parallel import and no drug at all. As has been shown, $p_{CI}^* = p_{RP}^*$, so c is constant regardless of coinsurance or reference pricing. Under the alternative policies,

$$\hat{v}_{CI} = \frac{r\left(p_{CI} - p_{CI}^*\right)}{1-\gamma} \quad \text{(Figure 2)} \quad \text{and} \quad \hat{v}_{RP} = \frac{p_{RP} - p_{RP}^*}{1-\gamma} \quad \text{(Figure 3)}$$

Changing from coinsurance to reference pricing does not change the volume of the parallel import for two reasons. First, the home-country consumer who is indifferent between the parallel import and no drug at all is unchanged, as the price in the foreign country, and thus the price of the parallel import, stays the same. Hence, as noted, c is constant. Second, the home-country consumer who is indifferent between the parallel import and the locally-sourced drug is also unchanged. This means the first term $\left(\hat{v}_i\right)$ of the demand function is the same under the two alternative policies. Since the price of the locally-sourced drug has fallen under reference pricing, one might have guessed that some consumers who preferred to buy the parallel import under simple coinsurance would switch to the locally-sourced drug, so that

$\hat{v}_{RP}$ would be larger than $\hat{v}_{CI}$. But the locally-sourced drug remains more expensive than the parallel import, and, since consumers are now paying the entire price difference, there is a countervailing effect. These two effects cancel, so that $\hat{v}_{RP} = \hat{v}_{CI}$.

Welfare Analysis

In a static partial-equilibrium framework, this section compares the welfare implications (changes in consumer surplus, manufacturer's profit, and public expenditure) of parallel trade combined with either coinsurance or reference pricing. We have seen that parallel trade reduces home price more under reference pricing than it does under coinsurance, while leaving foreign price unchanged. Hence, home-country consumers enjoy both decreased prices for the locally sourced-drugs and the alternative availability of cheaper parallel imports, while foreign consumers' prices do not change. This means that a change from coinsurance to reference pricing does not change consumer surplus in the foreign country, but home-country consumers pay a larger share of the price difference under reference pricing. So it is not clear whether the change improves consumer surplus in the home country. Moreover, savings accrue to the home-country government as public insurer, but manufacturer's profit is lower, due to increased competition in the home country. The overall welfare effect of the change is then not obvious.

Change in Consumer Surplus

As we have seen, changing from coinsurance to reference pricing does not change the price or the quantity of the parallel import (see Table I). The price of the locally-sourced drug in the home country has fallen, but home country consumers who consume it pay a larger share of the price difference out of their pocket. As a result, the change in consumer surplus in the home country is ambiguous. On the other hand, in the foreign country, since the price and the amount consumed stay the same, consumer surplus remains unchanged. So the change in global consumer surplus is determined by the change in the home-country consumer surplus, which is

$$\Delta CS = \int_{\hat{v}_{CI}}^{\bar{v}} (v - r\, p_{CI})\, dv - \int_{\hat{v}_{RP}}^{\bar{v}} \left(v - r\, p_{RP}^{\,*} - \left(p_{RP} - p_{RP}^{\,*}\right)\right) dv$$

$$= \frac{\bar{v}}{2}\left[\underbrace{r\left(p_{RP}^{\,*} - p_{CI}\right)}_{gain} + \underbrace{\left(p_{RP} - p_{RP}^{\,*}\right)}_{loss}\right] \qquad \text{(Eq. 25)}$$

$$= 0$$

The main determinants of the change in consumer surplus are the ***gain*** from paying a share of the price of the parallel import instead of the more expensive locally sourced drug and the ***loss*** incurred by paying the price difference. The gain and loss cancel each other, leaving consumer surplus unchanged.

Table 1: Equilibrium quantities demanded in home and foreign countries under coinsurance and reference pricing

	Coinsurance		Reference Pricing	
	Home Country	Foreign Country	Home Country	Foreign Country
Locally sourced	$\frac{\bar{v}}{2}$ (from Eq.7, Eq.9 & Eq.10)	$\frac{\bar{v}^*}{2} - \Lambda$ (from Eq.2 & Eq.10)	$\frac{\bar{v}}{2}$ (from Eq.14, Eq.16 & Eq.17)	$\frac{\bar{v}^*}{2} - \Lambda$ (from Eq.2 & Eq.17)
Parallel imported	$\Lambda = \frac{\gamma r^* \bar{v} - r\bar{v}^*}{2\left(\gamma r^* + r\right)}$ (from Eq.6, Eq.9 & Eq.10)		$\Lambda = \frac{\gamma r^* \bar{v} - r\bar{v}^*}{2\left(\gamma r^* + r\right)}$ (from Eq.12, Eq.16 & Eq.17)	
Total	$\frac{\bar{v}}{2} + \Lambda$	$\frac{\bar{v}^*}{2} - \Lambda$	$\frac{\bar{v}}{2} + \Lambda$	$\frac{\bar{v}^*}{2} - \Lambda$

Change in Manufacturer's Profit

Since foreign equilibrium price and quantity demanded (Table I) remain the same, manufacturer's profit from foreign sales does not change. However, the lower home price, with no change in quantity demanded, erodes profit. The fall in profit under reference pricing is

$$\Delta\Pi = \frac{\bar{v}}{2}\left(p_{CI} - p_{RP}\right) = -\frac{(1-\gamma)(1-r)\bar{v}^2}{4r} \qquad \text{(Eq. 26)}$$

Change in Public Expenditure

Since foreign equilibrium price and quantity demanded have not changed, the cost to the foreign public insurance has not changed either. However, since home equilibrium price has fallen with no change in quantity demanded in the home country, the cost to the home public insurance has fallen by

$$\Delta PE = \left(PE_{CI} - PE_{RP}\right)$$

where PE_{CI} stands for public expenditure under coinsurance, and PE_{RP} for that under reference pricing.

$$\Delta PE = \frac{\overline{\nu}}{2}(1-r)\,p_{CI} + \frac{\gamma\, r^{*}\overline{\nu} - r\overline{\nu}^{*}}{2\left(\gamma r^{*} + r\right)}(1-r)\,p_{CI}^{\,*} - \frac{\overline{\nu}}{2}(1-r)\,p_{RP}^{\,*} - \frac{\gamma\, r^{*}\overline{\nu} - r\overline{\nu}^{*}}{2\left(\gamma r^{*} + r\right)}(1-r)\,p_{RP}^{\,*} \quad \text{(Eq. 27)}$$

$$= \frac{\overline{\nu}}{2}(1-r)\left(p_{CI} - p_{RP}^{\,*}\right) \quad \text{(Eq. 28)}$$

The first two terms of Eq. 27 represent public insurance costs under coinsurance, accrued from consumption of the locally-sourced drug and the parallel import, respectively, while the last two represent the same under reference pricing.

Given that $p_{CI} = \frac{(1-\gamma)\,\overline{\nu}}{2r} + p_{CI}^{\,*}$ (Eq. 12) and $p_{CI}^{\,*} = p_{RP}^{\,*}$ (Lemma I)

then

$$\Delta PE = (1-\gamma)(1-r)\frac{\overline{\nu}^{2}}{4r} \quad \text{(Eq. 29)}$$

A change from coinsurance to reference pricing thus reduces public insurance costs because the home country government pays less to reimburse consumers' drug expenditures.

Change in Total Welfare

Whether total welfare (TW) has risen or fallen depends on the extent to which reduced public expenditure compensates for the loss in manufacturer's profit, where

$$\Delta TW = \Delta \Pi + \Delta PE$$

$$= -\frac{(1-\gamma)(1-r)\bar{v}^2}{4r} + \frac{(1-\gamma)(1-r)\bar{v}^2}{4r} \qquad \text{(from Eq. 26, and 29)}$$

$$= 0$$

Thus total welfare does not change under reference pricing, which simply favours public insurance at the expense of manufacturer's profit. Hence, a change from coinsurance to reference pricing results in a transfer of wealth from the pharmaceutical manufacturer to public insurance.

Extensions – Robustness Check

This section performs a sensitivity analysis and checks whether the main implications of the model hold by

I. solving the model using a general rule of reference pricing defined as a weighted average of the home and foreign prices, such that
$p_r = \beta\, p^* + (1-\beta)\, p$ where $0 < \beta < 1$; and

II. relaxing the assumptions
(a) that income distribution is the same in each country and normalized to 1, $\bar{v} - \underline{v} = \bar{v}^* - \underline{v}^* = 1$, and
(b) that market size in each country is normalized to 1.

Relaxing assumptions (a) and (b) allows the restrictive symmetric model used so far account for differences between the countries, which might enlighten the debate on parallel trade between, for example, the U.S. and Canada. Canadians might otherwise believe that, since they are a much smaller market, benefits will be biased towards the U.S.

I. Introducing a General Rule of Reference Pricing

The reference price in the home country can be defined more generally as a weighted average of the home price and the foreign price

$$p_r = \beta\, p^* + (1-\beta)\, p \quad \text{where } 0<\beta<1$$

Equilibrium prices are then

$$p^* = \frac{\gamma\left(\bar{v}^* + \bar{v}\right)}{2\left(\gamma\, r^* + r\right)} \quad \text{and} \quad p = \frac{\gamma\left(\bar{v}^* + \bar{v}\right)}{2\left(\gamma\, r^* + r\right)} + \frac{(1-\gamma)\bar{v}}{2\left[r + (1-r)\beta\right]}$$

As $\beta \to 1$ (i.e., as we approach the situation modelled earlier) competition increases and home price falls, since

$$\frac{\partial p}{\partial \beta} = -\frac{(1-\gamma)(1-r)\bar{v}}{2\left[r + (1-r)\beta\right]^2} < 0$$

When the model is solved using this general rule of reference pricing, the main implications of the model still hold, namely

- that parallel trade reduces home price more under reference pricing than under coinsurance, while leaving foreign price unchanged, and
- that changing from coinsurance to reference pricing does not change total welfare, though there is a transfer of wealth from the pharmaceutical manufacturer to the public insurer.

II. Relaxing Assumptions of Equal Income Distribution and Market Size

It is now assumed that both average income and distribution of income differ between the two countries so that $\bar{v} - \underline{v} \neq \bar{v}^* - \underline{v}^*$. Since consumers' valuations are shaped by their incomes, relaxing the assumption of equal distributions affects the demand functions and hence pricing in each country. In order to account for these differences we define

$$\bar{v} = \mu + s \qquad \underline{v} = \mu - s \qquad \text{and} \qquad \bar{v}^* = \mu^* + s^* \qquad \underline{v}^* = \mu^* - s^*$$

where μ and μ^* represent average incomes, and s and s^* represent deviations from the means in the home and foreign country respectively

Equilibrium prices under coinsurance are

$$p_{CI} = \frac{\left(\gamma(1-\gamma) g r^* + r\right)\bar{\nu} + \gamma g r \bar{\nu}^*}{2r\left(\gamma g r^* + r\right)} \quad \text{and} \quad p_{CI}{}^* = \frac{\gamma\left(g\bar{\nu}^* + \nu\right)}{2\left(\gamma g r^* + r\right)}$$

where $g = \frac{s}{s^*}$ is the relative distribution of income in the home country.

Equilibrium prices under reference pricing are

$$p_{RP} = \frac{\gamma g \bar{\nu}^* + \left[(1-\gamma)\left(\gamma g r^* + r\right) + \gamma\right]\bar{\nu}}{2\left(\gamma g r^* + r\right)} \quad \text{and} \quad p_{RP}{}^* = \frac{\gamma\left(g\bar{\nu}^* + \bar{\nu}\right)}{2\left(\gamma g\ r^* + r\right)}$$

indicating that $p_{RP}{}^* = p_{CI}{}^*$ and that $p_{RP} < p_{CI}$.

Next it is assumed that market size differs between the two countries. Equilibrium prices under coinsurance are then

$$p_{CI} = \frac{\left(\gamma(1-\gamma) r^* + r m\right)\bar{\nu} + \gamma r \bar{\nu}^*}{2\left(\gamma r^* + r m\right)} \quad \text{and} \quad p_{CI}{}^* = \frac{\gamma\left(\bar{\nu}^* + \bar{\nu} m\right)}{2\left(\gamma\ r^* + r m\right)}$$

where $m = \frac{n}{n^*}$ stands for the relative market size of the countries.

Equilibrium prices under reference pricing are

$$p_{RP} = \frac{\gamma \bar{\nu}^* + \left[(1-\gamma)\left(\gamma r^* + r m\right) + \gamma m\right]\bar{\nu}}{2\left(\gamma r^* + r m\right)} \quad \text{and} \quad p_{RP}{}^* = \frac{\gamma\left(\bar{\nu}^* + \bar{\nu} m\right)}{2\left(\gamma\ r^* + r m\right)}$$

indicating that $p_{RP}{}^* = p_{CI}{}^*$ and that $p_{RP} < p_{CI}$.

Once again, when the model is solved allowing for differences in income distribution and market size, the main implications of the model still hold, namely

- that parallel trade reduces home price more under reference pricing than under coinsurance, while leaving foreign price unchanged, and
- that changing from coinsurance to reference pricing does not change total welfare, though there is a transfer of wealth from the pharmaceutical manufacturer to the public insurer.

Where Will Adjustment Take Place?

The common intuition is that parallel trade is triggered by the price difference between two countries, which determines the strength of competition and hence the amount of price convergence. But that initial price difference is not the only important factor for predicting the effects of parallel trade.

Price change under coinsurance in each country can be defined as a function of (i) the price difference in autarky, and (ii) the rate of convergence (Θ and Θ^*). The foreign price change is then

$$p_{CI}^{\ *} - p_A^{\ *} = \Theta^* \left(\gamma\, p_A - p_A^{\ *} \right) \quad \text{where} \quad \Theta^* = \left[\gamma \frac{r^*}{r} + 1 \right]^{-1} \qquad \text{(Eq. 22)}$$

while the home price change is

$$p_{CI} - p_A = -\Theta \left(\gamma\, p_A - p_A^{\ *} \right) \quad \text{where} \quad \Theta = \left[\frac{1}{\gamma} \frac{r}{r^*} + 1 \right]^{-1} \qquad \text{(Eq. 23)}$$

so that $\Theta + \Theta^* = 1$

The initial price difference must be measured using quality-adjusted prices. The rate of convergence (Θ) thus depend on the relative coinsurance rates and on the subjective value discount factor (γ). Given the initial price difference, the effect of parallel trade on foreign price will be larger

1. as the home coinsurance rate is larger than the foreign rate, i.e., as $r^* < r,$ or
2. as home consumers perceive parallel imports to be poor substitutes for locally-sourced drugs, i.e., as γ diverges from unity.

Similarly, the effect on home price will be larger as $r<r^*$ and as γ converges towards unity. One might say that $\frac{r^*}{r}$ and γ determine in which country price will change more. If r^* is relatively large, home price will change more, foreign price will change less. Moreover, home price will change more, if γ is large.

Equation 22 implies that, given the initial price difference, foreign price increases more as the home coinsurance rate increases. Intuitively, when the home coinsurance rate increases, consumers pay more for drugs, so more opt for the cheaper parallel import. Hence, demand for the parallel import increases, allowing the manufacturer to charge a higher foreign price. On the other hand, home price falls more due to increased competition. Equation 23, however, contradicts this intuition, so one must understand why the initial prices are different when making predictions about the likely effect of parallel trade.

Consider the case of parallel trade between two North American countries, the USA and Canada, and between two European Union countries, Sweden and Greece. Assume that, before parallel trade is introduced, the price difference between the U.S. and Canada is the same as that between Sweden and Greece, with the price in the U.S. (Sweden) much higher than that in Canada (Greece). These two cases are illustrated in Figure 5, where $p_A(p_A^*)$ represents optimal autarky price in the U.S. (Sweden) and $p_A^*(p_A)$ represents optimal autarky price in Canada (Greece). One might expect price to fall a lot in the U.S. (Sweden) when parallel trade is allowed, but that is not necessarily the case. It depends why price was so high in the U.S. (Sweden) in the first place. It could be high because of a high valuation of the drug (which might be more likely in the U.S.) or because copayment is low (which might be more likely in Sweden).

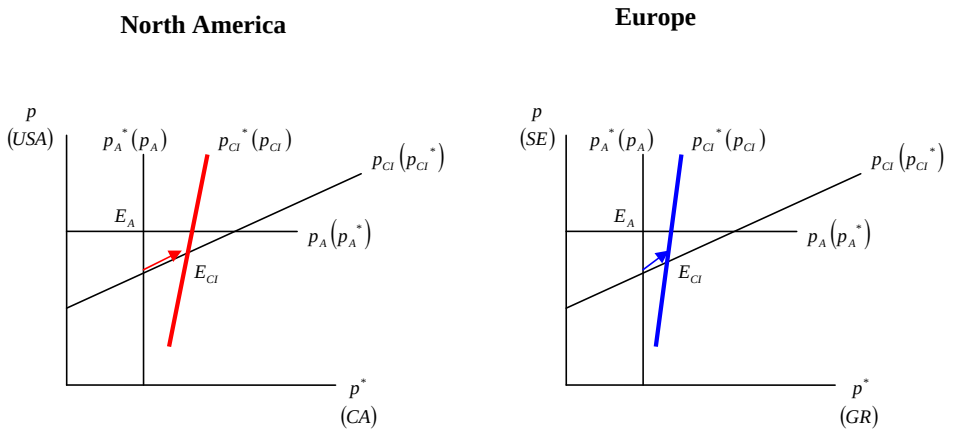

Figure 5: Impact of parallel trade on price convergence

When parallel trade is allowed under coinsurance in both pairs of countries, price in the US (Sweden) goes down and price in Canada (Greece) goes up, but not necessarily equally across the pairs. Equilibrium occurs at E_{CI}, the intersection of $p_{CI}(p_{CI}^*)$ and $p_{CI}^*(p_{CI})$. Although prices converge due to parallel trade in both cases, the amount of convergence differs. In North America, with a high coinsurance rate, parallel trade induces a lot of Americans to buy the drug in Canada. Therefore the manufacturer increases price in Canada more (due to both the normal commercial motives and the strategic response). This large price increase in Canada tends to lessen the price reduction in the U.S., represented by movement along $p_{CI}(p_{CI}^*)$, due to the complementarity of prices. One would then expect price in the U.S. to fall by less than in Sweden. Thus one has to be careful when making predictions, based on the European experience, about the likely price effect of parallel trade in North America.

Price convergence under reference pricing is defined as under coinsurance, but with an additional component of level effect, such that

$$p_{RP} - p_A = -\Theta\left(\gamma\, p_A - p_A^*\right) - (1-\gamma)(1-r)\, p_A \qquad \text{(Eq. 24)}$$

where the second term accounts for increased competition induced by reference pricing.

When the price convergence is further redefined under the assumption that average income and its distribution differ between the countries, it turns out that price convergence also depends on each country's income distribution, so that

$$p_{CI}^{*} - p_{A}^{*} = \Theta^{*}\left(\gamma\, p_{A} - p_{A}^{*}\right)$$

where the rate of convergence

$$\Theta^{*} \equiv \left[\gamma \frac{r^{*}}{r}\frac{S}{S^{*}} + 1\right]^{-1} \in (0,1)$$

The rate of convergence thus depends on the relative coinsurance rates and on the relative income inequality in the two countries, but not on differences in average income. Taking the initial price difference as given, the effect on foreign prices will be smaller

1. as the home coinsurance rate is smaller than the foreign rate, or
2. as inequality in the home country is larger than that in the foreign country.

What does this say about the case of the U.S. and Canada? Probably the debate in Canada has focused on the observable and substantial price-difference between the two countries, perhaps causing a fear of large price increases. But convergence might be relatively modest since, although U.S. coinsurance rates are not on average so different from Canadian ones, income inequality is higher in the U.S. Consider the following example: If $\gamma = 0.9$, $r^{*}/r = 1.2$, and $S/S^{*} = 1.3$, Canadian price would increase by only 40% of the (quality-adjusted) price difference between the countries.[13]

Summary and Conclusions

How much do healthcare reimbursement policies affect the results of parallel trade? Policymakers allow parallel trade in order to increase competition and thereby reduce prices. However, if individuals are reluctant to buy parallel imports, or are price insensitive because of medical insurance, prices in the importing (home) country won't fall very much. On the other hand, consumers in the exporting (foreign) country might face higher prices or supply

[13] The relative coinsurance rate is calculated as the ratio of share of per capita out-of-pocket payments in total health expenditures in Canada to that in the U.S. based on OECD figures for 2007. Relative income inequality is taken as the ratio of Gini coefficients in Picot and Myles (2005).

shortages, since manufacturers want to deter parallel trade. Besides, consuming parallel imports, which are perceived as inferior, creates a social cost of its own.

It has been shown here theoretically that parallel trade under reference pricing, compared to under coinsurance, can reduce home price while leaving foreign price unchanged, because strategic and competition effects counteract each other. The manufacturer has incentive to strategically increase foreign price to offset increased competition in the home country. But when home price falls as a result of more intense competition, the manufacturer also has incentive to lower the foreign price, since reduced home price causes the demand for parallel import to fall.

The fact that these two effects exactly offset each other is probably not a robust result, but they should be present even in a more general model. It is then an open question which effect would dominate, and whether foreign consumers might be hurt, or might benefit from reference pricing in the home country.

The fact that foreign price does not increase as a result of reference pricing has positive effects in the home country. The price of the parallel import remains the same. Since marginal consumers buy parallel imports, their price is constant, and hence there is no decline in the share of prescriptions filled.

Reference pricing does not change the volume of parallel imports, which has two implications. First, reference pricing does not increase the social cost incurred by the consumption of ‘inferior” parallel imports. Second, price reduction is achieved without wasting any resources, for example in transportation costs.

As foreign price and volume of parallel imports remain constant after a change from coinsurance to reference pricing, foreign consumers are left unaffected. So, contrary to intuition, parallel trade when combined with reference pricing – compared to coinsurance – need not harm foreign consumers. Thus reference pricing does not add to the beggar-thy-neighbour quality which parallel trade itself admittedly has even under coinsurance.

A change from coinsurance to reference pricing is also found to result in a transfer of wealth from the pharmaceutical manufacturer to the public insurer, leaving global welfare

unchanged. Thus, reference pricing, as a cost containment policy, fulfils its task in reducing price and saving public expenditure.

Price change is not only a function of the initial (autarky) price difference, but also of a convergence factor, which depends on the relative coinsurance rate and on the extent to which consumers perceive the parallel import as a substitute for the locally-sourced drug. However, one, when making predictions about the likely price effect of parallel trade, needs to understand why prices were different between two countries in the first place.

These results may offer some insight to the ongoing debate whether the U.S. should allow parallel trade of pharmaceuticals from Canada. But if the U.S. healthcare system were restructured to be compatible with reference pricing, parallel trade – compared to what would be realized under simple coinsurance – could favour Americans without harming Canadians. However, as Kanavos and Reinhardt (2003) point out, it might be difficult for U.S. policymakers to decide how to introduce reference pricing, whether as a highly centralized system, or as a decentralized one with private insurers composing the groups of drugs and setting the reference prices. It might be equally difficult to decide how to form the groups of drugs: narrow clusters with the same active substance, or broad clusters with similar indication.

These results should be interpreted with caution, for several reasons. One is that pharmaceutical manufacturers do not set prices freely. Another is that, for strategic reasons, they may not supply all that is demanded at a given price. And a third is that government authorities might change the coinsurance rate when changing to reference pricing, which is the subject of further research.

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Appendix A: Equilibrium Prices in Autarky versus Parallel Trade

Compared to equilibrium prices in autarky, while foreign prices rise, home prices fall due to increased competition via parallel trade, by

$$\frac{\gamma\left(\bar{v}+\bar{v}^*\right)}{2\left(\gamma r^*+r\right)}-\frac{\bar{v}^*}{2r^*}=\frac{\gamma r^*\bar{v}-r\bar{v}^*}{2r^*\left(\gamma r^*+r\right)}>0$$

$$\frac{\bar{v}}{2r}-\frac{\left(\gamma(1-\gamma)r^*+r\right)\bar{v}+\gamma r\bar{v}^*}{2r\left(\gamma r^*+r\right)}=\frac{\gamma\left(\gamma r^*\bar{v}-r\bar{v}^*\right)}{2r^*\left(\gamma r^*+r\right)}>0$$

given $\gamma r^*\bar{v}>r\bar{v}^*$ which follows from the assumption that $\frac{\bar{v}}{r}>\frac{\bar{v}^*}{r^*}$ and the condition that $p^*<\gamma p$.

Appendix B.1: Comparison of the Slopes of $p_{CI}{}^*(p_{CI})$ and $p_{RP}{}^*(p_{RP})$

$$\frac{2\gamma r}{2\left[\gamma(1-\gamma)r^*+r\right]}<\frac{2\gamma}{2\left[(1-\gamma)\left(\rho r^*+r\right)+\gamma\right]}$$

$$\gamma(1-\gamma)r^*r+(1-\gamma)r^2+\gamma r<\gamma(1-\gamma)r^*+r$$

$$(1-\gamma)r^2+\gamma r-r<\gamma(1-\gamma)r^*-\gamma(1-\gamma)r^*r$$

$$(1-\gamma)r^2-(1-\gamma)r<\gamma(1-\gamma)r^*(1-r)$$

$$-r(1-r)<\gamma r^*(1-r)$$

$$\gamma r^*+r>0$$

So, $p_{CI}{}^*(p_{CI})$ is steeper than $p_{RP}{}^*(p_{RP})$.

Appendix B.2: Relative Positions of the Lines $p_{CI}{}^{*}(p_{CI})$ and $p_{RP}{}^{*}(p_{RP})$

Given $p^{*}=\gamma\, p$

Intersection of $p_{CI}{}^{*}(p_{CI})$ with $p^{*}=\gamma\, p$

$$p_{CI}{}^{*}=\frac{\gamma\,(1-\gamma)\bar{v}^{*}+2\gamma r\, p_{CI}}{2\left[\gamma(1-\gamma)r^{*}+r\right]}$$

$$\gamma\, p_{CI}=\frac{\gamma\,(1-\gamma)\bar{v}^{*}+2\gamma r\, p_{CI}}{2\left[\gamma(1-\gamma)r^{*}+r\right]}$$

$$2\gamma(1-\gamma)r^{*}\, p_{CI}+2r\, p_{CI}=(1-\gamma)\bar{v}^{*}+2\, r\, p_{CI}$$

$$2\gamma(1-\gamma)r^{*}\, p_{CI}=(1-\gamma)\bar{v}^{*}$$

$$p_{CI}=\frac{\bar{v}^{*}}{2\gamma\, r^{*}}$$

Intersection of $p_{RP}{}^{*}(p_{RP})$ with $p^{*}=\gamma\, p$

$$p_{RP}{}^{*}=\frac{\gamma\,(1-\gamma)\bar{v}^{*}+2\gamma\, p_{RP}}{2\left[(1-\gamma)\left(\gamma\, r^{*}+r\right)+\gamma\right]}$$

$$\gamma\, p_{RP}=\frac{\gamma\,(1-\gamma)\bar{v}^{*}+2\gamma\, p_{RP}}{2\left[(1-\gamma)\left(\gamma\, r^{*}+r\right)+\gamma\right]}$$

$$2\gamma(1-\gamma)r^{*}\, p_{RP}+2\,(1-\gamma)r\, p_{RP}+2\gamma\, p_{RP}=(1-\gamma)\bar{v}^{*}+2\, p_{RP}$$

$$2\left[\gamma(1-\gamma)r^{*}\, p_{RP}+\,(1-\gamma)r\, p_{RP}-(1-\gamma)\, p_{RP}\,\right]=\,(1-\gamma)\bar{v}^{*}$$

$$2(1-\gamma)\left[\gamma\, r^{*}+r-1\right]\, p_{RP}=\,(1-\gamma)\bar{v}^{*}$$

$$p_{RP}=\frac{\bar{v}^{*}}{2\left(\gamma\, r^{*}+r-1\right)}$$

Note that $\gamma\, r^{*}+r>1$

Since $\frac{\bar{v}^*}{2\gamma r^*} < \frac{\bar{v}^*}{2(\gamma r^* + r - 1)}$, $p_{CI}{}^*(p_{CI})$ intersects with $p^* = \gamma p$ at a point below where $p_{RP}{}^*(p_{RP})$ intersects with $p^* = \gamma p$.

Intersection of $p_{CI}{}^*(p_{CI})$ and $p_{RP}{}^*(p_{RP})$

$$\frac{\gamma(1-\gamma)\bar{v}^* + 2\gamma r p}{2[\gamma(1-\gamma)r^* + r]} = \frac{\gamma(1-\gamma)\bar{v}^* + 2\gamma p}{2[(1-\gamma)(\gamma r^* + r) + \gamma]}$$

$$\frac{(1-\gamma)\bar{v}^* + 2 r p}{\gamma(1-\gamma)r^* + r} = \frac{(1-\gamma)\bar{v}^* + 2 p}{(1-\gamma)(\gamma r^* + r) + \gamma}$$

$$(1-\gamma)\bar{v}^*[\gamma(1-\gamma)r^* + (1-\gamma)r + \gamma - \gamma(1-\gamma)r^* - r] =$$

$$2 p[\gamma(1-\gamma)r^* + r - \gamma(1-\gamma)r^* r + (1-\gamma)r^2 + \gamma r]$$

$$(1-\gamma)\bar{v}^*[(1-\gamma)r + \gamma - r] = 2(1-\gamma)p[\gamma r^* - r(\gamma r^* + r) + r]$$

$$\bar{v}^*[r - \gamma r + \gamma - r] = 2 p[\gamma r^* - r(\gamma r^* + r) + r]$$

$$p = \frac{\gamma \bar{v}^*(1-r)}{2[\gamma r^* - r(\gamma r^* + r) + r]}$$

Besides, $p_{CI}{}^*(p_{CI})$ and $p_{RP}{}^*(p_{RP})$ intersect each other at point $\frac{\gamma \bar{v}^*(1-r)}{2[\gamma r^* - r(\gamma r^* + r) + r]}$, denoted by A in Figure 4, which can be shown to lie below the point $\frac{\bar{v}^*}{2\gamma r^*}$.

$$\frac{\gamma \bar{v}^{*}(1-r)}{2\left[\gamma r^{*}-r\left(\gamma r^{*}+r\right)+r\right]}<\frac{\bar{v}^{*}}{2\gamma\ r^{*}}$$

$$\gamma^{2} r^{*}(1-r)<\gamma r^{*}-\gamma r^{*} r-r^{2}+r$$

$$\gamma^{2}\ r^{*}-\gamma^{2}\ r^{*} r<\gamma r^{*}-\gamma r^{*} r-r^{2}+r$$

$$\gamma r^{*} r-\gamma^{2}\ r^{*} r<\gamma r^{*}-\gamma^{2}\ r^{*}-r^{2}+r$$

$$\gamma r^{*} r(1-\gamma)<\gamma r^{*}(1-\gamma)+r(1-r)$$

$$\gamma(1-\gamma) r^{*}(1-r)+r(1-r)>0$$

$$(1-r)\left(\gamma(1-\gamma) r^{*}+r\right)>0$$

Paper II

COMPASSION AND COST:
The Dual Role of Reference Pricing

Miyase Yesim Köksal[*]

Abstract

Providing health insurance involves a trade-off between the benefits from risk spreading and the costs due to moral hazard. Focusing on pharmaceuticals consumption, this paper examines theoretically whether reference pricing, requiring individuals to pay the price difference if, in this case, they don't buy the cheaper parallel imported drug, can ease this trade-off – an issue which has not previously been pointed out in the debate on health insurance. The results indicate that, if individuals are extremely risk-averse, a policy shift from coinsurance to reference pricing would do this by providing more insurance while decreasing moral hazard.

JEL Code: F13, L12, I10, D82

Keywords: reference pricing, moral hazard, pharmaceuticals, parallel imports

[*] University of Gothenburg, Department of Economics, Vasagatan 1, P. O. Box 640, SE 405 30 Göteborg, Sweden, e-mail: Miyase.Yesim@economics.gu.se

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Introduction

Individuals cannot predict whether they will have a serious illness, or when; or whether it will disappear or recur, and how much medical treatment will cost. This inherent unpredictability of medical consumption is the reason for health insurance. However, if individuals were fully insured, they would over-consume, use more or prefer more costly, medical care, which raises moral hazard issues. For example, fully insured individuals would visit physicians more often, or would prefer more expensive brand-name drugs to cheaper alternatives: to generics, in the case of off-patent drugs, and to parallel imports in the case of on-patent drugs. Not only would individuals over consume (demand-side moral hazard), but healthcare providers and pharmaceutical producers would also overcharge (supply-side moral hazard), as a result of the distortion in price sensitivity caused by insurance.[1] Thus, insurers must trade off the benefits from more generous insurance - primarily the reduction in risk it affords – against the costs of more generous insurance - primarily moral hazard (Cutler and Zeckhauser, 1999).

Experimental studies conducted in various parts of the world (Namibia: Asfaw et al., 2008; Wuhan, China: Liu et al., 2007) found that individuals were willing to pay 5%-11% of their income for health insurance. Thus, on the one hand, individuals attach high value to health insurance. But, on the other hand, as the RAND Health Insurance Experiment (HIE) demonstrated, in the presence of generous health insurance they over-consume healthcare, resulting in welfare loss. [2] Per capita expenses on the free plan (no out-of-pocket costs) were 45% higher than those for the least generous cost-sharing plan, where individuals paid 95% of the costs (Manning et al., 1987). Based on HIE data, Manning and Marquis (1989) estimated that, when individuals paid only 1% instead of paying the full cost, moral hazard losses were more than twice the gains from risk-avoided (US$1596 vs. US$706 per family in 1988 dollars). More recently, Feldstein and Gruber (1994) estimated a potential $34 billion per year increase in aggregate welfare from switching to a modest health insurance.

[1] Feldstein (1973) shows that more insurance increases the price of care.
[2] The RAND Health Insurance Experiment, initiated in 1974 and completed in 1982, has been the only long-term experimental study of cost-sharing and its effect on service use, quality of care, and health.

Demand response to insurance-induced change in out-of-pocket cost has also been estimated focusing specifically on pharmaceuticals consumption. Insurance provides incentives for individuals to consume both more (Coulson and Stuart, 1995; Coulson et al., 1995; Rudholm, 2005; Costa-Font et al., 2007), and more expensive (Lundin, 2000), prescription pharmaceuticals. Lundin (2000) showed that patients getting most of their costs reimbursed were more likely to have more expensive brand-name drugs prescribed than patients paying a larger share of the cost.

Insurance has also been found to create moral hazard on the supply side: Pharmaceutical prices change significantly as a response to a change in health insurance (Pavcnik, 2002). When the cost is shared by the insurer, both individuals and physicians are less price-sensitive than they would otherwise be. As a result, demand is less price-elastic, and pharmaceutical producers naturally charge higher prices.

As evidenced, providing optimal health insurance involves a trade-off between the benefit from risk reduction and the cost of deleterious incentives. Thus, it is extremely important to find ways to ease this trade-off, "a happy compromise with some risk-spreading and some incentive" (Zeckhauser, 1970:10) for individuals to be cost-conscious in the purchase of healthcare. This paper demonstrates that reference pricing, a consumer-driven healthcare reimbursement policy, can provide just that – something that has not previously been pointed out in the debate.

To correct for the distortion in price-sensitivity caused by insurance and make individuals more price-sensitive, reference pricing has been introduced in many countries: Germany, Netherlands, Denmark, Sweden, Spain, Belgium, Italy, Poland, and Slovenia in Europe; also Canada (British Colombia), New Zealand, and Australia (Lopez-Casasnovas and Puig-Junoy (2000) review the variations in their practices). The common feature of these cost-containment policies is that pharmaceuticals are classified into groups with similar active ingredients or indications and a reference price is set for each group. If the price of a consumer-chosen product is higher than the reference price, then the consumer pays the

price difference, so that they are more exposed to the "real" cost, reducing moral hazard. It has been shown empirically that such reference pricing increases consumer price-sensitivity and competition (Aronsson, Bergman and Rudholm, 2001; Pavcnik, 2002; Bergman and Rudholm, 2003; Brekke et al., 2008). It has also been shown theoretically that, under reference pricing, parallel trade of pharmaceuticals increases competition and decreases price more in the importing country than under coinsurance, where a flat percentage of the cost is paid by the consumer and the rest is paid by the insurer (Köksal, 2009). Although there are empirical and theoretical studies supporting policy change from coinsurance to reference pricing, the implications of reference pricing for the trade-off between risk pooling and moral hazard haven't previously been discussed in the literature. Focusing specifically on pharmaceuticals consumption, this paper primarily attempts to fill this gap by examining theoretically whether reference pricing provides more insurance, while decreasing moral hazard.

A two country model of price differentiation is developed where a manufacturer produces a patented drug treating a certain disease, and supplies both countries. The two countries differ in terms of individuals' valuations of the drug and in terms of the coinsurance rate, the percentage of the price consumer pays. Hence the manufacturer price differentiates between the two countries. Parallel trade is legal, so that parallel traders can buy the drug in the low-price (exporting, foreign) country and resell it in the high-price (importing, home) country. As a result, the drug is both locally sourced in the high-price country, directly from the manufacturer, and parallel imported from the low-price country.

Each individual faces the risk of getting sick with a certain probability. There are two types of individuals, high type (H-type), and low type (L-type) in the home country. Depending on their type, individuals have higher or lower severity of the disease. Sick individuals choose either the parallel imported or the locally sourced drug, given their prices and the coinsurance rate (the percentage of price paid out-of-pocket).

Although the two drugs are therapeutically equivalent, some might perceive the parallel import as inferior, since it is repackaged or relabeled by parallel traders. Differences in

labeling might cause individuals to get confused and question the quality, safety and efficacy of the parallel imports. Apart from differences in packaging and labeling, differences in price might also affect individuals' quality expectations which in turn might influence therapeutic efficacy.[3] Waber et al. (2008) have clinically demonstrated this so called *placebo response* to lower prices.[4] Thus it is assumed in the model that both types value the locally sourced drug more than the parallel import, but H-types value both treatments more than do L-types.

The model is solved as a three stage game under two alternative healthcare reimbursement policies (i) coinsurance, and (ii) reference pricing. Although, reference pricing is structured differently from country to country, it is assumed that drugs therapeutically equivalent -with the same active substance in the same dosage form- are clustered together, and reference price is set equal to the price of the cheapest drug in the cluster. The timing of the game is as follows. First, the home-country government sets socially optimal coinsurance rate. Second, the manufacturer sets profit maximizing prices in the home and foreign countries. Third, individuals in the home-country choose which drug to consume, locally sourced or parallel import.

The results show that individuals are not fully insured under either policy. Under coinsurance, they pay a percentage of the cost and the rest is paid by the insurance. However, under reference pricing individuals are subsidized by an amount equal to a percentage of the price of the parallel imported drug regardless of their choice, and those who consume locally sourced drug in the optimum pay the price difference out of their pocket. The comparative risk analysis indicates that individuals are provided more insurance under reference pricing than they are under coinsurance. As a result, when individuals are extremely risk averse, reference pricing both corrects for the moral hazard problem and provides more insurance.

[3] Pharmaceuticals are credence goods about which individuals have no information. Lacking knowledge of a product, they tend to use price as an indicator of quality, that more expensive must be better.

[4] Waber et al. (2008) argue that "placebo responses" to commercial features may help explain why patients switching from branded medications may report that their generic equivalents are less effective. With reference to Waber et al. (2008), Sapone et al. (2009) claim that, paradoxically, the "conscious" choice of the generic drug, because of financial benefits, can "unconsciously" reduce its therapeutic efficacy.

The next section presents the model in detail and solves for optimal cost-sharing under coinsurance and under reference pricing. Then, the following section discusses the change in welfare caused by a policy shift from coinsurance to reference pricing. The section after that carries out a comparative risk analysis based on Rothschild and Stiglitz's (1970) definition of increasing risk. Finally, the last section derives policy implications and conclusions.

Model

In a two country model of price differentiation, a manufacturer is assumed to produce a patented drug, treating a certain disease, and to supply both countries. The manufacturer price discriminates, since the countries are assumed to differ in their valuations of the drug and the coinsurance rate. Parallel trade is assumed to be legal, so that parallel traders can buy the drug in the low price country (exporting foreign country) and resell it in the high price (importing home) country.

In the home country, there are two types of individuals, high type (H-type) with share α of the population, and low type (L-type) with share $1-\alpha$. Initially, both types are healthy, represented by a health stock of φ, which gets impaired when, with probability q, they become sick. H-types, in comparison to L-types, are assumed to be affected more severely, and hence have a lower health stock when sick. Then they have a health stock of φ_S^H, while L-types have a health stock of φ_S^L, such that $\varphi_S^H < \varphi_S^L < \varphi$. As treatment, sick individuals are assumed to choose either the locally sourced drug or, if available, the parallel imported drug. After treatment, an individual i's health status improves to φ_j^i where $i = H, L$ denotes individual's type and $j = A, B$ denotes the chosen drug, locally sourced or parallel imported.

Parallel imports are therapeutically equivalent to locally sourced drugs, with no real difference between them. However, they differ in packaging, since parallel imports are repackaged or relabelled by parallel traders before being sold in the home country. Differences in packaging and labelling might create uncertainty among consumers about

the product's quality, safety and efficacy, possibly causing them to perceive parallel imports as inferior. Such concerns make them question the drug side effects and responsiveness. Apart from differences in packaging and labeling, differences in price might also affect individuals' quality-expectations, which can in turn influence therapeutic efficacy. Individuals might have placebo responses to lower prices, as clinically shown by Waber et al. (2008)[5], and might consider the parallel imported drug of low efficacy and hence value parallel imported drug less. Thus, it is assumed that both types prefer the locally sourced drug, valuing it more than the parallel import, so that $\varphi_B^H > \varphi_A^H$ and $\varphi_B^L > \varphi_A^L$. Moreover, since H-types are affected severely when sick, they value each treatment more than L-types do, implying that $\varphi_B^H > \varphi_B^L$ and $\varphi_A^H > \varphi_A^L$. It is also assumed that H-types gain not only higher total utility but also higher marginal utility than do L-types from consuming a locally sourced drug (the *single crossing property*), resulting in the following condition:

$$\varphi_B^H - \varphi_A^H > \varphi_B^L - \varphi_A^L$$

Both types are assumed to be covered by insurance with individuals paying an actuarially fair premium of p, which satisfies the zero profit condition for the insurers, and sharing the cost of treatment when sick.[6] Utility, then, depends on being healthy or sick; and, when sick, on whether treated by a locally sourced drug or a parallel imported drug. Individual i's state dependent utility is defined using the exponential utility function

$$V = -\exp\left(-\gamma U(r)\right)$$

where $U(r)$ is ordinal utility and γ is the coefficient of absolute risk aversion. Larger values of γ imply that individuals are more risk averse and thus willing to pay higher

[5] Waber et al. (2008) show that the discounted low-price medication was less effective than the regular price one.

[6] The insurance market is assumed to be perfectly competitive where insurance companies earn zero expected profits and charge actuarially fair premiums.

premiums for more generous heath insurance. Given exogenous income y, cardinal utility is then

$u = -\exp\left(-\gamma\left(y - p + \varphi\right)\right)$ when individual i is healthy,

$u = -\exp\left(-\gamma\left(y - p + \varphi_S^i\right)\right)$ when individual i is sick,

and

$u = -\exp\left(-\gamma\left(y - p - p_j + \varphi_j^i\right)\right)$ when individual i is sick but treated by one of the drugs,

where p_j is the out-of-pocket cost of the chosen treatment, defined as a function of price c_j subject to the reimbursement policy.

Expected social utility is then

$$EU = -(1-q)\exp\left(-\gamma\left(y - p + \varphi\right)\right) - q\left[\alpha\exp\left(-\gamma\left(y - p - p_j + \varphi_j^H\right)\right) + (1-\alpha)\left(y - p - p_j + \varphi_j^L\right)\right]$$

which is a function of the probability of becoming sick and the choice of treatment when sick.

In the analysis, two alternative health care reimbursement policies (i) coinsurance, and (ii) reference pricing are considered. Under coinsurance, cost is shared, so that individuals pay a percentage $\left(r_{CI}\right)$ of the price, and public insurance pays the rest, $\left(1 - r_{CI}\right)$. Under reference pricing, however, individuals pay only a percentage $\left(r_{RP}\right)$ of the price of the chosen drug if it is lower than the reference price, otherwise they pay the percentage of the reference price and the full price difference.

Given preferences, prices of the drugs, and reimbursement regime, either both types consume the same drug, or each type consumes a different drug in the optimum. Thus four cases – two pooling and two separating – are possible under each regime, namely: AA where both types consume the parallel imported drug; BB where both types consume the locally sourced drug; AB where H-types consume the locally sourced drug and L-types consume the parallel imported drug; and BA where H-types consume the parallel

imported drug and L-types consume the locally sourced drug. But BA could never be optimal, since, everything else equal, given the single crossing property, a higher social welfare could always be attained by simply swapping drugs between two individuals of different types. The other three cases could each be optimal under certain conditions, which are defined solving the model as a three stage game. In the first stage, the public insurer sets the socially optimal coinsurance rate given the reimbursement policy. Then, in the second stage, the monopolist sets profit maximizing prices in each country taking the coinsurance rate as given. In the last stage, individuals choose one of the drugs given prices and the reimbursement policy. The game is solved using backward induction under both coinsurance and reference pricing.

If individuals were of one type, everyone would consume the same drug and everyone would be fully insured. A similar situation would arise if there were perfect information and individual types were known. However, since types are individuals' private information, the monopolist and the government induce individuals to reveal their type by self-selecting the appropriate drug. Hence, in each case, individuals' choices are determined by two constraints: the individual rationality constraint (IR), and the incentive compatibility constraint (*self-selection constraints*) (IC). First, each type, when sick, must want to consume a drug and be willing to pay the out of pocket cost $\left(p_j\right)$, so that they are at least as well off consuming the drug as not. Second, each type must prefer one drug to the other. Both types then consume parallel imports if

$$IR_A^L : \varphi_A^L - \varphi_S^L \geq p_A \qquad IC^L : \varphi_B^L - \varphi_A^L \leq p_B - p_A$$

and

$$IR_A^H : \varphi_A^H - \varphi_S^H \geq p_A \qquad IC^H : \varphi_B^H - \varphi_A^H \leq p_B - p_A$$

or both consume the locally sourced drug if

$$IR_B^L : \varphi_B^L - \varphi_S^L \geq p_B \qquad IC^L : \varphi_B^L - \varphi_A^L \geq p_B - p_A$$

and

$$IR_B^H : \varphi_B^H - \varphi_S^H \geq p_B \qquad IC^H : \varphi_B^H - \varphi_A^H \geq p_B - p_A$$

But if

$$IR_A^L : \varphi_A^L - \varphi_S^L \geq p_A \qquad IC^L : \varphi_B^L - \varphi_A^L \leq p_B - p_A$$

and

$$IR_B^H : \varphi_B^H - \varphi_S^H \geq p_B \qquad IC^H : \varphi_B^H - \varphi_A^H \geq p_B - p_A$$

then H-types consume the locally sourced drug while L-types consume the parallel import.

Since out of pocket cost (p_j) depends on the reimbursement policy, the model is solved first under coinsurance, and then, separately, under reference pricing.

Coinsurance

Under coinsurance, an individual pays a percentage (r_{CI}) of the price (c_j) of the chosen drug, and the rest is paid by public insurance. The out of pocket cost (p_j), is then

$$p_j = r_{CI}\, c_j \quad \text{where} \quad j = A, B$$

We solve the model starting from the third stage of the game, where individuals choose, given prices and coinsurance rate. Individuals of type i will choose a parallel import if consuming it makes them better off than not consuming at all, and if they prefer it to the locally sourced drug, so that

$$IR_A^i : \frac{\varphi_A^i - \varphi_S^i}{r_{CI}} \geq c_A \text{ and } IC^i : \frac{\varphi_B^i - \varphi_A^i}{r_{CI}} \leq c_B - c_A$$

Similarly, individuals of type i will choose the locally sourced drug if consuming it makes them better off than not consuming at all, and if they prefer it to the parallel import, so that

$$IR_B^i : \frac{\varphi_B^i - \varphi_S^i}{r_{CI}} \geq c_B \text{ and } IC^i : \frac{\varphi_B^i - \varphi_A^i}{r_{CI}} \geq c_B - c_A$$

The constraints that shape individuals' preferences are then

$$IR_A^L : \frac{\varphi_A^L - \varphi_S^L}{r_{CI}} \geq c_A \qquad IR_B^L : \frac{\varphi_B^L - \varphi_S^L}{r_{CI}} \geq c_B \qquad IC^L : \frac{\varphi_B^L - \varphi_A^L}{r_{CI}} \geq c_B - c_A$$

, and

$$IR_A^H : \frac{\varphi_A^H - \varphi_S^H}{r_{CI}} \geq c_A \qquad IR_B^H : \frac{\varphi_B^H - \varphi_S^H}{r_{CI}} \geq c_B \qquad IC^H : \frac{\varphi_B^H - \varphi_A^H}{r_{CI}} \geq c_B - c_A$$

Let, for simplicity, V_j^i denote the valuation of drug j by an individual of type i, so that $V_j^i = \varphi_j^i - \varphi_S^i$. Redefined accordingly, the constraints are then illustrated in Figure 1 to show the conditions under which both types consume the same drug (AA, BB); they consume different drugs (AB); only H-types consume a drug $(\Phi A, \Phi B)$; or neither consumes any drug $(\Phi\Phi)$.

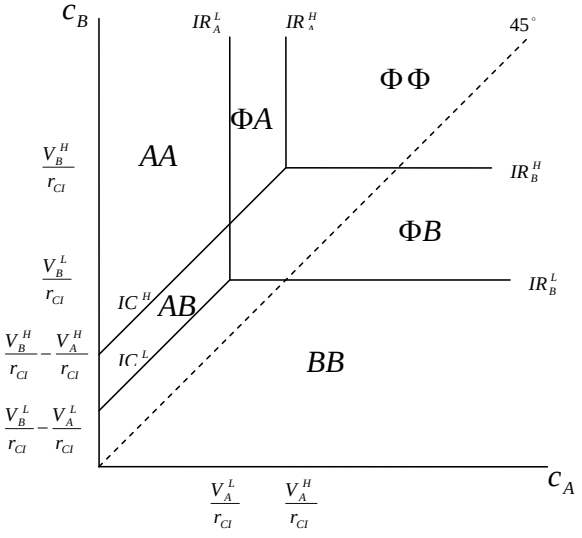

Figure 1. Individual rationality constraints, incentive compatibility constraints, and feasible allocations under coinsurance

Demand in the foreign country can be described by a negatively sloped demand function

$$D = v^* - r^* c_A$$

where v^* denotes the highest willingness to pay for the drug there, and r^* the rate of coinsurance.

In Autarky, when parallel trade is forbidden by law, the equilibrium price in the foreign country is then

$$c_A = \frac{v^*}{2r^*}$$

and assuming both types consume a drug, the equilibrium price in the home country is

$$c_B = \frac{\varphi_B^L - \varphi_S^L}{r_{CI}}$$

Suppose the two countries differ in such a way that the inequality $\frac{v^*}{2r^*} < \frac{\varphi_B^L - \varphi_S^L}{r_{CI}}$ holds, i.e., that the foreign price is lower than the home price. Then price in the home country is larger than that in the foreign country. Given sufficient price difference, if parallel trade is allowed, parallel traders in a perfectly competitive market can buy the drug in the foreign country and re-sell it in the home country. It is assumed that the home country is a small open economy such that it has no influence on the world prices and hence price in the foreign country stays the same when parallel trade is allowed.[7]

[7] If both types were to consume parallel imports in the home country, the monopolist profit would be then

$$\pi = M c_A + M^* \left(v^* - r^* c_A \right) c_A$$

where M represents the size of the home country market, and M^* that of the foreign country.
The profit maximizing equilibrium price of the parallel import would then be

$$c_A = \frac{1}{2mr^*} + \frac{v^*}{2r^*} \quad \text{where} \quad m = \frac{M^*}{M} \text{ is the relative market size.}$$

Even if both types prefer the locally sourced drug in equilibrium (i.e., BB), suppose some fraction epsilon (ε) amount of individuals always consume the parallel import. Although, demand in the out-patient market, which the analysis basically concerned with, is infinitesimal, the inpatient market (hospitals) creates a larger demand for parallel imports. So, given price difference, parallel imports are always available in the home country.

For the rest of the paper, we will assume that the inequality $\frac{v^*}{2r^*} \leq \frac{v_A^L}{r}$ holds, so that the IR constraint for L-types is fulfilled and both types consume a drug in the equilibrium. In addition, given the condition for parallel trade to take place, $c_A < c_B$, the relevant region for analysis is above the 45° line and left of the IR_A^L line in Figure 1, leaving three possibilities: AA, AB, or BB.

In the second stage of the game, given individual preferences', coinsurance rate and the price of the parallel import, the monopolist sets the profit maximizing price in the home country equal to

$c_B = \frac{\varphi_B^L - \varphi_A^L}{r_{CI}} + \frac{v^*}{2r^*}$ in the case of BB, which yields a profit of $\pi_{BB} = M\left[\frac{\varphi_B^L - \varphi_A^L}{r_{CI}} + \frac{v^*}{2r^*}\right]$

or

$c_B = \frac{\varphi_B^H - \varphi_A^H}{r_{CI}} + \frac{v^*}{2r^*}$ in the case of AB which yields a profit of

$\pi_{AB} = M\left[\alpha\left(\frac{\varphi_B^H}{r_{CI}} - \frac{\varphi_A^H}{r_{CI}}\right) + \frac{v^*}{2r^*}\right]$

If the home market is small compared to the foreign market, so that the term $\frac{1}{2mr^*}$ is negligible, then the equilibrium price in the foreign country is the same as in Autarky,

$c_A = \frac{v^*}{2r^*}$

The monopolist's profit is

$\pi_{AA} = M \frac{v^*}{2r^*}$ in the case of AA

AA cannot be optimal, since monopolist's profit in AA is less than in AB. Comparison of the corresponding profits indicates that either BB or AB would be optimal depending on the share of H-types.

Lemma I: If the share of H-types, α, is small, such that $0<\alpha<\frac{\varphi_B^L-\varphi_A^L}{\varphi_B^H-\varphi_A^H}$, then the optimal price charged by the monopolist will be $c_B=\frac{\varphi_B^L}{r_{CI}}-\frac{\varphi_A^L}{r_{CI}}+\frac{v^*}{2r^*}$ and BB will be chosen. However, if α is large, such that $\frac{\varphi_B^L-\varphi_A^L}{\varphi_B^H-\varphi_A^H}<\alpha<1$, then the optimal price charged by the monopolist will be higher, $c_B=\frac{\varphi_B^H-\varphi_A^H}{r_{CI}}+\frac{v^*}{2r^*}$ and AB will be chosen.

Given individuals' choices and optimal prices, in the first stage of the game, the home country government sets the optimal coinsurance rate that maximizes social welfare. Though a closed form solution cannot be derived for the coinsurance rate with either larger or smaller share of H-types, it is shown in Appendix A that, under a certain assumption, closed form solutions can be derived. If individuals are extremely risk averse, so that $\gamma\to\infty$, the government would set the optimal coinsurance rate to maximize the utility of the marginal individuals, L-types (the individuals with the lowest utility after treatment). As shown in Appendix A, this boils down to analytically assigning all the weight to the third term of the derivative of the welfare function, which can also be defined as a weighted average of the derivatives of utilities in various states. The results indicate that individuals will not be fully insured in equilibrium under coinsurance. They will pay a percentage of the price $r^*=\sqrt{\frac{q}{1-q}\frac{\varphi_B^L-\varphi_A^L}{c_A}}>0$ in the case of BB, and $r^*=\sqrt{\alpha\frac{q}{1-q}\frac{\varphi_B^H-\varphi_A^H}{c_A}}>0$ in the case of AB. Individuals pay a smaller share

in the case of BB, when H-types are fewer, than they do in the case of AB. Although both types consume the locally sourced drug in the case of BB, they are not fully insured. The reason is that the monopolist would then charge a higher price, since individuals would be less price elastic.

Reference Pricing

Suppose the home country government changes the reimbursement policy from coinsurance to reference pricing where the parallel import determines the reference price for the locally sourced drug. An individual pays only a percentage (r_{RP}) of the price of parallel import, plus the full price difference if choosing the more expensive locally sourced drug. The out of pocket cost, then, is

$$p_j = \begin{cases} r_{RP}\, c_A & if\ \ parallel\, import\, is\, chosen \\ r_{RP}\, c_A + (c_B - c_A) & if\ \ locally\, sourced\, drug\, is\, chosen \end{cases}$$

As in the previous section, the model is solved starting from the third stage of the game where individuals make their choices. Individual of type i will choose the parallel import if consuming it makes them better off than not consuming, and if they prefer it to the locally sourced drug, so that

$IR_A^i : \varphi_A^i - \varphi_S^i \geq r_{RP}\, c_A$ and $IC^i : \varphi_B^i - \varphi_A^i + c_A \leq c_B$

Similarly, individuals of type i will choose the locally sourced drug if consuming it makes them better off than not consuming, and if they prefer it to the parallel import, so that

$IR_B^i : \varphi_B^i - \varphi_S^i + (1 - r_{RP}) c_A \geq c_B$ and $IC^i : \varphi_B^i - \varphi_A^i + c_A \geq c_B$

The constrains that shape individuals' preferences are then

$$IR_A^L : \varphi_A^L - \varphi_S^L \geq r_{RP}\, c_A \quad IR_B^L : \varphi_B^L - \varphi_S^L + (1 - r_{RP}) c_A \geq c_B \quad IC^L : \varphi_B^L - \varphi_A^L + c_A \geq c_B$$

,

and

$$IR_A^H : \varphi_A^H - \varphi_S^H \geq r_{RP}\, c_A \quad IR_B^H : \varphi_B^H - \varphi_S^H + (1 - r_{RP}) c_A \geq c_B \quad IC^H : \varphi_B^H - \varphi_A^H + c_A \geq c_B$$

As before let, for simplicity, V_j^i denote the valuation of drug j by an individual of type i, so that $V_j^i = \varphi_j^i - \varphi_S^i$. Redefined accordingly, the constraints are then illustrated in Figure 2 to show the conditions under which both types consume the same drug (AA, BB); they consume different drugs (AB); only H-types consume a drug $(\Phi A, \Phi B)$; or neither consumes any drug $(\Phi\Phi)$.

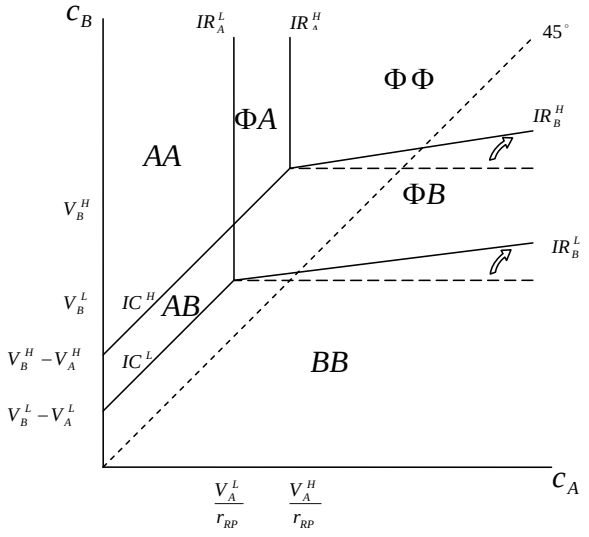

Figure 2. Individual rationality constraints, incentive compatibility constraints, and feasible allocations under reference pricing

The individual rationality constraints for consuming parallel imports (IR_A^i) remain the same under reference pricing. However, the individual rationality constraints for consuming the locally sourced drug (IR_B^i) change slope as indicated by the arrows, and become steeper while the incentive compatibility constraints shift upwards without any change in slope.

Similar to the analysis under coinsurance, given the inequality $\frac{v^*}{2r^*} \leq \frac{v_A^L}{r}$ and the condition for parallel trade to take place, $c_A < c_B$, the relevant region for analysis is above the 45° line and left of the IR_A^L line in Figure 2, leaving three possibilities; AA, AB, and BB.

In the second stage of the game, given the individuals' preferences, the coinsurance rate and the price of the parallel import, the monopolist sets the profit maximizing price in the home country equal to

$c_B = \varphi_B^L - \varphi_A^L + \frac{v^*}{2r^*}$ in the case of BB, which yields a profit of $\pi_{BB} = M\left[\varphi_B^L - \varphi_A^L + \frac{v^*}{2r^*}\right]$

or

$c_B = \varphi_B^H - \varphi_A^H + \frac{v^*}{2r^*}$ in the case of AB, which yields a profit of $\pi_{AB} = M\frac{v^*}{2r^*}$

The monopolist's profit in the case of AA is

$$\pi_{AA} = M\left[\alpha\left(\varphi_B^H - \varphi_A^H\right) + \frac{v^*}{2r^*}\right]$$

Again, AA cannot be optimal, since monopolist earns less in AA than in AB. Comparison of monopolist's profits indicates that either BB or AB would be optimal, depending again on the share of H-types.

Lemma II: If the share of H-types, α, is small, such that $0 < \alpha < \frac{\varphi_B^L - \varphi_A^L}{\varphi_B^H - \varphi_A^H}$, then the optimal price charged by the monopolist will be $c_B = \varphi_B^L - \varphi_A^L + \frac{v^*}{2r^*}$ and BB will be chosen. However, if α is large, $\frac{\varphi_B^L - \varphi_A^L}{\varphi_B^H - \varphi_A^H} < \alpha < 1$, then the optimal price charged by the monopolist will be higher, $c_B = \varphi_B^H - \varphi_A^H + \frac{v^*}{2r^*}$ and AB will be chosen.

The condition for optimal allocation in both cases (BB and AB) is independent of the rate of coinsurance which means that the government's choice of optimal cost sharing has no effect on the optimal allocation.

The price charged by the monopolist under reference pricing is lower than under coinsurance, due to increased competition. Although one might expect the price under reference pricing to be higher than that under no-insurance (or self-insurance), as shown in Köksal (2009), the price under reference pricing, in the present model, happens to be the same as what would be charged then. This means that reference pricing corrects totally for the supply-side moral hazard induced by insurance.

Given individuals' preferences and optimal prices, in the first stage of the game, the home country government sets the optimal coinsurance rate that maximizes social welfare. Appendix B shows that, in both cases (BB and AB) individuals, if extremely risk averse, will be subsidized by an amount equal to a percentage of the price of the parallel import, regardless of their choice. However, those who choose locally sourced drug will pay the price difference.

Will Everyone be Better-off?

An interesting question is whether everyone will be better off after a switch from coinsurance to reference pricing. The answer is not obvious, since both the premium and the out-of-pocket cost of the drug change (see Table 1). Both change since they are functions of the price and the coinsurance rate, both of which change as a result of the policy shift. When reference pricing is introduced, the price of the locally sourced drug falls due to increased competition. However, the change in the premium is not that clear-cut, since both the price and the coinsurance rate have changed. But we can compare total cost (out-of-pocket cost plus the premium paid) under coinsurance with that under reference pricing for both types. The comparisons (in Appendix C) indicate that, in both cases if the probability of getting sick is small, then all sick individuals will be better off under reference pricing. Assuming that there is no cash payment under reference pricing,

i.e., that the optimal coinsurance rate is zero, healthy people will also be better off. As a result, given that individuals get sick with a small probability, a policy shift from coinsurance to reference pricing would make all individuals better off.

Table 1. Costs of and benefits from various allocations for H-types and L-types under coinsurance and reference pricing

			Cost	**Benefit**
Coinsurance	BB	L-Type	$p_{CI} + r_{CI}\, c_B$	φ_B^L
		H-Type	$p_{CI} + r_{CI}\, c_B$	φ_B^H
	AB	L-Type	$p_{CI}^{'} + r_{CI}^{'}\, c_A$	φ_A^L
		H-Type	$p_{CI}^{'} + r_{CI}^{'}\, c_B^{'}$	φ_B^H
Reference Pricing	BB	L-Type	$p_{RP} + r_{RP}\, c_A + (c_B - c_A)$	φ_B^L
		H-Type	$p_{RP} + r_{RP}\, c_A + (c_B - c_A)$	φ_B^H
	AB	L-Type	$p_{RP}^{'} + r_{RP}^{'}\, c_A$	φ_A^L
		H-Type	$p_{RP}^{'} + r_{RP}^{'}\, c_A + (c_B^{'} - c_A)$	φ_B^H

"More Insurance" under Reference Pricing

The analyses under coinsurance and reference pricing have shown that (i) individuals will not be fully insured under either policy; (ii) under coinsurance, they pay a percentage of the price of the chosen drug; (iii) under reference pricing, they are paid cash back equal to a percentage of the price of the parallel imported drug regardless of choice but asked to pay the price difference out-of-their pocket if they choose to consume locally sourced drug. Since the cost-sharing rule and the price of the locally sourced drug have both changed because of the policy shift, the out-of-pocket cost may differ under the two policies. But whether the policy shift will provide more or less insurance is still an open question.

Health insurance helps individuals avoid risk of financial loss in case of illness. More insurance lets individuals enjoy greater risk-avoidance. A natural measure of change in insurance provided thus depends on the change in risk avoided. If insurance pays more of the cost, individuals face less risk of financial loss. The share of cost paid by insurance can thus be used as a measure of riskiness. The analysis indicates that, in both cases (*BB* and *AB*) the share of cost paid by insurance is larger under reference pricing than it is under coinsurance.

Proposition I. If individuals are extremely risk averse, then a policy shift from coinsurance to reference pricing will correct for moral hazard and provide individuals with more insurance.

Proof. In the case of BB, the share of cost paid by insurance is $\frac{q(1-r_{CI})c_B}{qc_B}$ under coinsurance, and $\frac{q(1-r_{RP})c_A}{qc_B}$ under reference pricing. In the case of AB, it is $\frac{q[\alpha(1-r_{CI})c_B+(1-\alpha)(1-r_{CI})c_A]}{q[\alpha c_B+(1-\alpha)c_A]}$ under coinsurance, and $\frac{q(1-r_{RP})c_A}{q[\alpha c_B+(1-\alpha)c_A]}$ under reference pricing.

Given optimal cost sharing under the assumption of extreme risk aversion ($\gamma\to\infty$), the share of cost paid by the insurer is larger under reference pricing than under coinsurance in the case of BB since

$$-\sqrt{\frac{q}{1-q}\frac{\varphi_B^L-\varphi_A^L}{c_A}}<1+\frac{\varphi-\overline{\varphi}_B}{\varphi_B^L-\varphi_A^L+c_A}$$

and in the case of AB since

$$1-\sqrt{\frac{q}{1-q}\frac{\varphi_B^L-\varphi_A^L}{c_A}}<\frac{c_A+\varphi-\overline{\varphi}_A}{\alpha\left(\varphi_B^H-\varphi_A^H\right)+c_A}.$$ [8]

[8] As $\varphi>\varphi_B^H$ and $\varphi_A^H>\overline{\varphi}_A$, $c_A+\varphi-\overline{\varphi}_A>\alpha\left(\varphi_B^H-\varphi_A^H\right)+c_A$, and hence $\frac{c_A+\varphi-\overline{\varphi}_A}{\alpha\left(\varphi_B^H-\varphi_A^H\right)+c_A}>1$

As a result, a policy shift from coinsurance to reference pricing would smooth the trade-off between risk spreading and possible perverse incentives provided. It would both provide more insurance and correct for moral hazard.

A more founded approach to comparing risk is to use the Rothschild and Stiglitz's classic (1970) characterization of "increasing risk". They showed that, of two random variables with the same mean, the one with more weight in the tails is more risky. They say:

If X and Y have density functions f and g, and if g was obtained from f by taking some of the probability weight from the centre of f and adding it to each tail of f, in such a way as to leave the mean unchanged, then it seems reasonable to say that Y is more uncertain than X. (Rothschild and Stiglitz, 1970)

In the model here, income equivalent when healthy or sick under each reimbursement policy can be represented by a discrete variable, F_{CI} under coinsurance and F_{RP} under reference pricing, each taking three values with certain probabilities (Table D2 in Appendix D). Since means of these two discrete variables differ, we cannot directly apply the Rothschild and Stiglitz definition. In order to use it, we first introduce a sequence of mean preserving spreads, $\tilde{G}$ and $\tilde{\tilde{G}}$. Expected income equivalence is higher under reference pricing than under coinsurance (see Appendix D) by

$$\Delta = q\alpha\frac{1-r_{CI}}{r_{CI}}\left(\varphi_B^H - \varphi_A^H\right)$$

A discrete variable $\tilde{G}$ is constructed by taking Δ amount of money from everybody and giving it away such that the mean of $\tilde{G}$ is the same as the mean of F_{CI}. Since the same amount of money is taken from everyone, F_{RP} and $\tilde{G}$ don't differ in terms of risk.[9] Using the sequence of mean preserving spreads, it is shown in Appendix D that $\tilde{G}$ and

[9] More specifically, they cannot be compared in terms of risk, and they have the same risk.

F_{CI} have the same mean, but $\tilde{G}$ has less weight in the tails, and is thus less risky. By transitivity, F_{RP} is less risky than F_{CI}, meaning that more insurance is provided under reference pricing.

Conclusion

This paper has examined how the introduction of healthcare reimbursement policy of reference pricing for pharmaceuticals might affect the level of medical insurance. By covering part of the cost, insurance enables individuals to buy and consume drugs prescribed by their doctors, while reducing variations in real income between sick and healthy people. The drawback is moral hazard. With insurance, people become less price-sensitive and may choose more expensive drugs over cheaper but therapeutically equivalent alternatives. For example, people may continue to buy brand name or locally sourced drugs over generics or parallel imports. As a result, pharmaceutical companies have little reason to compete in prices, leading to higher costs for society. Reference pricing means that the insurance only covers part of the cost of the cheapest alternative among a set of drugs considered therapeutically equivalent. If one buys a more expensive alternative, one has to pay the full *extra* cost.

Reference pricing has previously been shown to reduce moral hazard arising from medical insurance. Introducing reference pricing, consumer price-sensitivity increases, competition increases, and the prices of drugs fall. The main contribution of the current paper is to point out, and to demonstrate, that reference pricing also eases the trade-off between proper incentives and the demand for insurance. With reference pricing, the optimal amount of medical insurance will be higher.

The results of this normative analysis might add a new insight to the ongoing debate about healthcare reform in the US, aimed at controlling costs and increasing health insurance. The reform proposes subsidies and regulation to provide more insurance, and possibly a “medicare” style public health insurance plan to create competition in the insurance market and thereby decrease cost. Although they seem like opposing

alternatives, Paul Krugman stated in his New York Times column on July 24, 2009 "when it comes to reforming health care, compassion and cost-effectiveness go hand in hand." If U.S. health insurance plans were restructured to be compatible with reference pricing, they would have a stake in achieving the two goals, controlling healthcare costs and increasing health insurance at the same time.

Nevertheless, the results here should be interpreted with some caution, due to limitations of the model, which does not account for the effect of income on demand for pharmaceuticals. It also does not allow for individuals who cannot afford any drug. And the results hold when individuals are extremely risk averse.

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Appendix A. The Optimal Rate of Cost Sharing under Coinsurance

The social welfare function

$$W = -(1-q)\exp(-\gamma(y-p+\varphi)) - q\left[\alpha\exp\left(-\gamma\left(y-p-p_j+\varphi_j^H\right)\right)+(1-\alpha)\left(y-p-p_j+\varphi_j^L\right)\right]$$

where $j = A, B$

can be rewritten as

$$W = \pi V(U(r)) + \pi_H V(U_H(r)) + \pi_L V(U_L(r))$$

where

$$\pi = 1-q; \pi_H = q\alpha; \pi_L = q(1-\alpha); U(r) = y-p+\varphi; U_H(r) = y-p-p_j+\varphi_H^j; U_L(r) = y-p+p_j+\varphi_L^j;$$

and $V(.) = -\exp(-\gamma(.))$

so that $\frac{\partial W}{\partial r} = \pi V'(U(r))U'(r) + \pi_H V'(U_H(r))U_H'(r) + \pi_L V'(U_L(r))U_L'(r) = 0$

Dividing both sides of the equation by $\frac{1}{V'(U(r))+V'(U_H(r))+V'(U_L(r))}$ and solving it for r yields the optimal r as a weighted average

$$r^* = \kappa r + \kappa_H r_H + \kappa_L r_L$$

There is no closed form solution of this welfare maximization problem. However, under the assumption that individuals are extremely risk averse $(\gamma \to +\infty)$, a closed form solution can be obtained. The social planner would then assign all weight to the least-healthy individuals, or in the model, to the L-types. This means that, to determine the optimal r, in the equation above, $\kappa = \kappa_H = 0$ and $\kappa_L = 1$.

Let's calculate optimal r for both cases BB (both types consuming the locally sourced drug) and AB (L-types consuming parallel imported drug and H-types locally sourced drug) under the assumption that $\gamma \to +\infty$.

The Case of BB

When both types consume the locally-sourced drug, social welfare would be

$$W = -(1-q)\exp\left(-\gamma\left(y-p+\varphi\right)\right) - q\left[\alpha\exp\left(-\gamma\left(y-p-p_B+\varphi_B^H\right)\right) + (1-\alpha)\left(y-p-p_B+\varphi_B^L\right)\right]$$

The optimal r which maximizes social welfare, must then satisfy

$$\frac{\partial W}{\partial r} = (1-q)\left[q\frac{1}{r^2}\left(\varphi_B^L-\varphi_A^L+r\,c_A\right) - q\frac{(1-r)}{r}c_A\right]\kappa + q\left[q\frac{1}{r^2}\left(\varphi_B^L-\varphi_A^L+r\,c_A\right) - q\frac{(1-r)}{r}c_A - c_A\right]\left(\alpha\,\kappa_H + (1-\alpha)\kappa_L\right) = 0$$

Assuming that $\kappa = \kappa_H = 0$ and $\kappa_L = 1$, then optimal r is

$$r^* = \sqrt{\frac{q}{1-q}\frac{\varphi_B^L-\varphi_A^L}{c_A}} \;>\; 0$$

If the condition $\varphi_B^L - \varphi_A^L < \frac{1-q}{q}c_A$ holds, then the optimal coinsurance rate is $0 < r^* \le 1$

The Case of AB

When L-types instead consume the parallel imports, social welfare would be

$$W = -(1-q)\exp\left(-\gamma\left(y-p+\varphi\right)\right) - q\left[\alpha\exp\left(-\gamma\left(y-p-p_B+\varphi_B^H\right)\right) + (1-\alpha)\left(y-p-p_A+\varphi_A^L\right)\right]$$

As above, the optimal r, which maximizes social welfare, must satisfy

$$\frac{\partial W}{\partial r} = (1-q)\left[q\frac{1}{r^2}\left(\alpha\left(\varphi_B^H-\varphi_A^H\right)+r\,c_A\right) - q\frac{(1-r)}{r}c_A\right]\kappa + q\left[q\frac{1}{r^2}\left(\alpha\left(\varphi_B^H-\varphi_A^H\right)+r\,c_A\right) - q\frac{(1-r)}{r}c_A - c_A\right]\left(\alpha\,\kappa_H + (1-\alpha)\kappa_L\right) = 0$$

Assuming that $\kappa = \kappa_H = 0$ and $\kappa_L = 1$, then optimal r is

$$r^* = \sqrt{\alpha \frac{q}{1-q} \frac{\varphi_B^H - \varphi_A^H}{c_A}} > 0$$

If the condition $\varphi_B^H - \varphi_A^H < \frac{1}{\alpha} \frac{1-q}{q} c_A$ holds, then the optimal coinsurance rate is $r^* < 1$.

Appendix B. The Optimal Rate of Cost Sharing under Reference Pricing

The Case of BB

When both types consume the locally-sourced drug, social welfare would be

$$W = -(1-q)\exp\left(-\gamma\left(y - p + \varphi\right)\right) - q\left[\alpha \exp\left(-\gamma\left(y - p - p_B + \varphi_B^H\right)\right) + (1-\alpha)\exp\left(-\gamma\left(y - p - p_B + \varphi_B^L\right)\right)\right]$$

where $p = q(1-r)c_A$; $p_B = r c_A + (c_B - c_A) = \varphi_B^L - \varphi_A^L + r c_A$ and $c_B = \varphi_B^L - \varphi_A^L + c_A$.

At the socially optimal r, the welfare function is maximized, so that

$$\frac{\partial W}{\partial r} = \gamma q(1-q)c_A \exp\left(\gamma q(1-r)c_A\right)\left[A - \exp\left(\gamma r c_A\right)B\right] = 0$$

where $A = \exp\left(-\gamma\left(y + \varphi\right)\right)$; and

$$B = \exp\left(\gamma\left(\varphi_B^L + \varphi_A^L\right)\right)\left[\alpha \exp\left(-\gamma\left(y + \varphi_B^H\right)\right) + (1-\alpha)\exp\left(-\gamma\left(y + \varphi_B^L\right)\right)\right]$$

Solving the F.O.C. for r results in

$$r = -\frac{1}{\gamma} \frac{\gamma\left(y + \varphi + \left(\varphi_B^L - \varphi_A^L\right)\right) + \left(\ln\left(\alpha\left(\exp\left(-\gamma\left(y + \varphi_B^H\right)\right)\right) + (1-\alpha)\left(\exp\left(-\gamma\left(y + \varphi_B^L\right)\right)\right)\right)\right)}{c_A}$$

$$r = -\frac{y + \varphi + \left(\varphi_B^L - \varphi_A^L\right)}{c_A} - \frac{\ln C}{\gamma c_A}$$

where $C=\alpha\left(\exp\left(-\gamma\left(y+\varphi_B^H\right)\right)\right)+(1-\alpha)\left(\exp\left(-\gamma\left(y+\varphi_B^L\right)\right)\right)$

It is ambiguous here whether r is larger or smaller than 0 in the optimum.

If one defines a function F of γ and α such that

$$F(\gamma,\alpha)=-\frac{\ln C(\gamma,\alpha)}{\gamma c_A}$$

$$\text{then } F(\gamma,\alpha)=\begin{cases}\dfrac{y+\varphi_B^L}{c_A} \ \textit{if} \ \ \alpha=0\\[2ex] \dfrac{y+\varphi_B^H}{c_A} \ \textit{if} \ \ \alpha=1\end{cases}$$

Given that F is an increasing function of α, since $F_\alpha>0$, then for $0<\alpha<1$

$$F(\gamma,\alpha)=\frac{y+\overline{\varphi}_B}{c_A} \quad \text{where } \overline{\varphi}_B\in\left(\varphi_B^L,\varphi_B^H\right).$$

Then,

$$\lim_{\gamma\to\infty}-\frac{\ln C(\gamma,\alpha)}{\gamma c_A}=\frac{y+\overline{\varphi}_B}{c_A}$$

Since, $\varphi>\varphi_B^H>\overline{\varphi}_B>\varphi_B^L$

$$\lim_{\gamma\to\infty} r_{RP}=-\frac{y+\varphi+\left(\varphi_B^L-\varphi_A^L\right)}{c_A}+\frac{y+\overline{\varphi}_B}{c_A}<0$$

Then optimal r^*, again, under the assumption that $\gamma\to+\infty$, is

$$r_{RP}{}^*=-\frac{\varphi+\left(\varphi_B^L-\varphi_A^L\right)-\overline{\varphi}_B}{c_A}$$

The Case of AB

When L-types instead consume the parallel imports, social welfare would be

$$W=-(1-q)\exp\left(-\gamma\left(y-p+\varphi\right)\right)-q\left[\alpha\exp\left(-\gamma\left(y-p-p_B+\varphi_B^H\right)\right)+(1-\alpha)\exp\left(-\gamma\left(y-p-p_A+\varphi_A^L\right)\right)\right]$$

where $p = q(1-r)c_A$; $p_B = r c_A + (c_B - c_A) = \varphi_B^H - \varphi_A^H + r c_A$ and $c_B = \varphi_B^H - \varphi_A^H + c_A$; $p_A = r c_A$

At the socially optimal r, the welfare function is maximized so that

$$\frac{\partial W}{\partial r} = \gamma q(1-q)c_A \exp(\gamma q(1-r)c_A)[(A - \exp(\gamma r c_A)C)] = 0$$

where $A = \exp(-\gamma(y+\varphi))$; and $C = \alpha \exp(-\gamma(y+\varphi_A^H)) + (1-\alpha)\exp(-\gamma(y+\varphi_A^L))$

Solving the F.O.C. for r results in

$$r_{RP}^{*} = -\frac{(y+\varphi)}{c_A} - \frac{\ln C}{\gamma c_A}$$

Again, it is ambiguous whether r is larger or smaller than 0 in the optimum.

If one defines a function G of γ and α such that

$$G(\gamma,\alpha) = -\frac{\ln C(\gamma,\alpha)}{\gamma c_A}$$

$$\text{then } G(\gamma,\alpha) = \begin{cases} \dfrac{y+\varphi_A^L}{c_A} & \text{if } \alpha = 0 \\ \dfrac{y+\varphi_A^H}{c_A} & \text{if } \alpha = 1 \end{cases}$$

Given that G is an increasing function of α since $G_\alpha > 0$, for $0 < \alpha < 1$

$$G(\gamma,\alpha) = \frac{y+\overline{\varphi}_A}{c_A} \quad \text{where } \overline{\varphi}_A \in (\varphi_A^L, \varphi_A^H)$$

Then,

$$\lim_{\gamma\to\infty} -\frac{\ln C(\gamma,\alpha)}{\gamma c_A} = \frac{y+\overline{\varphi}_A}{c_A}$$

Since $\varphi > \varphi_A^H > \overline{\varphi}_A > \varphi_A^L$

$$\lim_{\gamma \to \infty} r_{RP} = -\frac{y+\varphi}{c_A} + \frac{y+\overline{\varphi}_A}{c_A} < 0$$

Then optimal r^*, again under the assumption that $\gamma \to +\infty$, is

$$r_{RP}{}^* = -\frac{\varphi - \overline{\varphi}_A}{c_A}$$

Appendix C. Changes in Welfare from a Change to Reference Pricing

The Case of BB

In the case of BB, total cost – which is the same for both types - is

$$\left[q(1-r_{CI})+r_{CI}\right]\left(\frac{\varphi_B^L - \varphi_A^L}{r_{CI}} + c_A\right) \text{ under coinsurance}$$

and

$$q(1-r_{RP})c_A + r_{RP}\,c_A + \left(\varphi_B^L - \varphi_A^L + c_A\right) - c_A \text{ under reference pricing.}$$

Both types will be better off under reference pricing if

$$\left[q(1-r_{CI})+r_{CI}\right]\left(\frac{\varphi_B^L - \varphi_A^L}{r_{CI}} + c_A\right) > q(1-r_{RP})c_A + r_{RP}\,c_A + \left(\varphi_B^L - \varphi_A^L + c_A\right) - c_A$$

$$\Rightarrow q\left(\frac{1}{r_{CI}} - 1\right)\left(\varphi_B^L - \varphi_A^L\right) + (1-q)r_{CI}\,c_A > (1-q)r_{RP}\,c_A$$

Since $(1-q)r_{RP}\,c_A$ is negative, the inequality will hold if $q < \frac{c_A}{\varphi_B^L - \varphi_A^L + c_A}$, so that $0 < r_{CI} < 1$

The Case of AB

In the case of AB, the total cost which H-types face is

$$q(1-r_{CI})\left(\alpha\frac{1}{r_{CI}}\left(\varphi_B^H-\varphi_A^H\right)+c_A\right)+r_{CI}\left(\frac{\varphi_B^H-\varphi_A^H}{r_{CI}}+c_A\right) \text{ under coinsurance}$$

and

$$q(1-r_{RP})c_A+r_{RP}\,c_A+\left(\varphi_B^H-\varphi_A^H+c_A\right)-c_A \quad \text{under reference pricing}$$

H-types will be better of under reference pricing if

$$q(1-r_{CI})\left(\alpha\frac{1}{r_{CI}}\left(\varphi_B^H-\varphi_A^H\right)+c_A\right)+r_{CI}\left(\frac{\varphi_B^H-\varphi_A^H}{r_{CI}}+c_A\right)>q(1-r_{RP})c_A+r_{RP}\,c_A+\left(\varphi_B^H-\varphi_A^H+c_A\right)-c_A$$

$$\Rightarrow\ q\alpha\left(\frac{1}{r_{CI}}-1\right)\left(\varphi_B^H-\varphi_A^H\right)+(1-q)r_{CI}\,c_A>(1-q)r_{RP}\,c_A$$

Since $(1-q)r_{RP}\,c_A$ is negative, the inequality will hold if $q<\dfrac{c_A}{\alpha\left(\varphi_B^L-\varphi_A^L\right)+c_A}$, so that

$0<r_{CI}<1$

On the other hand, total cost which L-types face is

$$q(1-r_{CI})\left(\alpha\frac{1}{r_{CI}}\left(\varphi_B^H-\varphi_A^H\right)+c_A\right)+r_{CI}\,c_A \quad \text{under coinsurance}$$

and

$$q(1-r_{RP})c_A+r_{RP}\,c_A \quad \text{under reference pricing}$$

L-types will be better of under reference pricing if

$$q(1-r_{CI})\left(\alpha\frac{1}{r_{CI}}\left(\varphi_B^H-\varphi_A^H\right)+c_A\right)+r_{CI}\,c_A>q(1-r_{RP})c_A+r_{RP}\,c_A$$

$$\Rightarrow\ q\alpha\left(\frac{1}{r_{CI}}-1\right)\left(\varphi_B^H-\varphi_A^H\right)+(1-q)r_{CI}\,c_A>(1-q)r_{RP}\,c_A$$

Again, since $(1-q)r_{RP}\,c_A$ is negative, the inequality will hold if $q<\frac{c_A}{\alpha\left(\varphi_B^L-\varphi_A^L\right)+c_A}$ such that $0<r_{CI}<1$.

On the other hand, the change in the welfare of healthy individuals depends on the premiums they pay under the two policies. In the case of BB, they pay

$q\,(1-r_{CI})\left(\frac{\varphi_B^L-\varphi_A^L}{r_{CI}}+c_A\right)$ under coinsurance

and

$q\,(1-r_{RP})c_A$ under reference pricing

Healthy people will be better off under reference pricing if they pay less premium than under coinsurance, that is, if

$$q\,(1-r_{CI})\left(\frac{\varphi_B^L-\varphi_A^L}{r_{CI}}+c_A\right)>q\,(1-r_{RP})c_A$$

Under the assumption that $r_{RP}^{*}=0$, this inequality implies that

$$\frac{1}{q\,(1-q)}>\frac{\varphi_B^L-\varphi_A^L}{c_A}+4$$

If the probability of getting sick is low, then individuals would pay a lower premium under reference pricing than under coinsurance.

In the case of AB, individuals instead pay

$q\,(1-r_{CI})\left(\alpha\frac{\varphi_B^H-\varphi_A^H}{r_{CI}}+c_A\right)$ under coinsurance

and

$q\,(1-r_{RP})c_A$ under reference pricing

Healthy people will be better off under reference pricing if they pay less premium than under coinsurance, that is, if

$$q\,(1-r_{CI})\left(\alpha\frac{\varphi_B^H-\varphi_A^H}{r_{CI}}+c_A\right)>q\,(1-r_{RP})c_A$$

Under the assumption that $r_{RP}^{*}=0$, this inequality implies that

$$\frac{1}{q\,(1-q)} > \alpha\frac{\varphi_B^L-\varphi_A^L}{c_A}+4$$

If the probability of getting sick is low, then individuals would again pay a lower premium under reference pricing than under coinsurance.

Appendix D. Comparison of Risk Based on Rothschild and Stiglitz's Definition of "Increasing Risk"

Table D1. The income equivalent for H- and L-types when sick or healthy under coinsurance or reference pricing

	Probability	**Income Equivalent**	
		Coinsurance	**Reference Pricing**
Healthy (both types)	$1-q$	$y-p_{CI}+\phi$	$y-p_{RP}+\phi$
H-types Sick	$q\alpha$	$y-p_{CI}-r_{CI}\,c_A+\varphi_A^H$	$y-p_{RP}-r_{RP}\,c_A+\varphi_A^H$
L-types Sick	$q(1-\alpha)$	$y-p_{CI}-r_{CI}\,c_A+\varphi_A^L$	$y-p_{RP}-r_{RP}\,c_A+\varphi_A^L$

Expected income under coinsurance is

$$Ey_{CI}=\underbrace{(1-q)\varphi+q\alpha\varphi_B^H+q(1-\alpha)\varphi_A^L}_{\text{expected health stock}}-\underbrace{q\alpha\left(\varphi_B^H-\varphi_A^H\right)-qc_A}_{\text{expected total cost}}-\underbrace{q\alpha\left(\frac{1-r_{CI}}{r_{CI}}\right)\left(\varphi_B^H-\varphi_A^H\right)}_{\Delta}$$

and under reference pricing

$$Ey_{RP}=\underbrace{(1-q)\varphi+q\alpha\varphi_B^H+q(1-\alpha)\varphi_A^L}_{\text{expected health stock}}-\underbrace{q\alpha\left(\varphi_B^H-\varphi_A^H\right)-qc_A}_{\text{expected total cost}}$$

Ey_{RP} is thus larger than Ey_{CI} by the amount Δ.

If we denote income equivalent under reference pricing by F_{RP}, that under coinsurance by F_{CI}. Let denote the other two discrete variables by $\tilde{\tilde{G}}$ and $\tilde{\tilde{\tilde{G}}}$ where $\tilde{\tilde{G}}$ is constructed by taking Δ from every single individual so that the mean of $\tilde{\tilde{G}}$ is the same as that of F_{CI}, and $\tilde{\tilde{\tilde{G}}}$ is introduced for technical reasons as F_{CI}, F_{RP} and $\tilde{\tilde{G}}$ attribute the same weight to all but six points. However, by definition "if two discrete random variables attribute the same weight to all but four points and if their differences satisfy some conditions we shall say that Y differs from X by a single mean preserving spread".

Table 2 - Discrete Distributions, income equivalent and probability

	Healthy	**Sick**	
		H-type	**L-type**
F_{RP}	I_o' $1-q$	I_H' $q\alpha$	I_L' $q(1-\alpha)$
$\tilde{\tilde{G}}$	$I_o'-\Delta$ $1-q$	$I_H'-\Delta$ $q\alpha$	$I_L'-\Delta$ $q(1-\alpha)$
$\tilde{\tilde{\tilde{G}}}$	$I_o \quad I_o'-\Delta$ $\delta \quad 1-q-\delta$	I_H $q\alpha$	$I_L'-\Delta$ $q(1-\alpha)$
F_{CI}	I_o $1-q$	I_H $q\alpha$	I_L $q(1-\alpha)$

* Expressions in the upper part of each cell of Table 2 represent income equivalent of utility in different states of being for different types, and terms in the lower part denote probability.

In Table D2 I_i where $i=o,H,L$ represents income equivalent of utility in different states of being, health and sick, for different types, H-types and L-types, explicit forms of which are given in Table D1.

Given that $r_{RP}=0$, it is straight forward that

(i) $I_o^{'}>I_H^{'}>I_L^{'}$

(ii) $I_o>I_H>I_L$

(iii) $I_o^{'}>I_o>I_o^{'}-\Delta>I_H^{'}>I_H^{'}-\Delta>I_H>I_L^{'}>I_L^{'}-\Delta>I_L$

First we compare the distribution F_{CI} and $\tilde{\tilde{G}}$. They attribute the same weight to all but four points that corresponds to I_L, $I_L^{'}-\Delta$, $I_o^{'}-\Delta$ and I_o. If we denote the difference in weight, the two distributions attached to each point by x_1, x_2, x_3 and x_4 respectively such that

$$x_1=\Pr\left(F_{CI}=I_L\right)-\Pr\left(\tilde{\tilde{G}}=I_L\right)$$

$$x_2=\Pr\left(F_{CI}=I_L^{'}-\Delta\right)-\Pr\left(\tilde{\tilde{G}}=I_L^{'}-\Delta\right)$$

$$x_3=\Pr\left(F_{CI}=I_o^{'}-\Delta\right)-\Pr\left(\tilde{\tilde{G}}=I_o^{'}-\Delta\right)$$

$$x_4=\Pr\left(F_{CI}=I_o\right)-\Pr\left(\tilde{\tilde{G}}=I_o\right)$$

Since , following Rotschild and Stiglitz (1970)

(i) $x_1=q(1-\alpha),\ x_2=-q(1-\alpha)$ such that $x_1=-x_2\geq 0$

(ii) $x_3=-1+q+\delta, x_4=1-q-\delta$ such that $x_4=-x_3\geq 0$

F_{CI} has more weight in the tail than $\tilde{\tilde{G}}$ does meaning that F_{CI} is riskier than $\tilde{\tilde{G}}$.

Then we compare the two distributions $\tilde{\tilde{G}}$ and $\tilde{G}$. They attribute the same weight to all but four points that corresponds to I_H, $I_H^{'}-\Delta$, $I_o^{'}-\Delta$ and I_o. If we denote the difference in weight, the two distributions attached to each point, by y_1, y_2, y_3 and y_4 respectively such that

$$y_1 = \Pr\left(\tilde{\tilde{G}} = I_H\right) - \Pr\left(\tilde{G} = I_H\right)$$

$$y_2 = \Pr\left(\tilde{\tilde{G}} = I_H{}' - \Delta\right) - \Pr\left(\tilde{G} = I_H{}' - \Delta\right)$$

$$y_3 = \Pr\left(\tilde{\tilde{G}} = I_o{}' - \Delta\right) - \Pr\left(\tilde{G} = I_o{}' - \Delta\right)$$

$$y_4 = \Pr\left(\tilde{\tilde{G}} = I_o\right) - \Pr\left(\tilde{G} = I_o\right)$$

Since , following Rotschild and Stiglitz (1970)

(i) $y_1 = q\alpha$, $x_2 = -q\alpha$ such that $x_1 = -x_2 \geq 0$

(ii) $y_3 = -\delta$, $x_4 = \delta$ such that $x_4 = -x_3 \geq 0$

$\tilde{\tilde{G}}$ has more weight in the tails than $\tilde{G}$ does meaning that $\tilde{\tilde{G}}$ is riskier than $\tilde{G}$. By transitivity, since F_{CI} is riskier than $\tilde{\tilde{G}}$ which is in turn riskier than $\tilde{G}$, then F_{CI} is riskier than $\tilde{G}$.

Paper III

Parallel Imports and Mandatory Substitution Reform

*A Kick or A Muff for Price Competition in Pharmaceuticals?**

David Granlund[1] and Miyase Yesim Köksal[2]

Abstract

What has been the effect of competition from parallel imports on prices of locally-sourced on-patent drugs? Did the 2002 Swedish mandatory substitution reform increase this competition? To answer these questions, we carried out difference-in-differences estimation on monthly data for a panel of all on-patent prescription drugs sold in Sweden during the 40 months from January 2001 through April 2004. On average, facing competition from parallel imports caused a 15-17% fall in price. While the reform increased the effect of competition from parallel imports, it was only by 0.9%. The reform, however, did increase the effect of therapeutic competition by 1.6%.

JEL Classification: I11, L51, L65.

Keywords: parallel imports; pharmaceutical drugs; price competition; reference pricing; therapeutic competition.

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[1]The Swedish Retail Institute (HUI), SE-103 29 Stockholm, Sweden; and Department of Economics, Umeå University, SE-901 87 Umeå, Sweden. E-mail: david.granlund@econ.umu.se
[2]Department of Economics, School of Business, Economics and Law, University of Gothenburg, SE-405 30 Gothenburg, Sweden. E-mail: Miyase.Yesim@economics.gu.se

Introduction

During the period 1998-2008, average annual real growth in pharmaceutical spending has exceeded that in overall health spending in the EU. Spending on pharmaceuticals averaged 4.7% growth per year, while overall health spending grew 4% (OECD, 2010). Pharmaceutical spending accounted for 1.7% of GDP on average across the EU countries in 2008.[1] The largest part of pharmaceutical spending, about 50%, is for on-patent locally-sourced drugs, i.e. drugs with patent protection that are directly supplied by the manufacturer via authorized wholesalers. Until the patent expires and generics enter the market – unless parallel trade is allowed – these drugs are only subject to competition from therapeutic alternatives. We here analyze the price-effects of competition for these drugs, focusing on competition from parallel imports and the effects of a mandatory substitution reform on the intensity of such competition.

Parallel imported drugs are legally produced goods bought in low price countries for resale in high price countries without the authorization of the patent holder. They have the same active ingredient in the same amount and the same dosage form (e.g., tablet or capsule) as the locally-sourced drugs. However, they might differ in packaging as, depending on the requirement of the importing country, they might be repackaged or relabeled, and the brand name might even differ slightly. Parallel trade of pharmaceuticals is legally allowed within the EU towards fulfilling the objective of creating a single market. But, in the United States, for example, allowing parallel trade of pharmaceuticals has for many years, since the Clinton administration, been a hot topic in debate on rising pharmaceutical costs. Advocates have claimed that allowing parallel imports from Canada, for example, would reduce the pharmaceutical costs substantially, while opponents have stated that the safety of parallel imported drugs cannot be guaranteed (Pecorino, 2002).

Medical insurance is likely to reduce the price competition in pharmaceuticals by making consumers' less price sensitive. To counteract this, substitution policies, giving the right to or obliging the pharmacists to substitute the prescribed drug with a cheaper alternative, have been introduced in many European countries and American states. These are intended to make

[1] The share of pharmaceutical spending in GDP ranged from below 1% in Luxembourg, Norway, and Denmark, to more than 2% in Lithuania, Greece, Bulgaria, Hungary, Portugal, and the Slovak Republic. The share in Sweden was 1.2%.

consumers react more to prices, decreasing cost both directly, as prescribed drugs are replaced with cheaper versions, and indirectly, through increased price competition. Sweden introduced a mandatory substitution reform in October 2002, requiring pharmacists to dispense, with the consent of the consumer, the cheapest available generic or parallel-imported drug, unless the prescribing physician opposed substitution for medical reasons. The reform brought in a special form of "reference pricing", whereby drugs with the same active substance – e.g., an off-patent drug and its generics, or an on-patent drug and its parallel imported versions – are grouped together and the price of the cheapest drug in each group is set as the reference price for reimbursement. Maximum reimbursement is fixed at a percentage of that price, but the amount consumers actually pay depends on which drug they buy. Consumers who choose a drug with the reference price pay only a certain "deductible", while consumers who choose a drug with a higher price still pay that deductible but, in addition, also pay the full price difference.

The 2002 reform changed the Swedish reference price system which had been introduced in January 1993. Before 2002, the reference price system only covered off-patent drugs and their generics with the reference price set at 110% of the price of the cheapest available substitute. The reform, however, required substitution not only between off-patent drugs and their generics but also between on-patent drugs and their parallel imported versions, and set the reference price at 100% of the price of the cheapest available substitute. The reform also made it mandatory for pharmacists – who otherwise have no incentive for substitution – to dispense the cheapest available substitute.[2] The new system thus both increased consumers' information about available alternative drugs and their prices and also exposed them more to the prices.

Such conditional reimbursement is expected to increase consumer price sensitivity and thus competition as well. This is consistent with both theoretical results (Mestre-Ferrandiz, 2003; Brekke et al., 2007, and Miraldo, 2009) and empirical results (Pavcnik, 2002; Aronsson, Bergman, and Rudholm, 2001; Bergman and Rudholm, 2003; Brekke et al., 2009; Granlund, 2010; Granlund and Rudholm, 2011) that reference pricing type policies promote substitution

[2] For example, the UK, Netherlands and Norway provide financial incentives for pharmacists to dispense parallel imported drugs (Kyle, 2009). However, other than an annual ex post payment by the county councils, responsible for reimbursement, to the Swedish pharmacy state monopoly (the National Corporation of Swedish Pharmacies, Apoteket AB) to compensate it for purchasing and dispensing parallel imports and generics, there are no explicit financial incentives to Swedish pharmacies to dispense parallel imports (Kanavos et al., 2005).

and increase price competition between brand-name drugs and their generics. Regarding substitution reforms in general, Buzzelli et al. (2006) estimated that they lowered pharmaceutical prices by 3% on average across 16 OECD countries. In country specific analyses, Granlund (2010) and Granlund and Rudholm (2011) estimated that the Swedish mandatory substitution reform reduced average unweighted prices by 4%, and average weighted prices by 10%.

Despite the attention that substitution reforms and reference pricing have received, there have been, to the best of our knowledge, no empirical studies on how they affect competition from parallel imports. This paper attempts to fill this gap. There is, however, a theoretical paper by Köksal (2009) showing that reference pricing should increase price competition from parallel imports. The theoretical literature regarding parallel trade also includes Pecorino (2002), Ganslandt and Maskus (2004), Maskus and Chen (2004), Jelovac and Bordoy (2005), and Chen and Maskus (2005), which show, among other things, that parallel imports should create price competition and cause prices to fall in the destination country. The empirical literature about the effects of competition from parallel imports is limited to Ganslandt and Maskus (2004), Kanavos and Costa-Font (2005), and Kyle (2011), none of which addressed reference pricing or substitution reforms in general.

Ganslandt and Maskus (2004) used Swedish data from 1994-1999 to study the effect of competition from parallel imports on the prices of the 50 molecules with largest sales values. Using instrumental variable method to account for potential endogeneity in the entry decisions of parallel traders, they found that competition from parallel imports reduced prices by 12-19%. Using OLS, they found that competition from three or more parallel traders was associated with 5% lower prices, while no statistically significant association was found between prices and competition from only one or two parallel traders. Using data on 30 countries, Kyle (2011) examined the effect of both potential and actual entry of parallel imports on prices of locally-sourced drugs, and reported results consistent with the OLS results of Ganslandt and Maskus (2004). On the other hand, Kanavos and Costa-Font (2005) estimated the effect of the market share of parallel imports on price competition and found no statistically significant effect.

The analyses in this paper were carried out using a product level panel dataset covering all on-patent prescription drugs sold in Sweden during January 2001 through April 2004. To identify

the effects of competition from parallel imports and how these effects were influenced by the mandatory substitution reform, following Pavcnik (2002) and Brekke et al. (2009), we used difference-in-differences estimation. Following Ganslandt and Maskus (2004), we also used instrumental variable estimation to address potential endogeneity in the entry decisions of parallel traders.

This study adds to the limited knowledge of competition from parallel imports by analyzing how the price effects of competition from parallel imports is affected by a mandatory substitution reform as well as how it depends on the length of time the parallel imports have been available in the market. The dataset also allowed us to control for competition from therapeutic alternatives – drugs with different active ingredients but similar therapeutic effects in treating a particular disease – including indirect generic competition from off-patent therapeutic alternatives themselves facing generic competition.

The present study thus complements Ganslandt and Maskus (2004) by controlling for both "therapeutic competition" (inter-brand competition) and "indirect generic competition" (intra-brand competition), as well as by analyzing a period when parallel trade had been legal in Sweden for many years (it became legal when Sweden joined the EU in 1995) and investigating a somewhat different segment of the market. We restricted our attention to on-patent drugs, but not just to big sellers. Like Ganslandt and Maskus (2004), we confined our analyses to the price-effects of facing competition from parallel imports; that is, for example, we did not analyze entry and exit decisions of parallel traders, or how those decisions might have been affected by the mandatory substitution reform.

We found that facing competition from parallel imports caused prices of locally-sourced drugs to fall on average with 15-17%. The mandatory substitution reform increased this effect causing prices to fall further, but only by one percentage point. The full effect of competition from parallel imports was not realized immediately, but instead prices kept decreasing over time.

Our analysis has implications for the effect of reform on therapeutic competition as well. We found that the prices of drugs facing therapeutic competition would have been 1.5% less on average than if they had not faced such competition. The mandatory substitution reform

increased the effect of therapeutic competition by 1.6 percentage points. The effect of therapeutic competition depended on whether the therapeutic alternatives were subject to generic competition. Facing therapeutic competition led to a statistically significant fall in prices if the therapeutic alternatives were themselves subject to generic competition. The mandatory substitution reform increased this fall, indicating that the reform increased the effects of generic competition.

The next section presents the institutional structure of the Swedish pharmaceutical market, focusing first on reimbursement for prescription drugs and the implications of mandatory substitution reform in this regard, and then on price setting and distribution of pharmaceuticals. The following two sections first provide a theoretical framework, and then an overview of the dataset including descriptive statistics. A section then explains the empirical strategy based on which the econometric analysis is carried out, followed by a section which reports and discusses the estimation results. Finally, the last section summarizes and concludes the paper.

The Institutional Structure of the Swedish Pharmaceutical Market

Reimbursement and Mandatory Substitution Reform

Statutory health insurance has covered the whole Swedish population and also subsidized a large part of pharmaceutical costs ever since pharmaceutical benefits scheme was introduced in 1955.[3] The subsidy for prescription drugs increases stepwise over any 12-month period. Since June 1999, consumers pay 100% of the cost up to SEK 900; 50% of the cost from SEK 900 to 1700; 25% from SEK 1700 to 3300; 10% from SEK 3300 to 4300; and then are fully subsidized during the remainder of the 12-month period. During the study period, about 70% of total pharmaceutical costs were borne publicly, specifically by the 21 county councils (Köping Höggård and Redman, 2007; National Board on Health and Welfare, 2006). The county councils – also responsible for providing health care – are required to have at least one "drug and therapeutic committee", the purpose of which is to promote safe and cost effective use of

[3] This section refers to law SFS (1981:49) on control of pharmaceutical costs and subsequent changes in this law, listed at www.notisum.se/rnp/sls/fakta/a9810049.htm, accessed 30 October 2008.

pharmaceuticals, e.g., by writing recommendations to physicians regarding choices of pharmaceuticals (Anell and Persson, 2005).

Reference pricing was introduced as reimbursement scheme in Sweden in 1993. Each off-patent drug and its generics were grouped together, with substitution allowed only within groups. A reference price was set for each group at 110% of the price of the cheapest available drug within the group, usually a generic. Costs exceeding the reference price were not included in the maximum annual copayment limit (RFFS 1992:20, 1996:31). Thus consumers who bought an expensive drug had to pay the entire difference between it and the reference price, in addition to a certain percentage (the coinsurance rate) of the reference price.

This reference price system was reformed with the introduction of mandatory substitution in October 2002. The rule for setting the reference price was changed so that it now was set at 100% of the price of the cheapest available drug within the group. Still drugs with the same active ingredient are grouped together, but since October 2002 on-patent drugs and their parallel imported versions are also part of the reference price system (SOU 2000:86, Medical Products Agency, 2002).[4,5] The reform made substitution compulsory within the group of interchangeable drugs, requiring pharmacists to inform consumers of such drugs and to dispense the cheapest available generic instead of the off-patent brand-name drug, or the parallel import instead of the on-patent brand-name drug (with the consent of the consumer) unless the prescribing physician prohibited the substitution for medical reasons.[6] The pharmacist must also inform consumers that they can buy the more expensive prescribed drug instead of the cheapest substitute if they pay

[4] Läkemedelsverket – The Medical Products Agency (MPA) – defines a product as a substitute if it has the same active substance, strength, and form (e.g., pills or fluid) as the prescribed product, and if its package size is approximately the same as that of the prescribed one.

[5] Parallel imported drugs are covered within the reference pricing system only in Sweden and Denmark (see Lopez-Casasnovas and Puig-Junoy (2000) for an extensive review on reference pricing).

[6] If the physician prohibits the substitution for medical reasons, the consumer is still reimbursed based on the full price of the more expensive prescribed drug. Physicians only prohibited substitution for 3% of the prescriptions during October 2002 to December 2003 (National Corporation of Swedish Pharmacies et al., 2004). The corresponding figure for January 2003 to October 2006 for physicians in the county of Västerbotten was 2%(Granlund, 2009). Andersson et al. (2005) reports that during the one-year period from October 2002 to October 2003 physicians in Västra Götaland region prohibited substitution in 1-8% of prescriptions for selected indicator drugs.

the difference. The reform clearly makes pharmacists substitute the available cheapest alternative within the reference price system where there had previously been no incentive for pharmacists to initiate substitution. Before the reform, Apoteket AB – the National Corporation of Swedish Pharmacies – recommended that pharmacists dispense parallel imported drugs only if the responsible drug and therapeutic committee had not recommended differently and if the prescribing physician had only written the name of the drug and thus had not specified either a locally-sourced package or a parallel import; and those committees only recommended dispensing parallel imports that had a record of reliable supply (Persson, Anell and Persson, 2001).

Three characteristics of the mandatory substitution reform may have contributed to making consumers more price sensitive, resulting in increased substitution and hence lower pharmaceutical prices. The reform lowered the transaction cost of substitution, since previously it had been recommended that physicians be contacted first if they had not explicitly consented to substitution on the prescription. Then, when substitution is offered (as it always should be after the reform), consumers gain information about the availability of cheaper substitutes, which might enhance their willingness to switch. Finally, only costs up to 100% of the cheapest substitutable product are now covered, compared with 110% previously.

Price Setting and Distribution

Pharmaceutical manufacturers and parallel traders need approval from Läkemedelsverket – the Medical Products Agency (MPA) – to sell their products in Sweden.[7] Manufacturers are free to set their own prices, but in order to be included in the pharmaceutical benefits scheme they must then be approved by Läkemedelsförmånsnämnden (LFN) – the Pharmaceutical Benefits Agency – which replaced the National Social Insurance Board as part of the mandatory substitution reform in 2002.[8] Before that, prices had been negotiated between the manufacturer and the

[7] The Medical Products Agency has as objective to send a first response to firms applying for approval for parallel import of pharmaceuticals within 120 days from when all necessary pharmaceutical information is received from the authorities in the source country (http://www.lakemedelsverket.se, accessed 101020).

[8] The name of the Pharmaceutical Benefits Agency (LFN) was changed to the Dental and Pharmaceutical Benefits

authority, but on the grounds of efficiency in the market the authority abolished negotiations and started to consider price setting as an integrated part of cost-effectiveness analysis.

Manufacturers can change price after the launch of a product in Sweden by getting approval from LFN.[9] During the study period, price comparisons played a crucial role in price-setting decisions. Both before and after the mandatory substitution reform, applications for price increases were required to include motivations for the price increase as well as information about the prices and treatment costs of comparable drugs (RFFS 1996:31, LFNFS 2003:1). An exception is if the requested price is the same as or less than the price of the most expensive substitutable product in the reference group: In this case no motivation is needed and the price increase is always accepted (LFNAR 2006:1). This is of little help for locally-sourced brand-name drugs, however, which are generally the most expensive in their reference group. In fact, price comparisons have probably made it harder for these drugs to get approval for price increases if they face competition. Even though a drug faces competition from parallel imports, the authority might still allow a price increase, since the supply of parallel imports is limited, and sometimes unreliable. If the drug would be removed from the market unless the price increase were approved and if supply of parallel imports was limited, patients would then face the risk of remaining untreated.

Unlike the regulations before the mandatory substitution reform (RFFS 1996:31), the regulations after the reform (LFNFS 2003:1) clearly state that the authority should consider marginal benefits and marginal costs of a drug when deciding whether or not to include it in the reimbursement scheme at the requested price. Hence competition between therapeutically equivalent drugs should be fiercer after the reform, not because of more price sensitive consumers – since the reform didn't allow substitution between therapeutic alternatives – but because of the requirement that marginal benefits and marginal costs should be considered to be included in the reimbursement system.

Agency (TLV) on September 1, 2008, since a dental care reform went into effect in July, 2008 and a new Dental Care Benefits Board was established.

[9] The National Social Insurance Board was allowed 90 days (or under some circumstances 180 days) to decide whether to approve price changes (RFFS 1996:31). The Pharmaceutical Benefits Board is required to decide whether to approve price cuts as soon as possible, but is allowed 90 days (or under some circumstances 150 days) to handle applications for price increase (SFS 2002:687).

During the first few months of the study-period, the National Social Insurance Board applied a specific rule for pricing parallel imports, approving an application only if the price was at least 10% below that of the locally-sourced drug. After the EU Commission ruled this discriminatory, the Board changed this rule in the spring of 2001. However, both before and after this change, a large majority of the prices of parallel imports were set about 10% below the price of the locally-sourced drug (National Social Insurance Board, 2002).

Retail pharmacies are the only legal entities in Sweden to dispense prescription drugs for outpatient care. Throughout the study period, all pharmacies were owned by the government monopoly, Apoteket AB – the National Corporation of Swedish Pharmacies – which paid and charged uniform prices nationwide for each drug. In July 2009, the pharmacy market was deregulated and private pharmacies were allowed to enter, but still the retail prices of prescription drugs remain uniform across the country.

Theoretical Framework

There are few studies examining the effects of parallel trade on prices in pharmaceuticals. Ganslandt and Maskus (2004) show the price-effect of parallel trade by setting up a model where each parallel trader supplies a limited quantity of drugs to the destination country and where the parallel imports are assumed to be sold at lower prices than locally-sourced drugs to guarantee that the entire quantity of parallel imports is sold, while price in the source country is held fixed. In this model, the residual demand that a locally-sourced drug faces, and hence its price, fall with the number of parallel traders.

Ganslandt and Maskus provide convincing reasons why parallel traders will not supply unlimited amounts, e.g., that the amounts they can buy in the low price countries are limited.[10] Still, they show that, if parallel traders could supply an unlimited amount without affecting the margin between the price they pay and the price they charge, then potential competition would result in price convergence up to the cost of trade. Similarly, Pecorino (2002) argues that there is no

[10] Supply of pharmaceuticals in source countries is limited, so the marginal cost of supply is likely to increase more, and to vary more, for parallel traders than for generic producers.

reason for the law of one price not to hold for pharmaceuticals if parallel trade is allowed and trade cost is zero. Jelovac and Bordoy (2005) analyze the case where consumers consider parallel imports inferior to locally-sourced drugs, e.g., due to differences in packing. Allowing parallel trade again leads to price convergence with lower prices in the destination country, though prices do not fully converge because of the perceived inferiority of the parallel imports.[11]

Different from the above mentioned studies, Frank and Salkever (1992) model competition from generics. Parallel imports differ from generics in terms of supply conditions and variation in marginal cost, but their model is general enough to derive effects of competition from parallel imports as well as effects of mandatory substitution on competition. The model includes one brand name producer, *n* identical generic producers, and two types of consumers: price-insensitive loyal consumers, whose demand is unaffected by the price of generics; and cross-price sensitive consumers, whose demand is influenced by both the brand-name and generic prices. Frank and Salkever show that the brand-name price would fall with entry of generic producers, unless entry leads to a fall in both demand for the brand-name drug and the own-price elasticity of its demand. So, unless a fall in demand also leads to less price-sensitive marginal consumers, entry of generics is likely to reduce brand-name price. Frank and Salkever also show that, under reasonable conditions, an increase in the share of price-sensitive consumers will enhance the downward pressure exerted by entry of generics on brand-name prices. This result should also apply for the effect of entry of parallel imports on prices of locally-sourced drugs. Hence, as mandatory substitution is likely to make consumers more price sensitive, it is likely to enhance the downward pressure exerted on brand-name prices by competition from both generics and parallel imports.

Demand models, like that of Frank and Salkever (1992), have implications for therapeutic competition as well. If demand is sensitive to relative prices among therapeutic alternatives, the price of a drug whose therapeutic alternatives gain generic competition would also fall. Given that price is a positive function of demand, this would happen: (i) if the price of the brand-name drug facing generic competition falls and brand name therapeutic alternatives are substitutes; (ii) if the generics are substitutes for therapeutically equivalent brand-name drugs. Also, entry of

[11] Maskus and Chen (2004) and Chen and Maskus (2005) provide theoretical analyses of parallel trade in general, not focusing just on pharmaceuticals.

therapeutic alternatives should reduce the price of a drug if it reduces demand for that drug (and again, if price is a positive function of demand). Mandatory substitution reform, by making consumers more price sensitive, has increased price competition in Sweden and reduced the prices of both generics and brand-name drugs facing generic competition (Granlund and Rudholm, 2011). Therefore, given that demand is sensitive to relative prices among therapeutic alternatives, we expect the effect of therapeutic alternatives gaining generic competition to be larger after the substitution reform.

Köksal (2009) also strengthens our expectation that mandatory substitution increases competition from parallel imports. Based on the two-country model of Jelovac and Bordoy (2005), where consumers perceived parallel imports as inferior, she examined theoretically the extent to which healthcare reimbursement policies should affect the results of parallel trade. It is assumed that a monopoly manufacturer produces a patented drug and supplies the two countries. The manufacturer price differentiates since the two countries are assumed to differ in their consumers' valuations of the drug, as well as in the share of the price paid directly by the consumers. Given the price difference between the two countries, parallel traders – in a perfectly competitive market with no cost of trade – buy the drug in low price country and resell it in the high price country. Parallel trade then causes greater price reduction under reference pricing than under simple coinsurance at a constant rate regardless of the price of the drug chosen. As the 2002 reform aimed to strengthen the effect of reference pricing by making substitution mandatory for the pharmacist and increasing out-of-pocket costs for the consumer, we expect it to have increased the competition from parallel imports.

Overview of the Data

The study is based on a panel-data set covering all prescription drugs sold in Sweden during 1992-2007. An observation in the dataset represents a product with a certain active ingredient, strength, form, and package size, supplied by a certain firm and sold in a certain month (though only quarterly data for 1992-1994). For each observation the dataset includes information about whether the product is brand-name or generic, locally-sourced or parallel imported, as well as

total units sold and the total value. In order to efficiently isolate the effect of the 2002 mandatory substitution reform on competition from parallel imports, only data from January 2001 through April 2004 was used. Using older data, due to adjustments to the existence of parallel imports, might have distorted the estimations. Parallel imports were allowed starting in 1995 when Sweden joined the European Union, but their extent was very limited the first two years, and Ganslandt and Maskus (2004) expressed the belief that the market was not in long-run equilibrium even at the end of their study period, in 1998.[12] Data after April 2004 was not used since 10 countries – new potential source countries for parallel imports – joined the EU in May 2004, possibly distorting the results.

Table 1. The Swedish prescription pharmaceutical market, 1997-2007

	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
GDP	1927001	2012091	2123971	2249987	2326176	2420761	2515150	2624964	2735218	2900790	3063145
TPS	13984	16270	18148	19934	21301	22872	23301	23807	24819	25943	23067
PI	272	1008	1402	1754	2012	2090	2100	2527	3018	3012	2707
PI/TPS	2%	6%	7,7%	8,8%	9,4%	9,1%	9%	10,6%	12,1%	11,6%	11,7%
# PI Firms	2	8	10	9	9	10	11	11	9	12	14

Notes: GDP, TPS and PI are in million SEK and expressed in nominal terms. TPS and PI are abbreviations for total pharmaceutical sales and total sales value of parallel imports respectively. PI/TPS represents the share of parallel imports in total pharmaceutical sales.
Source: Intercontinental Medical Statistics (IMS)

Prescription pharmaceutical sales constituted about 0.9% of GDP during 2001-2004 (Table 1). Both the share of parallel imports in total pharmaceutical sales (PI/TPS) and the number of parallel traders increased substantially in 1998, due to the integration of Sweden in the EU (Ganslandt and Maskus, 2004). While the share of parallel imports was 2% in 1997, it was 6% in 1998 and the number of parallel traders increased from 2 in 1997 to 8 in 1998. There was no

[12] It is possible that pharmacists and consumers changed their attitudes as they learned more about parallel imports during the first few years they were in the market. This might have changed the effect of competition from parallel imports in the years prior to our study period.

similar change in the share of parallel imports or in the number of parallel traders during 2001-2004.

The empirical analysis focuses only on locally-sourced on-patent prescription drugs. Off-patent and parallel imported drugs were used to create the relevant variables for the analysis but were excluded in the final dataset. No information on the dates of patent expiration was available. Instead, we defined pharmaceuticals as off-patent starting the first time any generic with the same active ingredient was sold in Sweden.

Table 2. Descriptive statistics for variables used in estimations

Variable	Mean	Std. Dev.	Min	Max
ln*p*	5.7571	1.5356	1.9201	11.7574
Picomp	0.1309	0.3373	0	1
Pifirms	0.3257	1.0297	0	9
Mpi	4.0016	11.6196	0	79
Thcomp	0.8437	0.3631	0	1
Nthcomp	3.1403	2.4750	0	12
Thgencomp	0.2071	0.3404	0	1
Ref	0.4666	0.4988	0	1
*Ref*Picomp*	0.0662	0.2487	0	1
*Ref*Pifirms*	0.1541	0.6863	0	8
*Ref*Mpi*	2.3156	9.6610	0	79
*Ref*Thcomp*	0.3847	0.4888	0	1
Ref Nthcomp*	1.4818	2.3239	0	12
*Ref*Thgencomp*	0.1040	0.2609	0	1
Time	20.2653	11.5346	1	40
Timepi	2.7899	8.3111	0	40
EURO/SEK	9.1794	0.1485	8.8963	9.6670
Lnlong	4.1716	0.7975	-0.6931	4.6868

Table 2 presents the variables used in the econometric analysis and the descriptive statistics on the data. The variable $\ln p_{it}$ is the natural logarithm of the real price (wholesale price in month t deflated by consumer price index). $Picomp_{it}$ is an indicator for whether drug i is subject to competition from parallel imports (hereafter PI-competition) and $Pifirms_{it}$ is the number of

parallel traders drug i faces competition from.[13] Mpi_{it} is defined as the number of months drug i had faced competition from parallel imports before month t. $Thcomp_{it}$ is a dummy controlling for whether a drug has any therapeutic competitors, $Nthcomp_{it}$ is the number of therapeutic competitors and $Thgencomp_{it}$ is the share of product i's therapeutic competitors facing generic competition.[14] Ref_t is a dummy variable taking the value one for the months after the mandatory substitution reform and the following six variables are interaction variables between Ref_t and the variables mentioned above. $Time_t$ is the number of the month, starting from January 2001, and $Timepi_{it}$ is an interaction variable between this variable and $Picomp_{it}$. The last two variables are instruments used in instrumental variable regressions: the Euro/SEK exchange rate and the logarithm of the number of months the product has been sold in Sweden ($Lnlong_{it}$).[15]

Of the 3,339 on-patent prescription drugs with different active ingredient, strength, and form (102,235 observations) 84% faced therapeutic competition while only 13% faced competition from parallel imports (Table 2). Descriptive statistics, not presented in the table, show that for drugs that face competition from parallel imports, the average market share in units for parallel imports is 39%.

Econometric Analysis

A difference-in-differences strategy was used to identify the effects of competition from parallel imports (hereafter PI-competition) on prices of locally-sourced drugs and how these effects were influenced by the 2002 mandatory substitution reform. The effects of facing PI-competition were identified by comparing changes in prices of drugs that gained or lost PI-competition with those of drugs that did not face changes in PI-competition. The effect of the reform was identified by comparing the price-effects of changes in PI-competition before the reform with those after, as

[13] A parallel imported drug is considered to be a pi-competitor to the locally sourced drug if it has the same substance (i.e., 7-digit ATC code), strength, and form (e.g. pill or fluid) as that drug and are sold in Sweden the same month. Since, for example, a 100-pill package can substitute for two 50-pill packages, it is not required that the parallel import be of the same package size as the locally-sourced drug.

[14] Following Brekke et al. (2008) and Pavcnik (2002) pharmaceuticals with the same 5-digit ATC code were classified as therapeutic competitors.

[15] In order to be able to take the natural logarithm we defined $long_{it}$ equal to 0.5 the first month a product was sold, and so on. $Lnlong_{it}$ is the natural logarithm of a variable truncated at 108.5 months due to lack of older data.

well as by comparing differences in prices before and after the reform for drugs that always faced PI-competition with those for drugs that never faced PI-competition.

In a difference-in-differences setting one or several parameters capture fixed differences among the drugs, while one or several other parameters capture changes over time that are common to all drugs. We included drug specific fixed effects, α_i, to control for fixed differences among individual drugs. For example, the fixed effects control for differences in severity of side effects and other aspects of the drugs themselves that might affect their price. The fixed effects also control for most of the variation in demand across observations, in fact for 87% of the variation in units sold. To control for changes over time that are common to all drugs we included a linear time-trend; a dummy variable taking the value one after the mandatory substitution reform; and dummy variables for calendar months.[16] We also included variables to control for price changes as a result of being subject to competition from parallel imports; number of parallel trading firms importing the drug; number of months a drug had faced such competition; being subject to competition from therapeutic alternatives; number of therapeutic alternatives; and share of therapeutic alternatives facing generic competition. Then the main specifications are

$$\begin{aligned}\ln p_{it} = {} & \beta_1 Picomp_{it} + \beta_2 Pifirms_{it} + \beta_3 Mpi_{it} + \beta_4 Timepi_{it} + \beta_5 Ref * Picomp_{it} + \beta_6 Ref * Pifirms_{it} \\ & + \beta_7 Ref * Mpi_{it} + \beta_8 Thcomp_{it} + \beta_9 Nthcomp_{it} + \beta_{10} Thgencomp_{it} + \beta_{11} Ref * Thcomp_{it} \\ & + \beta_{12} Ref * Nthcomp_{it} + \beta_{13} Ref * Thgencomp_{it} + \beta_{14} Time_t + \beta_{15} Ref_t \\ & + \sum_{m=2}^{12} \gamma_m Month_t + \alpha_i + \varepsilon_{it}\end{aligned} \tag{1}$$

$$\begin{aligned}\ln p_{it} = {} & \beta_1 Picomp_{it} + \beta_3 Mpi_{it} + \beta_4 Timepi_{it} + \beta_5 Ref * Picomp_{it} + \beta_7 Ref * Mpi_{it} + \beta_8 Thcomp_{it} \\ & + \beta_9 Nthcomp_{it} + \beta_{10} Thgencomp_{it} + \beta_{11} Ref * Thcomp_{it} + \beta_{12} Ref * Nthcomp_{it} \\ & + \beta_{13} Ref * Thgencomp_{it} + \beta_{14} Time_t + \beta_{15} Ref_t + \sum_{m=2}^{12} \gamma_m Month_t + \alpha_i + \varepsilon_{it}.\end{aligned} \tag{2}$$

The difference between specifications (1) and (2) is that $Pifirms_{it}$ and $Ref*Pifirms_{it}$ are not included in (2), to facilitate the use of an instrumental variable method. If these two variables

[16] As discussed in the Appendix, similar results were obtained using year-month dummies to control for common price changes. Year-month dummies were not included in the main specifications, however, in order to use time-variation in the instruments for identification.

were in the estimation, there would be too many endogenous variables to instrument. Specification (1) was estimated with fixed-effects OLS estimator, while specification (2) was estimated with fixed-effects OLS and a fixed-effects IV estimator, resulting in three estimations. To check the robustness of the results and to verify what the estimates describe, we also estimated many other specifications, described briefly in the Appendix and in footnotes where we also discuss their results.

The parameters β_1-β_4 describe the effects of competition from parallel imports before the mandatory substitution reform and, together with β_5-β_7, the effects after the reform. β_1 and β_4 describe the effect of facing PI-competition at all and how this effect changed over time. β_2 describes how the effect relates to the number of parallel trading firms importing the drug, and β_3 shows the effect of the number of months a drug had already faced competition from parallel imports.[17] The identifying assumption for these parameters is that no other variables, except those included in the specification, caused price changes that are correlated with facing competition from parallel imports. Since therapeutic competition can have important effects on prices and might be correlated with PI-competition, we included $Thcomp_{it}$, $Nthcomp_{it}$ and $Thgencomp_{it}$ in the specifications as well.[18,19]

The parameters β_5-β_7 for the interaction variables describe how the reform has influenced the price effect of competition from parallel imports. A requirement for these parameters to be correctly estimated is that no excluded variable influenced the price effect of facing PI-competition differently before the reform relative to after the reform. This requirement is one important motive for including Mpi_{it} and $Ref{*}Mpi_{it}$ in the specifications. There are several reasons why Mpi_{it} – which is correlated with the reform – could influence prices.[20] First, before the reform, the pharmaceutical committees recommended pharmacists dispense only parallel

[17] Separate effects of Mpi_{it} and $Timepi_{it}$ were identified by data on drugs changing from facing pi-competition to not facing it, or vice versa, at different times during the study period. For drugs that faced pi-competition none or all months of the study-period, Mpi_{it} and $Timepi_{it}$ are perfectly correlated.

[18] The share of drugs facing therapeutic competition is statistically significantly higher among the drugs facing competition from parallel imports than those not facing such competition at all, but the difference is small in size: only 5 percentage points.

[19] Ellison et al. (1997), Brekke et al. (2009), and Lichtenberg and Philipson (2002) provide evidence on therapeutic competition.

[20] The mean of Mpi_{it} is statistically significantly larger after the reform than before, and for drugs facing pi-competition this difference is large: 7.74 (std. err. 0.30).

imports that had a record of reliable supply (Persson, Anell and Persson, 2001). Second, the longer a parallel imported drug had been in the market, the more familiar consumers, physicians, and pharmacists would be with it, making it a stronger competitor for the locally-sourced drug.[21] Third, if a parallel import had been sold in Sweden for a long time, without any supply shortages, or even interruptions due to possible strategic response of manufacturers like supply rationing in the source countries, then the price approving authority might consider the parallel import a reliable alternative for the locally-sourced drug and therefore dare to be tougher in its decisions regarding approval of price increases for the locally-sourced drug.

The identifying requirement for the parameters β_5-β_7 was also the main reason why we included $Timepi_{it}$ in the specifications, to capture changes over time in the effect of facing PI-competition not caused by the substitution reform but perhaps by changed consumer attitudes toward parallel imports.[22] Lastly, interaction variables between the reform and controls for therapeutic competition were included since, as discussed before, there are reasons to expect that the effects of facing therapeutic competition were increased by the reform.

An obvious problem is that entry decisions of parallel traders are determined by the prices of pharmaceuticals. In other words, the variables controlling for PI-competition might be endogenous, and hence the OLS estimator might be biased. This problem is reduced by inclusion of fixed effects, since parallel traders then must react to price changes within the study-period for the OLS estimator to be endogenous. Still, we cannot rule out the possibility of endogeneity, and therefore also conducted an instrumental variable estimation.[23]

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[21] Using data on on-patent prescription drugs sold in the county of Västerbotten, Sweden, during 2003-2006 (see Granlund and Rudholm (2008) for details of the dataset), we found that patients were statistically significantly less likely to oppose substitution by a parallel import the larger Mpi_{it} was. Controlling for Mpi_{it}, however, the patients became more likely to oppose substitution over time. Since Mpi_{it} is correlated with sales volume of the parallel import, we estimated the fixed-effects IV specification including the market share of parallel imports, but got similar results regarding Mpi_{it}, suggesting that this is not the explanation to its effect.

[22] $Timepi_{it}$ accounts for the differences in the time trend of drugs subject to pi-competition and drugs not subject to it. Before the reform, the time trend of drugs subject to pi-competition was different from that of drugs not subject to it. Even though the time trend differs between the two groups, the difference in time trend is stable over time, implying that the difference could be captured by $Timepi_{it}$.

[23] The therapeutic competition variables might be endogenous to some degree as well, since high prices for a drug can make competing pharmaceutical firms more likely to invest in R&D for therapeutic alternatives. Moreover, firms could choose not to launch their products in Sweden if the prices of therapeutic alternatives in Sweden are low. The first source of endogeneity is likely to be small, since firms make their investment decision based on expectation of future prices around the world without having perfect foresight, and since the Swedish market, for

The five possible endogenous variables, $Picomp_{it}$, Mpi_{it}, $Ref*Picomp_{it}$, $Ref*Mpi_{it}$, and $Timepi_{it}$, are all functions of *Picomp* and highly correlated; with correlations among the five ranging from 0.54 to 0.91. To overcome the difficulties this creates for finding strong instruments, we employed a three-stage instrumental variable estimation. In the first stage, OLS estimation was employed to explain and predict *Picomp*, using the exogenous variables of specification (2), including fixed effects, and a set of instruments (explained below). Drugs with no variation in *Picomp* during the study period were not included in this regression since the instruments have no predictive power for *Picomp* for them, and since the inclusion of fixed effects means that there is no endogeneity problem for them either. Instead, true values were used as predictions for *Picomp* for these drugs. Then, the predictions for *Picomp* were used to create predictions for Mpi_{it}, $Timepi_{it}$, $Ref*Picomp_{it}$, and $Ref*Mpi_{it}$.[24] Lastly, the predictions for all five possible endogenous variables are used as instruments for their actual values in a 2SLS estimation, using the xtivreg2 command by Schaffer (2010).

This method has two advantages over a standard two-stage IV-method where all endogenous variables are instrumented directly, using the same set of instruments. First, this method will predict similar drugs to face PI-competition both before and after the reform, which means that the estimated effect of the reform on PI-competition will not be affected by changes in the drugs facing PI-competition. Second, and more importantly, it yields robust estimates for the possible endogenous variables. When predicting all endogenous variables directly, the instrument sets were found to be weak for at least one of the possible endogenous variables, resulting in unreliable estimates which were not robust even to small changes in the instrument sets.

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most drugs, constitutes a relatively small share of the entire market (Pharmaceutical consumption in Sweden constituted 0.7% of the total pharmaceutical consumption in the OECD in 2005, OECD, 2008). The second source of endogeneity is likely to be small as well since the prices of pharmaceuticals in Sweden are about the average of the large markets in the European Union (Lundkvist, 2002).

[24] The first stage regression also used only data from the period January 2001 through April 2004. Thus, only variations in Mpi_{it} within this period could be predicted for each product. With fixed effects, subtracting a product specific constant from Mpi_{it} did not affect the estimates for this variable. However, this prevented us from including Mpi_{it} nonlinearly, e.g., Mpi^2_{it}. OLS results including Mpi^2_{it} were, however, very similar to those excluding it, suggesting that it is not important to include it. OLS estimation using dummy variables for each value of Mpi_{it} also indicated that the effect of Mpi_{it} was nearly linear up to values of 50 months, but no additional effect was found for even higher values. Only 1.5% of the observations in the dataset had values of *Mpi* exceeding 50. These results are available from the authors upon request.

Several sets of instruments were tested, nearly all inspired by Ganslandt and Maskus (2004). We report the full results obtained when using the Euro/SEK exchange rate as instrument but also the key results obtained when using the logarithm of the number of months the product had been sold in Sweden ($Lnlong_{it}$), as well as key results obtained when using both the exchange rate and $Lnlong_{it}$ as instruments. The Euro/SEK exchange rate is the instrument thought most likely to be exogenous, though $Lnlong_{it}$ should also be exogenous since we controlled for therapeutic competition. Other instrument sets tested include interaction between *Euro/SEK* and sales values in 1995 and transformations of *Lnlong*.[25]

During the study period, important source countries such as Italy, Greece, and Spain switched to the Euro as currency or fixed their exchange rate towards the Euro. The Euro/SEK exchange rate therefore affected price differences between locally-sourced drugs in Sweden and the source countries, an important determinant for parallel traders' entry decisions. $Lnlong_{it}$ could also be a good instrument since the probability that a drug is also sold in low price countries increased with the number of months it had been sold in Sweden, and since it might take a few months after it was first sold in both Sweden and a source country before parallel traders could establish relevant contacts and get the approval from the Medical Products Agency. We used the natural logarithm since the effect of the number of months on entry of parallel traders was thought likely to decrease. Also, an untransformed variable representing the number of months from first sale would be perfectly correlated with $Time_{it}$ and therefore unusable as an instrument.

Results

The three main sets of full estimation results are presented in Table 3, while Table 4 presents the key results from regressions with other instruments. All reported coefficients and standard errors in the tables and elsewhere are the estimates multiplied by 100. In the Appendix we report the results of the robustness analyses, showing that the results are quite insensitive to changes in the specifications.

[25] As mentioned above, $Lnlong_{it}$ is the natural logarithm of a variable truncated at 108.5 months due to lack of older data. Including a dummy variable for those with a value of 108.5 or higher did not contribute to explaining $Picomp_{it}$, however, so it was not included as an instrument.

Differentials are also presented at the bottom of the Table 3 and in Table 4 describing the average effect of the variables of main interest on prices. The differential d*lnP*/d*Picomp* was calculated using the estimates for the seven pi-variables as well as the average value of these variables when *Picomp* equals one. For the IV estimation (Table 3), the differential indicates that drugs facing PI-competition had 15% lower prices on average compared to what they would have had if they had never faced PI-competition.[26] Similar results were obtained from estimations 4 and 5 (Table 4) and for other, not reported, IV estimations with different instruments. For the OLS estimations, the corresponding figures are less than 4%, indicating that endogeneity bias is considerable.

Pifirms and *Ref*Pifirms* both had positive coefficients in estimation 1, possibly caused by endogeneity, but perhaps because manufacturing firms might have increased prices to extract as much as possible from price-insensitive loyal consumers if competition from parallel imports became too fierce.[27] The coefficients for *Mpi* in all estimations indicate that the full effect of facing PI-competition was not felt immediately.[28] Compared to the estimates from the OLS regression (estimation 2 in table 3), that for *Mpi* from the IV regression is lower (i.e., more negative), but that for *Timepi* is approximately as much higher. These differences might not be caused by endogeneity, but perhaps by correlation between these variables, as high as 0.8, which means that the differences between the coefficients are estimated imprecisely (Greene 2003: Chapter 4). However, the joint effect of these variables is not affected by this high correlation.

The differential dln*P*/d (*Ref*Picomp)* indicates that mandatory substitution had increased the effect of PI-competition, but by less than one percentage point. For the OLS regressions the result is driven by the effect of *Ref*Picomp*, but for the IV regression it is mainly explained by the negative estimate for *Ref*Mpi*.

[26] Since the dependent variable is in logarithmic form, the exact change in price (in percent) should be calculated using the formula $100*[\exp(\beta)-1]$.

[27] Frank and Salkever (1992) discuss the similar so called "generic paradox" that brand name producers might react to generic competition by increasing their prices. Frank and Salkever (1997) and Grabowski and Vernon (1992) provide evidence that brand-name prices increase after entry of generics.

[28] For observations with *Picomp* equal to one, the average values for *Mpi* and *Ref*Mpi* are 27.26 and 15.49, respectively. The Mpi-variables thus account for more than 75% of the estimates for d*lnP*/d*Picomp* in all three estimations.

Table 3. Estimation results, multiplied by 100

	(1) OLS	(2) OLS	(3) IV
$Picomp_{it}$	0.041	0.323**	-11.076***
	(0.187)	(0.150)	(1.595)
$Pifirms_{it}$	0.197***		
	(0.072)		
Mpi_{it}	-0.145***	-0.135***	-0.444***
	(0.011)	(0.011)	(0.054)
$Timepi_{it}$	0.002	-0.004	0.360***
	(0.012)	(0.011)	(0.059)
$Ref*Picomp_{it}$	-1.247***	-1.043***	-0.028
	(0.314)	(0.252)	(0.410)
$Ref*Pifirms_{it}$	0.051		
	(0.082)		
$Ref*Mpi_{it}$	0.013**	0.010	-0.027**
	(0.005)	(0.006)	(0.011)
$Thcomp_{it}$	-0.395	-0.404	-0. 316
	(0.340)	(0.340)	(0.343)
$Nthcomp_{it}$	0.121**	0.126**	0.106**
	(0.050)	(0.050)	(0.051)
$Thgencomp_{it}$	-3.142***	-3.167***	-3.012***
	(0.360)	(0.360)	(0.365)
$Ref*Thcomp_{it}$	-0.826***	-0.819***	-0.726***
	(0.209)	(0.207)	(0.210)
$Ref*Nthcomp_{it}$	-0.185***	-0.185***	-0.189***
	(0.027)	(0.027)	(0.027)
$Ref*Thgencomp_{it}$	-0.521***	-0.542***	-0.649***
	(0.162)	(0.161)	(0.164)
Ref_t	1.146***	1.147***	1.155***
	(0.158)	(0.158)	(0.160)
$Time_t$	-0.037***	-0.037***	-0.038***
	(0.005)	(0.005)	(0.005)
d ln*P*/d *Picomp*	-3.776***	-3.848***	-16.066***
	(0.221)	(0.213)	(1.765)
d ln*P*/d (*Ref*Picomp)*	-0.733***	-0.735***	-0.867***
	(0.182)	(0.185)	(0.207)
d ln*P*/d *Thcomp*	-1.494***	-1.490***	-1.413***
	(0.357)	(0.357)	(0.361)
d ln*P*/d (*Ref*Thcomp)*	-1.659***	-1.659***	-1.606***
	(0.154)	(0.153)	(0.155)
Sample size	102,187	102,187	102,187
Log likelihood	148,563.8	148,558.8	147,868.2

Notes: The asterisks ***, ** and * denote that the coefficient is significantly different from zero at the 1%, 5%, and 10% levels. Standard errors that are robust against heteroskedasticity and autocorrelation are shown in parentheses. For the IV-specifications, F value for significance of the instrument (the Euro/SEK exchange rate) in the first stage regression was 17.70. The differentials were evaluated at the mean of each variable when the relevant explanatory variable, i.e., *Picomp*, *Ref*Picomp, Thcomp*, *or Ref*Thcomp*, took the value one. Estimation results for calendar months are suppressed to save space, but are available from the author upon request.

Table 4. Estimation results from IV regressions with instruments *Lnlong*, and both *EURO/SEK* and *Lnlong*, multiplied by 100

	(4) IV	(5) IV
d ln*P*/d *Picomp*	-18.720***	-17.461***
	(1.984)	(1.871)
d ln*P*/d (*Ref*Picomp)*	-0.855***	-0.861***
	(0.209)	(0.208)
Sample size	102,187	102,187
Log likelihood	147,567.9	147,728.2

Notes: For estimation 4, the F value for significance of the instrument (*Lnlong*) in the first stage regression was 108.32. For estimation 5, the F value for significance of the instruments (the Euro/SEK exchange rate and *Lnlong*) in the first stage regression was 65.26. See also notes to Table 3.

The estimates for the therapeutic competition variables, *Thcomp*, *Nthcomp*, and *Thgencomp*, indicate that, before the reform, the effect of facing such competition was small if the therapeutic alternatives did not face generic competition, but the effect increased substantially if they gained generic competition. The reform increased the importance of whether therapeutic competitors face generic competition, reflecting that the reform led to lower generic prices and lower prices of brand-name drugs facing generic competition. The reform also substantially increased the effect of *Thcomp*, probably because the Pharmaceutical Benefits Agency (LFN), unlike its predecessor prior to the reform, had a clear instruction to consider marginal benefits and costs of a drug before deciding whether or not to approve its suggested price and list it for reimbursement. The average effect of facing therapeutic competition during the study-period was a price reduction of 1.5% and the reform increased the effect of therapeutic competition by 1.6 percentage points. This means that the reform more than tripled this effect from 0.7% to 2.3%. Our results on therapeutic competition are consistent with Brekke et al. (2009) and Ellison et al. (1997) showing that drugs with the same active ingredient – generics in their case – are closer substitutes than drugs with different active ingredients but similar therapeutic effects.

Lastly, the estimates for $Time_t$ show that the prices of drugs not facing PI-competition fell over time. The estimates for Ref_t indicate that the prices of drugs not subject to pi- or therapeutic competition were positively associated with the reform, but this coefficient might capture something besides causal effects of the reform.

Conclusions

We analyzed the effects of competition from parallel imports on prices of all locally-sourced on-patent prescription drugs sold in Sweden during January 2001-April 2004 and whether 2002 mandatory substitution reform affected this competition.

Using an instrumental variable method, we found that drugs facing competition from parallel imports had 15-17% lower prices on average compared to what they would have had if they had never faced such competition. The corresponding estimate from OLS regressions was only 4%. The results are of similar magnitude to those of Ganslandt and Maskus (2004) despite that we controlled for therapeutic competition and indirect generic competition, covered all the on-patent prescription drugs, and analyzed a different period. Thus, our results confirm their conclusion that parallel imports substantially reduce prices of locally-sourced drugs.

The large difference between the IV and the OLS results indicates that it is important to account for endogeneity caused by simultaneous determination of prices and entry decisions of parallel traders. The OLS result describes the association between prices and competition from parallel imports which was affected both by high prices encouraging entry of parallel traders, causing more positive (or less negative) association, and by the causal effect of competition from parallel imports itself. Therefore, OLS result gives only a lower bound on the absolute causal effect of competition from parallel imports.

The mandatory substitution reform increased the effect of competition from parallel imports, but by less than one percentage point in absolute value. Thus, the effect of competition from parallel imports was large also when substitution was not mandatory. One reason could be that many pharmacies already before the mandatory substitution reform dispensed parallel imports to consumers whose physicians had not specified either a locally-sourced or parallel imported package. The full effect of parallel imports was not realized immediately, but rather the prices of locally-sourced drugs fell continuously as they faced competition from parallel imports. The IV-results indicate that the reform has increased the intensity of competition from parallel imports mainly by strengthening this gradual effect.

Our empirical strategy made it possible to analyse the full effect of competition from parallel imports over time. The same strategy could be used to analyze the full effect of generic competition, which is a subject for future research.

Our analysis has implications for the effect of mandatory substitution reform on therapeutic competition as well. The prices of drugs facing such competition were 1.5% less on average than they would have been otherwise. The reform increased the effect of therapeutic competition by 1.6%. The results also show that the effect of therapeutic competition depended on whether the therapeutic competitors were subject to generic competition. Facing therapeutic competition led to a substantial fall in prices if the therapeutic competitors themselves were subject to generic competition. The reform increased the effect of generic competition and thus this effect as well.

Lichtenberg and Philipson (1997) showed that between-patent competition (therapeutic competition), most of which occurs while a drug is under patent, costs the patent holder at least as much as within-patent competition (generic competition), which cannot occur until a drug is off-patent. The results of this paper are in line with theirs by showing that patent holders are significantly hurt by competition, both from parallel imports and therapeutic alternatives, and also by showing that these forms of competition, particularly therapeutic competition, was strengthened by the reform. This evidence points at the debate on potential drawback of parallel trade and substitution policies, that is, they might cause patent holders to lose profits and hence to invest less in innovation.

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Appendix: Robustness analysis of key results

We conducted OLS regressions including Mpi^2 and $Ref*Mpi^2$ as well as specifications including 40 year-month dummies instead of 11 month dummies (*Month*), the time trend (*Time*) and the dummy for the reform (*Ref*). Including Mpi^2 and $Ref*Mpi^2$ reduced d*lnP*/d*Picomp* by a half percentage point and d*lnP*/d (*Ref*Picomp)* by about 0.1 percentage point in absolute terms. Including year-month dummies reduced the average estimated effect of PI-competition by about 0.6 percentage point, but changed the estimate for d*lnP*/d(*Ref*Picomp)* by less than 0.1 percentage point. Thus, *Time* and *Ref* seem to have captured changes over time common to all drugs sufficiently well that such changes had little effect on the key results.

We also estimated specifications 1 and 2 separately for drugs that never, or always, faced PI-competition. The estimates for d*lnP*/d (*Ref*Picomp)* for this restricted sample was -0.432 (0.257) and -0.430 (0.250) for specifications 1 and 2, that is, slightly smaller compared to the estimates for the whole sample: -0.773 (0.182) and -0.735 (0.185), respectively.

As argued in the section on econometric analysis, including *Mpi* and *Timepi* might be important for estimating the effect of the mandatory substitution reform correctly. To test this, we ran regression 3 excluding *Mpi* and *Ref*Mpi*; excluding *Timepi*; and excluding all three simultaneously. Excluding only *Mpi* and *Ref*Mpi*, or only *Timepi*, had very little impact on the estimates for d*lnP*/d(*Ref*Picomp)*, but excluding all three simultaneously led to an estimate of -3.061 (0. 202) , compared to the estimate from regression 3 (-0.867 (0.207)).

As noted earlier, the identifying assumption for the effect of the mandatory substitution reform on the price-effect of PI-competition (d*lnP*/d(*Ref*Picomp)*) was that no excluded variable influence the price-effect of facing PI-competition differently before and after the reform. By including the interaction variable between time trend and dummy for facing PI-competition ($Timepi_{it}$), we allowed drugs facing such competition to have a different time trend relative to those not facing it, without this biasing the estimator of the effect of the reform on PI-competition. Still, this estimator might be biased if factors not accounted for in the regressions affected the two groups differently, and if these factors increased or decreased over time in an unstable manner so that their effects could not be captured by *Timepi*, for example, if something

affecting the two groups differently occurred only during a certain part of the study-period. To test the importance of this problem we ran regression 3 for different periods: January 2000-April 2004, January 2002-April 2004, and January 2001-June 2003. We also ran regression 3 using the normal study period but excluding observations from April 2002, when the law regarding mandatory substitution was passed by parliament, through October 2002; and excluding observations from January 2002, when the bill was presented to parliament, through October 2002. Besides functioning as sensitivity analyses, these latter two regressions were designed to give an idea whether firms started to adjust their prices even before the reform came into effect. We also ran regression 3 excluding the first 3, 6, or 9 months after the reform.

For these regressions, the estimated average reform-effect on PI-competition was in the range -1.279 to -0.830 and different from zero at the 5%-level of statistical significance. These results indicate that the estimates for d*lnP*/d(*Ref*Picomp)* are stable to changes in the study-period. No evidence was found of firms adjusting prices before the reform came into effect.

Would variation in *Mpi* in the distant past matter less than in the recent past? To examine this, we ran regression 2 including the following variables $Mpid01_{it}$, $Mpid13_{it}$, $Mpid36_{it}$, $Mpid612_{it}$, $Mpid1224_{it}$, $Mpid2436_{it}$ – where $Mpid01_{it}=Mpi_{it}-Mpi_{i,t-1}$, $Mpid13_{it}=Mpi_{i,t-1}-Mpi_{i,t-3}$, and so on – as well as interaction variables between the reform and each of these variables. We found no evidence that variation in *Mpi* in the distant past mattered less than more recent variation, since the differential with respect to $Mpid01_{it}$ was of similar magnitude to that with respect to $Mpid2436_{it}$.

We also investigated whether the relationship between *Mpi* and pharmaceutical prices might be explained by that drugs facing PI-competition were less able to adjust their prices to keep up with inflation. Since the Pharmaceutical Benefits Agency approves nominal prices, not real prices, this could be the case if the agency were less willing to allow price increases for drugs with PI-competition. To investigate this we ran a regression with the *Mpi* variables replaced by a variable describing the consumer price index (CPI) and variables describing changes in it that occurred during months when a drug faced PI-competition; as well as regressions including both the *Mpi* and the CPI variables. The likelihood values were lower when CPI variables were included instead of the *Mpi* variables, suggesting that the *Mpi* variables better explain the

variations in prices. Also, the estimates for the *Mpi* variables were relatively robust against inclusion of the CPI variables as well, while the estimates for several of the CPI variables became statistically non-significant when the *Mpi* variables were included. Therefore, we conclude that the relationship between *Mpi* and pharmaceutical prices is not explained by the Pharmaceutical Benefits Agency being less willing to approve price increases for drugs facing PI-competition. Instead, the relationship is likely explained by consumers and pharmacists becoming less reluctant to use parallel imports the longer they have been in the market, as discussed earlier.

Finally, we ran several regressions including $Pifirms^2$ (squared) or using dummy variables to account for the number of parallel traders. However, unlike Ganslandt and Maskus (2004), we found no evidence of prices being reduced more when additional parallel traders entered the market after the first, unless we simultaneously excluded the *Mpi* variables and *Timepi*. Since specifications including the number of parallel traders only could be estimated with OLS, we cannot interpret this as showing that there is no additional price reducing effect. But our results suggest that any additional effect might be exaggerated if one has not accounted for the lagged effect of entry of parallel traders. The correlations between *Pifirms* and *Mpi* and *Timepi*, respectively, is 0.67 and 0.80, so it is not surprising that controlling for *Mpi* and *Timepi* affects the estimates for *Pifirms*. Full results from all estimations mentioned here are available from the authors upon request.

Paper IV

EU Enlargement, Parallel Trade and Price Competition in Pharmaceuticals

What's to Blame? Derogation or Perception?[1]

David Granlund[2] and Miyase Yesim Köksal[3]

Abstract

Given the cost of trade and availability of pharmaceuticals, the driving force for parallel trade is the price difference between the source (exporting) and the destination (importing) country. An increase in the price difference or in the availability of pharmaceuticals for parallel trade should increase price competition in the destination country. Using 2003-2007 data from Sweden we investigated whether EU enlargement in 2004, when new countries with low pharmaceutical prices joined the EU, increased competition from parallel imports. Drugs facing competition from parallel imports are found to have on average 17% to 21% lower prices than they would have had if they had never faced such competition. But, contrary to expectation, EU enlargement is not found to have increased this effect, which might be explained by derogations and changes in consumer perceptions of parallel imports.

JEL Classification: I11, L51, L65.

Keywords: EU enlargement, parallel trade; pharmaceuticals; price competition.

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[2] The Swedish Retail Institute (HUI), SE-103 29 Stockholm, Sweden; and Department of Economics, Umeå University, SE-901 87 Umeå, Sweden. E-mail: David. Granlund@econ.umu.se

[3] Department of Economics, School of Business, Economics and Law, University of Gothenburg, SE-405 30 Gothenburg, Sweden. E-mail: Miyase.Yesim@economics.gu.se

Introduction

Pharmaceutical prices vary substantially across the European Union (EU) countries. For example, Lipitor is sold for €44.93 in Sweden, but for less than half that, just €20.30, in Greece (IHS Global Insight, 2010).[4] Such price differences lead to arbitrage or so called "parallel trade" which is allowed within the EU towards fulfilling the objective of creating a single market. Parallel traders can take advantage of price differences buying pharmaceuticals in low-price (exporting or source) countries such as Greece and reselling them in high-price (importing or destination) countries such as Sweden. Given the availability of drugs for parallel trade, and the cost of trade, the driving force for parallel trade is the price difference between the source and destination countries. An increase in the availability of drugs for parallel trade or in the price difference should increase the volume of parallel imports and hence competition in the destination country. Using 2003-2007 data from Sweden we investigated whether EU enlargement in 2004, when new countries with low pharmaceutical prices joined the EU, increased competition from parallel imports.

By the enlargement, Cyprus, Malta, and the Central and Eastern European countries – the Czech Republic, Hungary, Latvia, Lithuania, Estonia, Poland, Slovakia, and Slovenia – joined the EU on May 1, 2004. The prices of pharmaceuticals especially in the Central and Eastern European Countries were much lower than in the rest of the EU. Retail pharmaceutical price level was 71% of the OECD average in the Czech Republic in 2005; 70% in Slovakia , and 68% in Poland, while it is 73% in Greece and 77% in Spain, the two major source countries (OECD, 2008). Hence enlargement increased price differences between EU countries with a twofold effect: causing some not previously subject to competition from parallel imports to face it and increasing competition for those previously subject to it. That is, intra-EU price differences might have become sufficiently large for parallel traders to start importing drugs not previously subject to parallel trade, while the increased price difference and the increased availability of drugs for parallel trade might have increased competition for others. We here explore whether EU enlargement increased intensity of competition from parallel imports focusing on drugs already subject to it.

[4] Greece is one of the main EU countries from which parallel traders source drugs to Sweden. Medartuum, the biggest parallel trader in Sweden, sourced 19% of all its 2008 drug imports from Greece making Greece its third largest source country. Ganslandt and Maskus (2004) list Greece, Spain, and Italy as the most important source countries, accounting for 74% of all Swedish approvals for parallel trade of pharmaceuticals in 1998.

Given availability of drugs, and the cost of trade, parallel traders, as rational agents maximizing profits, would naturally source drugs first from the lowest-price country, which – after the EU enlargement – is likely to be one of the new members. Availability of new source countries with lower prices would also stimulate new parallel traders to enter the market. Both the volume of parallel imports and the number of parallel imported versions of each drug might thus increase in the destination countries, increasing competition from parallel imports. The enlargement could even affect prices of drugs subject to competition from parallel imports not sourced from the new members, since the availability of drugs for parallel trade in the new members might increase the amount of parallel imports a parallel trader could source from the existing members. For example, a parallel trader importing drugs to Great Britain from Spain might instead start sourcing drugs from the new EU members, thus increasing the amount of drugs available in Spain for import to Sweden, in turn increasing competition from parallel imports in Sweden.

However, EU enlargement might not lead to any substantial increase in parallel imports, due to the "derogation" covering all accession countries except Cyprus and Malta. This provision was part of the Accession Treaty because the patent laws in the eight Central and Eastern European accession countries were not in line with those in the existing EU members.[5] The derogation restrains parallel trade by allowing the patent holder of a drug to prevent parallel trade of the drug if the intellectual property (IP) rights in the accession country were not comparable with those in the existing member states at the time of the product's launch. The applicability of the derogation is assessed on a case-by-case basis, and its effect erodes over time as more and more products reach the end of their patent or supplementary protection certificate (SPC) term in the pre-existent EU members (Tobin and Turner, 2003).[6] Despite the derogation, a substantial number, about 6%, of the drugs facing competition from parallel imports, in Sweden had been granted approval for parallel import from the new EU members.

Parallel imported drugs are legitimately produced and legally imported by parallel traders without the authorization of the patent holder. They have the same active ingredient, strength, and form (e.g. pill or fluid) as the locally-sourced drug supplied directly by its patent-holding manufacturer via authorized wholesalers. However, parallel imports might differ in packaging

[5] All of the accession countries except for Cyprus and Malta have only had EU compliant patent laws and provided patent protection for pharmaceuticals since the early 1990s (see Tobin and Turner, 2003; von Uexkull, 2004). Patent laws in Cyprus and Malta had been comparable to those in the EU for longer, so they were exempted from the derogation.

[6] SPC is an extension of patent on drugs, introduced to compensate for the effective patent life lost during the review process for market authorization.

as, depending on the requirements of the importing country, they may be repackaged or relabeled, or even differ in brand name.[7] Consumers might thus consider parallel imports to be imperfect substitutes for the locally-sourced drugs. But, parallel imports are the main instrument for creating competition during the patent life of a drug. Unless parallel trade is allowed, on-patent drugs are only subject to competition from therapeutic alternatives – with different active ingredients but similar therapeutic effects – until the patent expires and generics enter the market.

Theoretical studies show that parallel imports should create competition, causing prices to fall in the destination country (Pecorino, 2002; Ganslandt and Maskus, 2004; Maskus and Chen, 2004; Jelovac and Bordoy, 2005; Chen and Maskus, 2005). Though few in number, empirical studies have found mixed results. Ganslandt and Maskus (2004) found supporting evidence from Swedish data, while Kanavos and Costa-Font (2005) found, on the contrary, that parallel trade did not create competition. Kanavos and Costa-Font (2005) examined whether a surge in parallel trade represented by the market share of parallel imports – taking into account the endogeneity of market share – has any effect on the prices of locally-sourced drugs in the six destination countries in the EU, namely Denmark, Germany, the Netherlands, Norway, Sweden and the UK. Using data from 30 countries covering all drugs in 36 therapeutic classes, Kyle (2010) examined both actual and potential entry of parallel imports finding statistically significant but economically small effects on prices of locally-sourced drugs, which could be due to the possible endogeneity of the entry decision. These studies all investigate the effect of parallel imports on the prices of locally-sourced drugs; while there have been only two studies on means to increase competition from parallel imports. Köksal (2009) examined theoretically the effect of reference pricing, promoting substitution in pharmaceuticals, on competition from parallel imports, while Granlund and Köksal (2011) analyzed this empirically for Sweden.

Using the difference-in-differences approach and data from Sweden from January 2003 through October 2007, this paper examines whether EU enlargement in 2004, despite the derogation, increased competition from parallel imports. We estimated the effects of facing competition from parallel imports on prices of on-patent locally-sourced prescription drugs,

[7] Blisters of parallel imported Diovan Comp are marked both as "Diovan Comp" and "Co-Tareg" one of the many trade names under which it is available in the EU. Similarly, blisters of parallel imported Nexium are marked both as "Nexium" and "Axagon".

and how these effects changed with the EU enlargement.[8] Drugs facing competition from parallel imports are found to have on average 17% to 21% lower prices than they would have had if they had never faced such competition. But, contrary to expectation, EU enlargement is not found to have increased this effect. For drugs always facing competition from parallel imports before and after the enlargement, there was no statistically significant effect of the enlargement.

Swedish case is interesting to study the effect of EU enlargement on competition from parallel imports, since the reimbursement system promotes use of parallel imports. The mandatory substitution policy introduced in 2002 requires pharmacists – with the consent of the consumer – to dispense the cheapest available drug in a substitution group. Drugs with the same active ingredient – an off-patent drug and its generics, or an on-patent drug and its parallel imported versions – are grouped together and the price of the cheapest drug in each group is set as the reference price for reimbursement. Consumers, if they accept substitution pay only some percentage of the reference price; but if not, also pay the full price difference.

The next section describes the legal framework, how rules regarding parallel trade of pharmaceuticals were affected by the EU enlargement, while the following section describes the institutional structure of the pharmaceutical market in Sweden, with focus on parallel imports. Then a section presents the theoretical framework in which the possible effects of EU enlargement are discussed. The following section describes the data and the variables, and the next section discusses the empirical strategy and the econometric analysis. A penultimate section presents the results, and the last section summarizes and draws conclusions.

Parallel Trade and EU Enlargement – Legal Framework

Parallel trade of pharmaceuticals is legal within the EU based on the principle of free movement of goods laid down in Article 28 of the EC Treaty to create a single market.[9] However, it is subject to restrictions to protect industrial and commercial property and human life and health, according to Article 30 (for extensive discussion see COM, 2003). Any other

[8] Out-patient prescription drugs, on average across the OECD countries, account for approximately 80% of total pharmaceutical expenditures (OECD, 2008).

[9] The legality of parallel imports stems from the territorial exhaustion of intellectual property rights (IPRs). Regional exhaustion applies in the EU, meaning that IPRs are exhausted upon first sale anywhere in the EU. So pharmaceuticals can be freely circulated – bought and resold – without the consent of the intellectual property right holder.

restriction, such as supply rationing or dual pricing – without appropriate justification - is appraised in accordance with the rules on competition in Articles 81 and 82 of the Treaty.[10]

An important exception to the rules emerged with the 2004 accession of Cyprus, Malta, the Czech Republic, Hungary, Estonia, Latvia, Lithuania, Poland, Slovenia and Slovakia to the EU.[11] A derogation preventing parallel import of some (but not all) drugs from these countries, except Cyprus and Malta, was included in Article 22 of the Accession Treaty because of lack of EU-compatible patent protection laws in these countries. All of the accession countries except for Cyprus and Malta have only had EU compliant patent laws and provided patent protection for pharmaceuticals since the early 1990s (see Tobin and Turner, 2003; von Uexkull, 2004). Patent laws in Cyprus and Malta had been comparable to those in the EU for longer, so they were exempted from the derogation. Annex IV.2 of the Treaty describes "Specific Mechanism" in the following terms (Van Bael and Bellis, 2005):

> With regard to the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovakia or Slovenia, the holder or his beneficiary, of a patent or supplementary protection certificate (SPC) for a pharmaceutical product filed in a Member State at a time when such protection could not be obtained in one of the above mentioned new Member States for that product, may rely on the rights granted by that patent or SPC in order to prevent the import and marketing of that product in the Member State or States where the product in question enjoys patent protection or supplementary protection, even if the product was put on the market in that new Member State for the first time by him or with his consent.[12]

The patent holder can thus prevent the parallel import of a drug from these eight countries if there was no equivalent patent protection in the exporting country at the time the patent or the SPC was filed in the destination country, one of the existing members. The following hypothetical example explains how the specific mechanism is triggered (Freshfields

[10] See, for example, the Bayer AG (Adalat) case (European Court of Justice Judgment of 6 January 2004) at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62001J0002:EN:HTML.

[11] Opening the gates to cheap imports, by the EU-enlargement, from accession countries to existing members created concerns about profits of researched-based manufacturers who would then be less able to re-invest in R&D of new products. The G10 high level group on Innovation and Provision of Medicines, in its final report to the Commission in May 2002, called for the Accession Treaty to include derogation on parallel imports to recognize differences in IP protection (Tobin and Turner, 2003).

[12] The derogation also requires the parallel trader intending to import a drug covered by the specific mechanism to give the patent holder one month's prior notice of that intention before applying for import approval (Van Bael and Bellis, 2005; Freshfields Bruckhaus Deringer, 2003; Arnold and Porter, 2004). On the basis of the mechanism, the patent holder has the right to object to the parallel import of the drug within this month.

Bruckhaus Deringer, 2003). Suppose a particular drug is sold by the patent holder in both the UK and Estonia. A patent application for the drug was filed in the UK in 1992, patent granted in 1998, and first marketing authorization in the European Economic Area (EEA) obtained in 2000. In Estonia, however, there was no patent protection for any pharmaceutical products in 1992, when the patent application was filed in the UK, so the special mechanism is triggered. The UK patent expires in 2012, and the UK SPC in 2015. The drug then may not be imported to the UK from Estonia until 2015. [13]

Derogation does not apply to all drugs but some *fixed and closed class* marketed in the accession countries. Besides, derogation erodes over time as patents/SPCs expire and the number of drugs covered thus falls.

Parallel Trade and Institutional Structure of the Swedish Pharmaceutical Market

Parallel trade of pharmaceuticals has been legal in Sweden only since it joined the EU in 1995. Sweden – where pharmaceutical prices are about the average of the markets in the EU (Lundkvist, 2002) – is among the main destination countries in the EU; parallel imports account for 12% of total pharmaceutical sales. Just like locally-sourced drugs, parallel imports need to be approved for sale either by Läkemedelsverket – the Medical Products Agency (MPA) – at national level or by the European Medicines Agency (EMA).

After getting this approval, manufacturers are free to set prices, but to get the drug included for reimbursement in the national health insurance system, they also need to get the price approved by Läkemedelsförmånsverket (LFN), the Pharmaceutical Benefits Agency.[14] To raise or lower the price later, they also need LFN approval. Requesting approval for a price increase incurs the risk of having the drug taken off the reimbursement list, since LFN processes applications for price increases as a new application for reimbursement. Manufacturers are required to first remove the drug from the reimbursement list and then apply again for reimbursement at the higher price (LFNAR 2006:1). Applications must include explanation for the price increase as well as information about prices and treatment costs of comparable drugs (LFNFS 2003:1). There are two cases where applications for price

[13] Derogations on parallel trade of pharmaceuticals were introduced when Spain and Portugal joined the EU, but then it was only for a limited period.

[14] The name of Läkemedelsförmånsverket (LFN) – the Pharmaceutical Benefits Agency – was changed to Tandvårds och Läkemedelsförmånsverket (TLV) – the Dental and Pharmaceuticals Benefits Agency – on September 1, 2008, since a dental care reform went into effect in July 2008.

increase will be accepted without resubmission of the drug for reimbursement: if the requested price is the same or less than the price of the most expensive substitutable drug in the group; or if the following two criteria are fulfilled: (i) there is a considerable risk that the drug will disappear from the Swedish market if the price is not approved, and (ii) the drug treats a serious condition threatening the patient's life or health, and there are patients who risk being without similar treatment if the drug disappears from the market (LFNAR 2006:1).

Even though drugs facing competition from parallel imports are generally the most expensive drug in their substitution group, price increases may still be allowed, if they treat a serious condition and are very likely to otherwise leave the market. In such a situation patients may again face the risk of being untreated, since the supply of parallel imports is limited and sometimes even intermittent. Hence, LFN, in order to secure availability of treatment, might allow a price increase even though the drug faces competition from parallel imports.

The Medical Products Agency requires a drug for which parallel import approval is being sought to be sufficiently similar to the locally-sourced one with common origin, containing the same active ingredient, and having the same therapeutic effect (LVFS 2004:8).[15] However, parallel imports might differ from locally-sourced drugs in color, taste, or shape, in which case the outer package should have information making that clear. Due also to differences in country-specific labeling requirements or standard package sizes, parallel imports might thus be repackaged or relabeled. The Medical Products Agency requires that such repackaging or relabeling not affect the original condition of the product or the reputation of the trademark or its holder.[16]

During the study period, there were no financial incentives for Swedish pharmacists to dispense parallel imports, but the reimbursement system promoted use of parallel imports.[17] The Mandatory Substitution Policy introduced in 2002 requires pharmacists – with the

[15] The expression "common origin" refers, for example, to whether the holder of the marketing authorization for the parallel imported drug in the exporting country is the same, or represents the same group of companies, as the holder of the marketing authorization for the locally-sourced drug in Sweden (LVFS 2004:8).

[16] The leading case is Bristol-Myers Squibb v Paranova AS. It was in this case that the European Court of Justice (ECJ) first comprehensively formulated the five general conditions with which a parallel trader of repackaged drugs must comply (collectively, the BMS Conditions) to avoid infringing the re-applied trade mark (Galimberti and Pors, 2008).

[17] For example, the UK, the Netherlands, and Norway provide financial incentives for pharmacists to dispense parallel-imported drugs (Kyle, 2009). However, other than annual ex post payment by the county councils, which are responsible for reimbursement, to Apoteket (the Swedish state pharmacy monopoly) to compensate it for purchasing and dispensing parallel imports and generics, there are no explicit financial incentives to Apoteket to dispense parallel imports (Kanavos et al., 2005).

consent of the consumer – to dispense the cheapest available drug, usually either a generic in the case of an off-patent drug, or a parallel import in the case of an on-patent drug. Drugs with the same active ingredient – an off-patent drug and its generics, or an on-patent drug and its parallel imported versions – are grouped together and the price of the cheapest in each group is set as the reference price. The Medical Products Agency defines a drug as a substitute if it has the same active ingredient, strength, and form as the prescribed drug and if its package size sums up to that of the prescribed drug as well. Consumers who accept substitution pay only some percentage of the reference price, but if they reject substitution, they also pay the full price difference.

Throughout the study period, retail pharmacies, owned by the state monopoly Apotek AB (National Corporation of Swedish Pharmacies), were the only legal entities to dispense the prescription pharmaceuticals for outpatient care. As both wholesale drug prices and the retail drug prices for reimbursable drugs are determined by the LFN, the state-monopoly pharmacies charged uniform prices nationwide. The pharmacy monopoly was abolished and private pharmacies were allowed to enter the market as of July 2009, but the retail prices of prescription drugs remain uniform.

A national health insurance system covers the whole population and has subsidized individual's pharmaceutical expenditures since pharmaceutical benefits scheme was introduced in 1955.[18] The subsidy increases in a stepwise fashion within any 12-month period. Since June 1999, consumers pay 100% of cost up to SEK 900; then 50% of cost up to SEK 1700; then 25% up to SEK 3300; then 10% up to SEK 4300; and finally, above SEK 4300, consumers are fully subsidized.

Price Difference and Parallel Trade - Theoretical Framework

Enlargement had two possible effects on competition from parallel imports: It might have increased the number of drugs subject to parallel competition, and it might have increased the intensity of such competition. Both effects could result from increased price differences between countries. As prices in most of the new EU members were lower than in most if not

[18] Regarding cost containment of pharmaceutical expenditures, the Swedish health insurance system is structured by the law SFS (1981:49) and bills on subsequent changes listed at http://www.notisum.se/rnp/sls/fakta/a9810049.htm, accessed 30 October 2008.

all pre-existent members, the new members were potential source countries. Price differences might then be large enough for parallel traders to import drugs that had not been subject to such competition before the enlargement. But even for drugs already subject to competition from parallel imports, the increased price differences and the increased availability of drugs for parallel trade might have increased the intensity of such competition. All else equal – e.g., product match and transportation costs – rational parallel traders using lowest-cost suppliers first would source drugs from the new EU members if possible. With lower costs, they might charge lower prices, thereby increasing the intensity of competition. Increased profit possibilities might also stimulate the entry of new parallel traders. Even if prices in the new EU members were the same as prices in the pre-existing source countries, increased availability of drugs for parallel trade might increase the volume of parallel imports in the destination countries which in itself might thus increase the price competition.

Köksal (2009) showed theoretically that the price difference between the source and destination countries should increase the intensity of competition from parallel imports. This result follows from the two-country model of third degree price discrimination with a monopolist manufacturer holding the patent for a particular drug, and supplying both countries. The monopolist price discriminates between the two countries since they differ in (i) consumer valuations of the drug, and (ii) the copayment rates that they pay. When parallel trade is allowed, drugs flow from the low-price to the high-price country. Since parallel imports differ in packaging or labeling, consumers may value them less than locally-sourced drugs. In a perfectly competitive market, parallel traders set the price of parallel imports equal to the price in the source country, with the cost of trade assumed zero.

This model is solved for both the benchmark case of autarky – where parallel trade is illegal – and the case of free trade, where parallel trade is legal. At equilibrium, the change in destination country price under free trade is a function of the initial price difference between the source and destination countries under autarky and the "rate of convergence". That is

$$p_{FT} - p_A = -\Theta\left(\gamma\, p_A - p_A^*\right)$$

where p_{FT} is the destination country price under free trade; p_A is the destination country price under autarky; p_A^* is the source country price under autarky; and $\Theta = \left[\frac{1}{\gamma}\frac{r}{r^*} + 1\right]^{-1}$ is the rate of convergence.

The initial price difference must be measured using prices quality-adjusted using a subjective value discount factor(γ) . The rate of convergence (Θ) then depends on the relative coinsurance rates in the destination and source countries – r and and r^*, respectively – and on γ. All else equal, the effect of parallel trade on the price of locally-sourced drugs in the destination country will be larger, the larger is the initial price difference between the destination and source countries.

Again in a two-country theoretical model, Ganslandt and Maskus (2004) showed that prices in the destination country fall as the number of parallel traders increases. They will enter the market if expected profit is positive, i.e., if revenue from parallel trade exceeds its cost. That is

$$E\ (\pi) = E\ [(p - p^* - t)q - F]$$

where p is the price in the destination country; p^* is the price in the source country; t is transport cost including repackaging; q is the quantity demanded of parallel imports in the destination country; and F is the fixed cost of getting approval for parallel trade. All else equal, if the price difference increases, the probability of entry by parallel traders also increases. Different from the model in Köksal (2009), the prices are here assumed regulated in the source country, and supply of parallel imports limited at level X, so that destination country demand for the locally-sourced drug is

$$D = a - bp - X$$

Given that the manufacturer first sets price in the destination country, and then the symmetric n parallel traders choose the amount to parallel import, equilibrium price is

$$p(n) = \frac{1}{2b}\left[a - \frac{n\left(a - 2b\left(p_f + t\right)\right)}{n+1}\right]$$

which is a decreasing function of the number of parallel traders.

Data and Description of Variables

We used the same panel dataset from IMS Health as in Granlund and Köksal (2011), consisting of all prescription drugs sold in Sweden during the period from January 1992

through October 2007. The dataset consists of monthly observations except the period 1992-1994 for which we have only quarterly data. An observation represents a product with a certain active ingredient, form, strength, and package size, supplied by a certain firm and sold in a certain month. For each observation there is also information about the type of drug, i.e., whether it is brand-name or generic, locally sourced or parallel imported, as well as total units sold and total value during the observation period. To isolate the effect of EU enlargement on competition from parallel imports, we used only the part of this dataset covering January 2003 through October 2007. We did not use earlier data in order to avoid possible biases that might result from adjustments to the mandatory substitution policy introduced in October 2002 (described in Granlund and Köksal 2011).

Prescription pharmaceutical sales constituted about 0.9% of GDP over the period 2003-2006. Both the share of parallel imports in total pharmaceuticals sales and the number of parallel traders increased substantially in 1998 (Table 1), because of the integration of Sweden in the EU (Ganslandt and Maskus, 2004). While the share of parallel imports was 2% in 1997, it was 6% in 1998, and the number of parallel traders increased from 2 in 1997 to 8 in 1998. After that both continued generally to increase through 2007. Starting from 2005 onwards, even though the share of parallel imports remained constant, the number of parallel traders gradually increased.

Table 1. The Swedish Prescription Drug Market, 1997-2007

	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
GDP	1927001	2012091	2123971	2249987	2326176	2420761	2515150	2624964	2735218	2900790	3063145
TPS	13984	16270	18148	19934	21301	22872	23301	23807	24819	25943	23067
PI	272	1008	1402	1754	2012	2090	2100	2527	3018	3012	2707
PI/TPS	2%	6%	7,7%	8,8%	9,4%	9,1%	9%	10,6%	12,1%	11,6%	11,7%
# PI Firms	2	8	10	9	9	10	11	11	9	12	14

Notes: GDP, TPS and PI are in million SEK expressed in nominal terms. TPS=total pharmaceutical sales; and PI=total sales value of parallel imports. PI/TPS is the share of parallel imports in total pharmaceutical sales.
Source: Intercontinental Medical Statistics (IMS)

The dataset includes off-patent brand-name drugs and generics as well as on-patent drugs and parallel imports, but our empirical analyses focused only on on-patent prescription drugs.

Data on off-patent brand-name drugs, generics, and parallel imports was used to create relevant variables for the analysis, but was not included in the final dataset. We had no information on patent expiration dates, so we defined drugs as off-patent starting from the first time any generic with the same active ingredient was sold in Sweden. This left us with 138,635 observations on 1,798 on-patent drugs with different active ingredient, form, or strength. Of these, 319 (about 18%) faced competition from parallel imports, of which about 6% had been granted approval by the MPA for parallel import from the new EU members. However, we had no information on parallel imports centrally approved by the EU-wide European Medicines Agency (EMA). But – considering the derogations – even the 6% approved in Sweden is a substantial number.

Table 2. Summary statistics for variables

Variable	Mean	Std. Dev.	Min	Max
ln*p*	5.9048	1.5953	1.9200	11.7041
Picomp	0.1601	0.3667	0	1
Pifirms	0.3722	1.0427	0	8
Mpi	6.7968	17.4634	0	118
Thcomp	0.8518	0.3552	0	1
Nthcomp	3.2421	2.6369	0	16
Thgencomp	0.2452	0.3524	0	1
Review	0.0243	0.1542	0	1
EU_Enlar	0.7116	0.4530	0	1
*EU*Picomp*	0.1186	0.3233	0	1
*EU*Pifirms*	0.2760	0.9170	0	8
*EU*Mpi*	5.3192	16.7301	0	118
Time	28.8636	16.7301	1	58
Timepi	4.7335	12.6790	0	58
EUR/SEK	9.2005	0.1233	8. 7986	9.5663
CZK/SEK	0.7116	0.4550	0	1.0685
Lnlong	4.1716	0.7975	-0.6931	4.6868

The variables used in the analysis and descriptive statistics are presented in Table 2. As in Granlund and Köksal (2011), the variable $\ln p_{it}$ is defined as the natural logarithm of the real price, the wholesale price in month t deflated by the consumer price index. $Picomp_{it}$ is an indicator of whether drug i is subject to competition from parallel imports (hereafter PI-competition), while $Pifirms_{it}$ is the number of parallel traders from which drug i faced

competition.[19] Mpi_{it} is the number of months drug i had faced competition from parallel imports before month t. $Thcomp_{it}$ is a dummy indicating whether drug i has any therapeutic competitors, drugs that have different active ingredients but the same therapeutic effect, while $Nthcomp_{it}$ is the number of therapeutic competitors, and $Thgencomp_{it}$ is the share of product i's therapeutic competitors facing generic competition.[20] $Review_{it}$ is a dummy indicating if drug i at month t belonged to a therapeutic group for which the review of reimbursement status had been completed by the LFN by then. EU_Enlar_t is a dummy taking the value one for the months after the enlargement in May 2004. The following three variables are interaction variables between EU_Enlar_t and the variables $Picomp_{it}$, $Pifirms_{it}$, and Mpi_{it}. $Time_t$ is the number of the months after December 2002 at month t, and $Timepi_{it}$ is an interaction variable between this variable and $Picomp_{it}$. The last three variables are instruments used in instrumental variable regressions: the Euro/SEK and the CZK/SEK exchange rates, and the logarithm of the number of months the product has been sold in Sweden ($Lnlong_{it}$).[21]

Table 3. Detailed summary statistics for key variables

Variable	Before EU Enlargement				After EU Enlargement			
	Mean	**Std. Dev.**	**Min**	**Max**	**Mean**	**Std. Dev.**	**Min**	**Max**
Picomp	0.1439	0.3667	0	1	0.1667	0.3727	0	1
Pifirms	0.3337	1.0427	0	8	0.3878	1.0669	0	8
Mpi	5.1239	17.4634	0	79	7.4748	18.6429	0	118
Thcomp	0.8454	0.3552	0	1	0.8544	0.3526	0	1
Nthcomp	3.1610	2.6369	0	12	3.2749	2.6365	0	16

Most of the drugs (85%) faced therapeutic competition, while only 16% faced competition from parallel imports (Table 2). The number of drugs facing competition from parallel imports after the enlargement is statistically significantly larger than that before the enlargement (Table 3). Almost all of the drugs facing competition from parallel imports (about 93%) faced therapeutic competition. Drugs facing competition from parallel imports

[19] A drug imported by a parallel trader is considered to be a competitor to the locally-sourced drug if it has the same active ingredient (i.e., the same 7-digit ATC code), strength, and form (e.g., pill or fluid) and both are sold in Sweden during the same month. Since, for example, a 100-pill package can substitute for two 50-pill packages, it is not required that the parallel-imported drug is of the same package size as the locally sourced drug.

[20] Following Brekke et al. (2008) and Pavcnik (2002), pharmaceuticals with the same 5-digit ATC code are classified as therapeutic competitors.

[21] In order to be able to take the natural logarithm, we defined $Lnlong_{it}$ as 0.5 for the first month a product was sold, and so on. The variable is truncated at 130.5 months due to lack of older data.

accounted on average for 23% of total sales value. Parallel traders thus targeted top-selling drugs that had also been subject to therapeutic competition from "me-too" drugs.

Empirical Analysis

We used a difference-in-differences method to examine how EU enlargement affected the price-effects on locally-sourced drugs of facing competition from parallel imports (hereafter PI-competition). This method was applicable because we had data, from both before and after enlargement, on drugs that had been either always or never subject to competition from parallel imports during the study period, as well as drugs that changed from being subject to such competition to not, or vice versa. Data on drugs that changed status allowed us to estimate the effect of competition from parallel imports, while data on all drugs allowed us to estimate the average effect of EU enlargement on competition from parallel imports. To isolate the effect of EU enlargement on the intensity of competition from parallel imports for drugs already subject to such competition, we also ran regressions on a restricted sample containing only the drugs that always or never faced such competition during the study period.

Estimating the effect of competition from parallel imports in general relies on changes in whether drugs face such competition or not. However, estimating the effect of EU enlargement on competition from parallel imports relies on comparison of changes in the prices of drugs always facing such competition with drugs never facing it both before and after the enlargement, as well as comparison of changes in the prices of drugs due to change in status (from being subject to PI-competition to not, or vice versa) before and after the enlargement.

This before and after comparison of differences in prices is attributed as the effect of the EU enlargement on PI-competition if possible biases have been removed by controlling for permanent differences between drugs as well as other factors causing price changes. We thus included in the estimations drug specific fixed effects (α_i) controling for time-invariant differences between individual drugs. We controlled for possible changes over time common to all drugs by including: a linear time-trend ($Time_t$); a dummy variable taking the value one after the enlargement (EU_t); and dummy variables for calendar months ($Month_t$).[22] We

[22] In order to control for common changes over time, we estimated, using fixed-effects OLS, a specification with

included the variables $Picomp_{it}$ to estimate the effect of being subject to competition from parallel imports, and $Pifirms_{it}$ to estimate the effect of the number of parallel traders importing the drug.

The estimated coefficients of these variables, $Picomp_{it}$ and $Pifirms_{it}$, would be estimated without any bias if no variables not included in the specification caused price changes correlated with facing PI-competition. Since therapeutic competition could influence prices and might be correlated with PI-competition, we thus also included $Thcomp_{it}$, $Nthcomp_{it}$, and $Thgencomp_{it}$ in the specification.[23] We also controlled for drugs whose reimbursement status was reviewed by the LFN for cost-effectiveness during the study period. The review, covering 49 therapeutic groups, started at the end of 2003, but only three therapeutic groups (migraine; diseases caused by excess stomach acid; and asthma, COPD, and coughs) were completed during the study period. These reviews could affect prices, since the drugs reviewed might lose reimbursement status (i.e., be de-listed) or be granted only restricted reimbursement. LFN might even directly recommend a reduction in the price of a drug, with which manufacturers would comply in order to retain the drug's reimbursement status. We controlled for these possible effects of the reviews on prices by including the dummy variable $Review_{it}$ in the specification.[24]

To estimate the effect of EU enlargement on competition from parallel imports we included interaction terms between EU_Enlar_t and the variables controlling for PI-competition. Such specification would identify the effect of EU enlargement if no variables not included in the estimation influenced the price effect of facing PI-competition differently before and after the enlargement. This requirement is the reason for including Mpi_{it} and $EU * Mpi_{it}$ in the specifications. Since Mpi_{it} could affect prices – because the longer a parallel imported drug has been in the market, the more familiar with it will be consumers, physicians and pharmacists – and since its effect could differ before and after the enlargement, we included Mpi_{it} as well as $EU * Mpi_{it}$ in the specifications. Granlund and Köksal (2011) reported that the larger Mpi_{it} is, the more likely were patients to accept substitution of a parallel imported

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the linear time trend replaced by year-month dummies, and obtained similar results. However, we did not include year-month dummies in the chosen specifications in order to use time-variation in the instruments (see below) for identification.

[23] The share of drugs facing therapeutic competition is statistically significantly larger among the drugs facing competition from parallel imports than among those not facing such competition. The difference is 9 percentage points.

[24] Of the 90 drugs in our dataset reviewed all but 15 had at least one therapeutic competitor.

drug for the prescribed locally-sourced drug. This implies that over time parallel imports become stronger competitors for locally-sourced drugs, and that the latter therefore have to reduce their prices in order to keep sales up. Besides, a parallel imported drug, sold in Sweden for a long time without any supply shortages or even interruptions due to possible strategic response of the manufacturer like supply rationing in source country, might be considered as a reliable alternative by the LFN which may then be tougher when acting on applications for price increases for the locally-sourced drug. Mpi_{it} is thus expected to reduce the price of drugs facing PI-competition, an effect which might be strengthened after EU enlargement since parallel traders might switch to sourcing parallel imports from the new lower-price members for drugs that faced PI-competition for a long time and thus have a large Mpi_{it}. This would be the case if parallel traders first try to increase their profits in a secure market niche for parallel imports that have already gained consumers' acceptance. However, the effect of Mpi_{it} on the prices of drugs facing PI-competition might also be weakened by the enlargement, since the parallel imports sourced from the new EU members might differ in packaging or labeling, possibly causing confusion among consumers, especially the elderly and those with chronic diseases.[25] The perception of parallel imports among consumers might thus change after the enlargement.

We also included $Timepi_{it}$ in the specifications to capture changes over time in the effect of facing PI-competition *not* caused by the enlargement.[26] The main specification is then

$$\begin{aligned}\ln p_{it} = {} & \beta_1 Picomp_{it} + \beta_2 Pifirms_{it} + \beta_3 Mpi_{it} + \beta_4 Timepi_{it} + \beta_5 EU * Picomp_{it} \\ & + \beta_6 EU * Pifirms_{it} + \beta_7 EU * Mpi_{it} + \beta_8 Thcomp_{it} + \beta_9 Nthcomp_{it} \\ & + \beta_{10} Thgencomp_{it} + \beta_{11} Review_{it} + \beta_{12} Time_t + \beta_{13} EU\_Enlar_t \\ & + \sum_{n=2}^{12} \gamma_n Month_t + \alpha_i + \varepsilon_{it}\end{aligned}$$ [27]

[25] Kanavos and Holmes (2005) discusses detailed evidence of confusion among patients.

[26] Before the enlargement, drugs subject to competition from parallel imports had a different time trend than drugs not subject to such competition. However, the difference in time trend was stable over time, so $Timepi_{it}$ accounts for the difference in the time trend and corrects for any bias otherwise introduced.

[27] We also estimated, using fixed-effects OLS, a specification where we accounted for possible nonlinear effects of *Mpi* by including Mpi^2 and $EU*Mpi^2$ but the key results did not change much. The effect of pi-competition on prices decreased by 0.3 percentage points in absolute terms and the effect of enlargement on PI-competition decreased by 0.2 percentage points.

The coefficients β_1-β_4 describe the effects of competition from parallel imports before EU enlargement. β_1 and β_4 describes the effect of facing competition at all and how this effect changed over time, while β_2 depicts how the effect relates to the number of firms, and β_3 describes the effect of the number of months a drug had faced competition from parallel imports before month *t*. The coefficients of the interaction variables, β_5-β_7 describe how EU enlargement influenced the price effect of competition from parallel imports. The coefficients β_8-β_{10} describe the effect of therapeutic competition on prices, while β_{11} depicts the effect of reimbursement reviews on prices, and β_{12} describes how the prices of drugs not subject to competition from parallel imports changed over time. Finally β_{13} describes how EU enlargement affected the prices of drugs not subject to competition from parallel imports.

We estimated the specification above with fixed-effects OLS-regression. However, the estimates would be biased due to the endogeneity of variables controlling for competition from parallel imports, which might arise since the entry decisions of parallel traders are determined by the prices of pharmaceuticals, or as a result of unobserved characteristics affecting both entry of parallel traders and the price of pharmaceuticals. We therefore also used an instrumental variables (IV) estimation method. Since we would otherwise have too many endogenous variables to instrument in the IV regression, we dropped $Pifirms_{it}$ and $EU * Pifirms_{it}$ from the specification and estimated it with both fixed-effects OLS and IV regression.

We estimate one of the three IV regressions using as instruments the Czech Koruna/Swedish Krona (CZK/SEK) exchange rate and the Euro/Swedish Krona (EUR/SEK) exchange rate (see column three of Table 4); another using the logarithm of the number of months the product had been sold in Sweden ($Lnlong_{it}$) (see column four of Table 4); and the other using all three instruments CZK/SEK, EUR/SEK, and $Lnlong_{it}$ (see column five of Table 4). These instruments are clearly exogenous – especially the two exchange rates - and they are powerful enough to explain the variation in endogenous variables. $Lnlong_{it}$ should also be exogenous, since we control for therapeutic competition. Exchange rates between the currencies of other new EU members and the Swedish Krona could have been used as instruments as well, but most of the approvals granted by the MPA for parallel import of drugs from the new EU members have the Czech Republic as the source country. Since

CZK/SEK does not account for much variation in PI-competition before the EU enlargement, we used EUR/SEK together with a transformation of CZK/SEK as instruments.[28]

As in Granlund and Köksal (2011), we used a three-stage IV method. In the first stage, a fixed-effects OLS estimation was employed to explain $Picomp_{it}$ using both the exogenous variables of the main specification and the instruments just discussed. We used those results to predict $Picomp_{it}$. However, as the instruments had no power to predict $Picomp_{it}$ for drugs that did not vary in $Picomp_{it}$ during the study period, we excluded those drugs in the first stage, instead used the observed values of $Picomp_{it}$ for these drugs as predictions. The predictions for $Picomp_{it}$ were then used to create predictions of the other four endogenous variables: Mpi_{it}, $Timepi_{it}$, $EU*Picomp_{it}$, and $EU*Mpi_{it}$. Predictions for all endogenous variables were then used as instruments for those variables in 2SLS estimation.[29] The main advantage with this method is that – compared to the standard two-stage IV – it yields robust estimates for the endogenous variables. Standard two-stage estimation, with the endogenous variables instrumented by the exchange rates or product longevity in the market, made clear that the instruments were weak in explaining at least one of the endogenous variables, which could have led to estimates sensitive to even small variations in the instruments.

To isolate the effect of EU enlargement on the intensity of competition from parallel imports, we restricted the analysis to drugs that always, or never, faced PI-competition during the study period. We did this analysis since these drugs constituted 83% of the full sample, and the effect of EU enlargement might differ for these drugs for two reasons. First, EU enlargement might have a larger effect on the prices of these drugs if parallel traders first increased their profits in a secure market, where consumers were used to parallel imports, by sourcing the drugs they had already been parallel importing to Sweden from the new EU members. Second, in this sample more than in the full sample, the interaction variables between EU-enlargement and the variables controlling for PI-competition were likely to identify the effect of facing competition from parallel imports from the new EU members, in addition to facing competition from parallel imports from existing members. This would be the case if most drugs that faced steady competition from parallel imports from old members before the enlargement were more likely to face competition from parallel imports from these

[28] We transformed the CZK/SEK exchange rate into an index which accounts for the ineffectiveness of CZK/SEK before the enlargement. We set the value of CZK/SEK equal to 0 before the enlargement and we normalize CZK/SEK after the enlargement with the mean. With the exception that we used CZK/SEK as an instrument and truncated $Lnlong_{it}$ at a different value, we used the same instrument as in Granlund and Köksal (2011).

[29] We used the *xtivreg2* command by Schaffer (2010) to run 2SLS estimation in Stata.

countries also after enlargement, compared to drugs that either faced intermittent PI-competition before enlargement or drugs that only started to face PI-competition after enlargement. In this estimation with the restricted sample, the dummy variable $Picomp_{it}$ was dropped since it was time-invariant and thus perfectly correlated with the fixed effects. $Timepi_{it}$ and Mpi_{it} would capture the same effect, so either could be included in the estimation. As $Picomp_{it}$ was time-invariant, there was no variable other than $Pifirms_{it}$ that varied endogenously, and so there was no problem of endogeneity in the estimation on the restricted sample where $Pifirms_{it}$ was excluded.

Results

Estimation results from the fixed-effects OLS regressions (with and without $Pifirms_{it}$ and $EU*Pifirms_{it}$) and the IV regressions are presented in Table 4, along with differentials indicating the average effect of the variables of main interest on prices. The differential $d\mathit{lnP}/d\mathit{Picomp}$ – representing the average effect of PI-competition on prices – was calculated using the estimated coefficients of all seven variables controlling for PI-competition (hereafter PI-variables) as well as the average values of these variables when the dummy variable $Picomp_{it}$ takes the value one. IV regression with exchange rates as instruments (column 3), indicates that drugs facing PI-competition had on average 21% lower prices than what they would have had if they had never faced such competition. The magnitude of this effect depends on the choice of instrument in the IV regressions, however. That it is a lot larger in the IV regressions than in OLS indicates that the variables controlling for the effect of PI-competition are endogenous. The positive estimates of $Pifirms_{it}$ and $EU*Pifirms_{it}$ (column 1) might be caused by endogeneity, but might also be caused by a generic competition paradox type situation as discussed in Frank and Salkaver (1992): In response to increased competition from parallel imports, manufacturers might increase prices to extract as much as possible from loyal (price-insensitive) consumers.

The differential $d\ln P/d(EU*Picomp)$ based on the results from fixed-effects OLS regressions (columns 1 and 2) indicates that EU enlargement increased the effect of PI-competition, but by less than one percentage point. If enlargement had only affected the number of parallel traders, then $d\ln P/d(EU*Picomp)$ would have been close to zero in estimation 1 where we controlled for $Pifirms_{it}$ and $EU*Pifirms_{it}$. That it is different from zero, suggests that EU enlargement might have also increased the intensity of competition (i) as a result of

incumbent parallel traders importing more at lower price, and/or (ii) as a result of the price effect of parallel imports sourced only from new EU members being larger than that of parallel imports sourced only from existing members.

On the other hand, the differential dln*P*/d(*EU*Picomp)* based on the results from the IV regressions indicates that EU enlargement reduced the effect of PI-competition, but again less than one percentage point. The estimated average effect of EU enlargement was somewhat larger when exchange rates were used as instruments in the IV regression (column 3). The positive sign of dln*P*/d(*EU*Picomp)* in the IV regressions is because the reduction in the immediate effect of pi-competition – captured by $EU*Picomp_{it}$ – dominates the increase in the gradual effect – captured by $EU*Mpi_{it}$ – after EU enlargement.

The reduced immediate effect of facing PI-competition might be due to changed consumer perceptions of parallel imports, perhaps driven by those sourced from the new members. Consumers might simply perceive drugs sourced from the new members as inferior. Those drugs – even when imported by an incumbent parallel trader – might differ in packaging or labeling, and hence might cause confusion among consumers as discussed earlier. However, such concerns might vanish over time, as those drugs stay in the market and consumers get used to them. This gradual effect of competition from parallel imports is reflected as negative coefficients on Mpi_{it} and $EU*Mpi_{it}$.

The estimated effect of EU enlargement on PI-competition could also be explained by the effect of PI-competition on prices of drugs that hadn't faced PI-competition before but became subject to such competition after the enlargement. For those drugs, if the price difference between the source country and Sweden was just large enough to engage in parallel trade but still small, and if the supply of parallel imports was limited, then the price effect of PI-competition might be small, which would be reflected as positive coefficients on variables interacting with the dummy for EU enlargement.

The individual estimates for the PI-variables indicate that PI-competition both before and after the enlargement had a large immediate effect captured by $Picomp_{it}$ accounting for the main effect of PI-competition. The estimates for $Timepi_{it}$ from the fixed-effects OLS regressions (column 1 and 2) indicate that this initial effect fell in absolute value over time, while the estimates are not statistically significant in the IV regressions. On the other hand,

the gradual effect of PI-competition was small in absolute terms before the enlargement, but larger after the enlargement.[30]

The estimated coefficients on the variables $Thcomp_{it}$, $Nthcomp_{it}$, and $Thgencomp_{it}$ provide evidence on how therapeutic competition affects prices. The differential $d\ln P/dThcomp$ indicates that the average effect of facing therapeutic competition during the study period was a less than 1% price reduction. However, the estimates for the therapeutic competition variables indicate that the prices of drugs tended to rise if they faced such competition, but also to decrease as the number of therapeutic competitors increased. Besides, the IV regressions (columns 3-5) indicate that the prices of drugs facing therapeutic competition increased if the competitors were subject to generic competition. These results imply that a generic competition paradox type situation is likely to arise when drugs face therapeutic competition, unless prices fall as a result of increased number of therapeutic competitors. The estimates for $Review_{it}$ also indicate that prices, on average, fell about 1.5% due to the reimbursement reviews conducted by TLV. Since the vast majority of the drugs reviewed, about 90%, had therapeutic competitors; the reviews particularly affected the prices of drugs facing therapeutic competition.

The estimated coefficients on $Time_t$ indicate that the prices of drugs not facing PI-competition fell over time. However, the estimates for the dummy EU_Enlar_t indicate that the prices of drugs not subject to PI-competition increased after the enlargement. This result should be interpreted with caution, however, since this variable might capture something other than causal effects of the EU enlargement.

To disentangle the effects of EU enlargement on the intensity of competition from parallel imports, we also restricted the analysis to only drugs that were either always or never subject to PI-competition during the study period. Irrespective of whether we controlled for $Pifirms_{it}$, enlargement had no effect on the price effect of PI-competition for these drugs (Table 5). The estimated effect of enlargement using the whole sample, which indicated a 1% decrease in the absolute price effect of PI-competition, must then have been caused by the changes in the prices of drugs that had never faced PI-competition before but started to face such competition after the enlargement, and by drugs that changed from facing PI-competition to

[30] In specifications 3 and 4, the estimated coefficients on *Mpi* imply about 3% decrease in prices of drugs facing PI-competition with average *Mpi* of 32 months before enlargement, while the coefficient implies a relatively large decrease, around 11%, in prices of drugs facing pi-competition with average *Mpi* of 37 months after enlargement.

not, or (more likely) vice versa. The effect of PI-competition on the prices of drugs that started to face it after the enlargement could be smaller if the price difference between Sweden and the source country (one of the new EU members) was small and/or consumers perceived the new parallel imports (sourced from the new members) as inferior. Besides, especially consumers with chronic diseases might become reluctant to accept parallel imports if each time they are offered a different version, sourced from a different country, or if they are offered parallel imports irregularly, due to problems in supply. Comparison of the estimates for PI-variables from the restricted sample with those from the whole sample indicates that the increase in the price effect of Mpi_{it} after enlargement was mostly driven by drugs changing status including drugs that started to face PI-competition.

Table 4. Estimation results (multiplied by 100)

	(1) FE, OLS	(2) FE, OLS	(3) FE, IV[a]	(4) FE, IV[b]	(5) FE, IV[c]
$Picomp_{it}$	-1.703***	-1.272***	-25.477***	-19.612***	-21.094***
	(0.403)	(0.347)	(3.126)	(2.982)	(2.815)
$Pifirms_{it}$	0. 659***				
	(0.142)				
Mpi_{it}	-0. 252***	-0.226***	-0.064	-0.085	-0.184***
	(0. 016)	(0.015)	(0.070)	(0.064)	(0.056)
$Timepi_{it}$	0.057***	0.062***	0.119	0.088	0.186***
	(0.012)	(0.012)	(0.082)	(0.077)	(0.069)
$EU*Picomp_{it}$	-0.674**	0.939***	11.379***	9.272***	9.059***
	(0.293)	(0.296)	(0.960)	(0. 859)	(0.831)
$EU*Pifirms_{it}$	0.798***				
	(0.123)				
$EU*Mpi_{it}$	-0.044***	-0.049***	-0.277***	-0.228***	-0.223***
	(0.808)	(0.007)	(0.023)	(0.021)	(0.020)
$Thcomp_{it}$	1.530	1.218***	1.138***	1.164*	1.196***
	(0.253)	(0.242)	(0.278)	(0.262)	(0.259)
$Nthcomp_{it}$	-0.532***	-0.555**	-0.587***	-0.580**	-0.588***
	(0.055)	(0.055)	(0.061)	(0.059)	(0.058)
$Thgencomp_{it}$	-0.308*	-0.242***	1.010***	0.723***	0.651***
	(0.184)	(0.184)	(0.249)	(0.230)	(0.226)
$Revision_{it}$	-2.073***	-1.729***	-1.495***	-1.548***	-1.561***
	(0.417)	(0.418)	(0.434)	(0.427)	(0.426)
$EU\ \ Enlar_i$	1.517***	1.515***	1.501***	1.467***	1.500***
	(0. 089)	(0. 089)	(0.097)	(0.096)	(0.096)
$Time_i$	-0.026***	-0.027***	-0.022***	-0.022***	-0.024***
	(0.002)	(0. 002)	(0.003)	(0. 003)	(0.003)
d ln*P*/d *Picomp*	-7.906***	-8.215***	-23.548***	-19.521***	-21.701***
	(0.446)	(0.463)	(2.917)	(2.798)	(2.601)
d ln*P*/d (*EU*Picomp)*	-0.464***	-0.895***	0.979***	0.719***	0.694***
	(0.249)	(0.252)	(0.275)	(0.265)	(0.262)
d ln*P*/d *Thcomp*	-0.582***	-0.968***	-0.806**	-0.836***	-0.855***
	(0.307)	(0.298)	(0.342)	(0.324)	(0.321)
Sample size	138635	138635	138635	138635	138635
Log likelihood	180,015.3	179,688	170,351.1	173,943.6	174,697.5

Notes: FE denotes fixed-effects regressions and IV denotes instrumental variable regressions.
IV[a] used CZK/SEK and EUR/SEK as instrument. IV[b] used $Lnlongevity_{it}$ as instrument.
IV[c] used CZK/SEK, EUR/SEK and $Lnlongevity_{it}$ as instrument.
F-values for significance of the instruments in the first-stage regression are 30.65, 451.09, and 173.10 for estimations 3, 4, and 5, respectively.
Asterisks ***, **, and * denote that coefficients are statistically significant at the 1%, 5% and 10% levels.
Standard errors robust against heteroskedasticity and autocorrelation are shown in parentheses. The differentials are evaluated at the mean of each variable when the relevant explanatory variable, i.e., *Picomp*, *EU*Picomp*, or *Thcomp*, takes the value one. Estimation results for calendar months are suppressed in order to save space, but are available from the authors upon request.

Table 5 - Estimation results with restricted sample (multiplied by 100)

	(6) FE, OLS	(7) FE, OLS
$Pifirms_{it}$	0.539*	
	(0.316)	
Mpi_{it}	-0.146***	-0.117***
	(0.030)	(0.024)
$EU*Picomp_{it}$	-1.118	0.699
	(1.110)	(1.023)
$EU*Pifirms_{it}$	0.412**	
	(0.188)	
$EU*Mpi_{it}$	-0.003	-0.018
	(0.014)	(0.017)
$Thcomp_{it}$	0.914	0.861
	(0.901)	(0.897)
$Nthcomp_{it}$	-0.713***	-0.728***
	(0.153)	(0.153)
$Thgencomp_{it}$	-0.884*	-0.921*
	(0.528)	(0.527)
$Revision_{it}$	-1.597***	-1.533***
	(0.475)	(0.485)
$EU\ \ Enlar_i$	1.454***	1.459***
	(0.198)	(0.198)
$Time_i$	-0.017***	-0.017***
	(0.009)	(0.009)
d ln*P*/d (*EU*Picomp*)	0.112	-0.273
	(0.571)	(0.593)
d ln*P*/d *Thcomp*	-2.020**	-2.139**
	(0.986)	(0.981)
Sample size	117228	117228
Log likelihood	152,776.4	152,716.4

Notes: FE denotes fixed-effects regressions.
Asterisks ***, **, and * denote that coefficients are statistically significant at the 1%, 5%, and 10% levels.
Standard errors robust against heteroskedasticity and autocorrelation are shown in parentheses.

Conclusion

Ten new countries joined the EU by the enlargement in 2004. Given that parallel trade of pharmaceuticals is legal within the EU, and prices were lower in these new members, the enlargement raised concerns about parallel trade and price competition in pharmaceuticals. Parallel import of pharmaceuticals from eight of the new members – all except Cyprus and Malta - was "derogated" (restricted) due to lack of proper patent protection. The derogation hinders parallel import of a drug if it did not have equivalent patent protection in the source country at the time the patent was filed in the destination country. It covers thus just a fixed and closed set of pharmaceuticals. That is, there are drugs eligible for parallel trade, so EU enlargement might still increase competition from parallel imports. Despite the derogations,

data on approvals granted by the Swedish Medical Products Agency show that at least 6% of drugs facing competition from parallel imports had competitors sourced from the new members.

Using Swedish data from 2003-2007 we examined whether EU enlargement increased the effect of competition from parallel imports on prices of on-patent prescription drugs. Drugs facing competition from parallel imports were found to have had on average 17- 21% lower prices than they would have had if they had never faced such competition. But, contrary to expectation, the enlargement was found to have reduced the effect of competition from parallel imports though slightly (at most one percentage points). The immediate effect of facing competition from parallel imports – which mainly determines the total effect – fell after the EU enlargement, while the gradual effect, taking place over ensuing months, rose. The immediate effect of PI-competition might have fallen after enlargement because of changes in consumer perceptions of parallel imports. Perhaps consumers perceive drugs sourced from the new members as inferior because of different packaging or labeling. However, such concerns might vanish over time as the drugs remain in the market and as consumers got used to them.

The estimated effect of EU enlargement on competition from parallel imports might also capture the change in prices of drugs that became subject to such competition only after the enlargement. If the price difference between the source country and Sweden was small and the supply of parallel imports was limited, then the effect of facing competition from parallel imports might be small, which would be reflected as a decreasing effect of EU enlargement on competition from parallel imports.

The effect of EU enlargement on competition from parallel imports might then be due both to the derogation restricting the set of drugs that could be parallel traded and to changes in consumer perceptions of parallel imports. The study period covered a short transition during which both parallel traders and consumers were adjusting to the availability of drugs from new EU members. The results may bode well for increased competition from parallel imports over a longer period, since they indicate that the gradual effect of PI-competition was strengthened by the enlargement.

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