

Pharmaceutical trade

SUMMARY

Pharmaceutical parallel trade in the European Union is a large and growing phenomenon, and hope has been expressed that it has the potential to reduce prices paid by health insurance and consumers and substantially to raise overall welfare. In this paper we examine the phenomenon empirically, using data on prices and volumes of individual imported products. We have found that the gains from parallel trade accrue mostly to the distribution chain rather than to health insurance and consumers. This is because in destination countries parallel traded drugs are priced just below originally sourced drugs. We also test to see whether parallel trade has a competition impact on prices in destination countries and find that it does not. Such competition effects as there are in pharmaceuticals come mainly from the presence of generics. Accordingly, instead of a convergence to the bottom in EU pharmaceutical prices, the evidence points at 'convergence to the top'. This is explained by the fact that drug prices are subjected to regulation in individual countries, and by the limited incentives of purchasers to respond to price differentials.

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Pharmaceutical parallel trade in Europe: stakeholder and competition effects

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1. INTRODUCTION

Parallel trade (PT) is one of the most salient controversies that emerged as a result of the European single market for pharmaceuticals. Pharmaceutical parallel imports (PI) are the legal importation of a patented product from one country where it is legally marketed into a second country where the patent holder also markets that product, but without the authorization of the patent holder. Within the European Union (EU), a series of European Court of Justice (ECJ) rulings (Philipson, 2001; ECJ, 1996, 1997, 1999, 2000a, 2000b, 2002, 2004), or opinions (ECJ, 2003), underpin its legitimacy and have led to its encouragement by several member states.

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The level of preoccupation with pharmaceutical PT has increased over the past few years for a number of reasons. First, different regulatory regimes for pharmaceuticals result in significant differences in pharmaceutical prices across countries. These price differences make it profitable for PT to take place, despite the obvious costs (transport and transaction costs, regulatory costs as well as hedging against currency variations). Second, PT has reached a significant proportion of total national pharmaceutical expenditure in many European countries, particularly those with high pharmaceutical prices, such as the UK, Germany, the Netherlands and Sweden. Third, PT represents an interesting policy dilemma, touching upon the principles of free trade policy, the determination of health and pharmaceutical policy, and the existence or not of industrial policy in the pharmaceutical sector at national level. Unavoidably, conflicts arise in a situation where the above policies meet: individual countries wish to exercise their legal right and autonomy to determine their own health and pharmaceutical policy; this right is also safeguarded within the EU. Parallel distributors perform arbitrage of pharmaceuticals across countries exercising their legal right provided by the principle of the free movement of goods within the EU; and some governments have an active industrial policy in place, with the objective of attracting investment and promoting innovative research and development (R&D) in the pharmaceutical sector through minimal interventions on the pricing of medicinal products. At the heart of this policy dilemma lie the freedom in the movement of goods and the regional exhaustion of intellectual property rights,¹ the former being a cornerstone of European integration, the latter a corollary thereof and a precondition for the existence of EU parallel trade.

1.1. How does parallel trade work in Europe?

Pharmaceutical parallel trade is the result of two key stylized facts of the European pharmaceutical market.² The first is variable price regulation of pharmaceuticals. The second is manufacturers' weak vertical control over the drug supply chain (Maskus and Chen, 2002, 2004). Pharmaceutical products, once licensed for human use by regulatory authorities are subject to price or profit regulation, which varies by country, and to distribution regulations. Health insurance organizations that provide comprehensive coverage, including prescription drug coverage (Mossialos *et al.*, 2002),

¹ The legal treatment of parallel imports varies widely across countries and stems from each jurisdiction's choice of territorial exhaustion of intellectual property rights (IPRs). Under international exhaustion, rights to control distribution expire upon first sale anywhere in the world and parallel imports are permitted. Under national exhaustion, first sale within a nation exhausts internal distribution rights but IPRs holders may legally exclude parallel imports or exports. Finally, a policy of regional exhaustion permits parallel trade within a group of countries but not from outside the region. This means that, within the European context, parallel trade of pharmaceuticals is legal within the EU as well as Norway, Iceland and Liechtenstein (forming the European Economic Area – EEA), but importation from outside this area is disallowed. The legality of parallel trade within the EEA is subject to fulfilling a number of regulatory conditions pertaining to the safety of the product in question and compliance with trademark law. National drug regulatory authorities or the EU drug regulator (the European Medicines Evaluation Agency – EMEA) are responsible for ensuring that parallel imported products are compliant with existing drug regulations.

² Pharmaceutical parallel trade as is taking place in Europe has nothing to do with phenomena such as the re-importation of HIV-AIDS drugs that were originally sold at low prices to African countries, but some quantities managed to find their way back to Europe (illegally).

in most cases regulate or negotiate the prices of prescription medicines (Kanavos and Reinhardt, 2003). Following these negotiations, prices of reimbursed medicines are rigid upwards.³ Differences in regulatory practices result in differences in prices for the same product across countries and, indeed, in manufacturers' flexibility to vary their prices and respond to competition. Regulation of the supply chain implies that manufacturers cannot sell directly to consumers; instead, they supply wholesalers who, in turn, supply pharmacies. Consumers acquire pharmaceutical products at the pharmacy, upon presentation of a prescription.⁴ Wholesalers and pharmacists are paid on the basis of a margin, based on the pharmaceutical product's ex-manufacturer's price.⁵ Payment of pharmacies is based on the list price that health insurance has agreed with the manufacturer plus the pharmacist's margin. In some countries, pharmacists may also receive discounts from manufacturers which, in the UK and the Netherlands, form the most significant part of their income, but in most cases such discounts are officially disallowed.

Whereas pricing, reimbursement and distribution of medicines are regulated in individual countries, the EU-wide principle of the free movement of goods implies that if price differences exist in pharmaceuticals, then arbitrage can take place. Parallel distributors (PDs), who are licensed wholesalers themselves, observe price differences across countries and are able to purchase medicines from wholesalers in low-price (exporting) countries and sell them in high-priced (destination) countries.⁶ Product homogeneity, including a common trademark, similar presentations and packaging across European countries as well as simplified regulations for allowing parallel traded medicines to cross borders, suggests that this process results in low transaction costs for parallel distributors once product stocks have been identified.⁷ However, product stocks are not infinite and, frequently, PDs need to procure from a source that can provide sufficient quantities but not the lowest possible price. Consequently, PDs may face barriers in sourcing products on a sustainable basis.

Parallel trade in the pharmaceutical sector in Europe could thus be thought of as a 'regulation-derived arbitrage', as 'market' prices are determined from a bargaining process between health insurers and manufacturers. Whereas European jurisprudence favours parallel trade, the fact that it exists poses a number of questions, which are

³ Meaning that a separate application by manufacturers needs to be submitted to health insurance each time a price revision is requested. Such applications need to justify the reasons for the price revision and that the revision is reasonable. Price revision applications may take some time to evaluate and the outcome is not always positive for the manufacturer.

⁴ Prescription-only medicines (POMs) require a prescription to be dispensed, whereas over-the-counter (OTC) products do not. In this paper we focus on POMs dispensed at pharmacy level, which account for over 85% of the total sales of POM pharmaceutical products.

⁵ Margins are fixed by regulation and are negotiated between the relevant professional associations and health insurance organizations in each country.

⁶ However, arbitrage may result in shortages in some exporting countries.

⁷ There is extensive EU jurisprudence on this subject, particularly in what concerns the repackaging and relabelling of parallel imported medicines and issues surrounding trademark law. Each member state in the EU together with Norway, Iceland and Liechtenstein has developed its own regulations on the approval of parallel traded medicines in their territory. Similarly, the EMEA has a blueprint for pan-European licensing of parallel traded medicines.

still unaccounted for: first, what are the factors determining entry into this activity? Second, once a decision has been made to engage in parallel trade activities, what are the factors determining its amplitude? Third, what are the pay-offs from its conduct and how are these allocated, particularly in destination countries? And, finally, would parallel trade encourage price competition in destination countries, as manufacturers have greater flexibility there to adjust prices due to less regulation? These are the questions to which this paper will attempt to provide an answer.

1.2. The organization of the paper

We use proprietary data from Intercontinental Medical Statistics (IMS) on 11 European countries, six of which are destination countries for pharmaceutical parallel imports,⁸ supplemented by OECD data on exchange rates and purchasing power parities to assess the direct and competition effects of pharmaceutical PT. We develop a methodology that allows us to analyse the impact of pharmaceutical PT on individual stakeholders (health insurance, patients, pharmacy, parallel distributors, and industry) and we analyse the extent of competition in product markets that are subjected in PT; finally, we develop a panel data model that allows us to explain the overall determinants of pharmaceutical PT and the determinants of price competition in parallel importing countries. Section 2 summarizes the findings of the literature on PT. Section 3 analyses the impact of pharmaceutical PT on stakeholders and discusses the likely competition effects that arise. Section 4 investigates the determinants of PT and the impact on prices, by developing and testing a panel data model. Section 5 discusses the results and the policy implications that arise. Finally, Section 6 draws the main conclusions and discusses directions for future research. The methodological approach employed in the paper is outlined in Boxes 1 and 2.

2. A GUIDE TO THE LITERATURE

The issue of pharmaceutical PT continues to generate controversy among stakeholders and has become an issue of intense debate in the global trading system (Ahmadi and Yang, 2000; Ganslandt and Maskus, 2001, 2004). Advocates of pharmaceutical PT, such as public health authorities, are interested in medicines' affordability rather than promoting R&D abroad (Abbott, 1998) and, thus, favour an open PI regime. Whether or not parallel imports actually occur, the threat that they might do, may force manufacturers to lower prices, thus making PT a favourable trade regime (Gallini and Hollis, 1999). Opponents of PT doubt its long-term benefits (Barfield *et al.*, 1999) and support a global policy of banning it, arguing that if PI were widely allowed they would reduce profits in the research-intensive pharmaceutical sector and ultimately

⁸ Destination countries are: Denmark, Germany, the Netherlands, Norway, Sweden, and the UK; source countries for parallel trade are Spain, Italy, Greece, France and Portugal.

slow down innovation. It is also claimed that parallel distributors free-ride on the marketing and service investments of authorized wholesalers (Barfield *et al.*, 1999).

2.1. The nature of parallel trade

PT (whether in pharmaceuticals or in other industries) is tantamount to arbitrage (Ganslandt and Maskus, 2004) where different countries are involved and where the principle of regional exhaustion applies. There are differences between PT in pharmaceuticals and PT in other consumer-related industries, which arise from the peculiarities of the pharmaceutical market and the fact that it is subjected to differential regulation. Therefore, the welfare improving effects associated with the conduct of arbitrage, might not apply in the case of pharmaceuticals because of price regulation, which also inhibits price equalization across borders. Furthermore, even when price equalization takes place, some authors point out that this might affect other dimensions such as that of drug quality through lower investment in R&D (Rey, 2003; Szymanski and Valletti, this issue).

2.1.1. Price discrimination and parallel trade. Economic analysis of parallel imports treats them as a channel for overcoming third-degree price discrimination across countries (Malueg and Schwartz, 1994). Ignoring distribution issues and differing demand elasticities across countries for homogeneous goods, parallel imports may lead to uniform international prices (Richardson, 2002; Malueg and Schwartz, 1994). Economic theory predicts that in unregulated markets and in the absence of product differentiation, arbitrage would give rise to a Bertrand-type price competition leading towards a ‘race towards the bottom’ where price equalization would occur. However, the creation of exclusive territories (which by definition minimizes intra-brand competition) may be used to dampen inter-brand competition (Kenny and McNutt, 1999).

Promoting PT would remove the incentives for price discrimination; this, in turn, might lead to welfare reduction. The paper by Szymanski and Valletti in this issue discusses in more detail the various kinds of impact that this might have on aggregate welfare as well as its distribution.

2.2. Welfare implications of PT

Overall, the welfare implications of PT are ambiguous, though in practice there is widespread belief among decision-makers that PT yields benefits to society and key stakeholders responsible for the organization, conduct, delivery and receipt of pharmaceutical care, notably health insurance, physicians and patients. Yet, the scanty empirical evidence on the benefits of pharmaceutical PT as well as their allocation among stakeholders presents limitations, either because it provides a partial assessment of stakeholder benefits (West and Mahon, 2003), or because of limitations in the coverage of these studies (Linnosmaa *et al.*, 2003; Ganslandt and Maskus, 2004).

More importantly, however, there is no evidence on the determinants of PT and the impact it is having on pharmaceutical prices in importing countries. This paper addresses these two issues in the sections that follow.

2.2.1. Market equilibrium with no health insurance price regulation.

Let us consider an area consisting of two countries ($i = 1, 2$), where the same pharmaceutical manufacturer distributes, through its official national wholesaler network, an identical novel pharmaceutical product protected by a patent in both countries. Prices in both countries are subjected to varying degrees of regulation by health insurance organizations, which decide on pharmaceutical reimbursement on the basis of criteria such as the therapeutic attributes of a product (novelty), overall budget impact, and health need. For simplicity, we assume that the demand for such a product in each of the two countries is determined by:

$$x_i(p_i) = \alpha_i - \beta_i p_i \quad (1)$$

Where α_i refers to those attributes associated with demand that are not directly affected by the price, for instance, health need. Given the above demand function, then $\alpha_i/\beta_i = \bar{\omega}_i$ is the maximum willingness to pay for the drug in each country i . We assume that the pharmaceutical manufacturer operates with constant (fixed) costs (F) and consumption is normalized to one. Assuming that markets are perfectly segmented, therefore pharmaceuticals are sold in both countries independently, total welfare – conventionally an aggregation of consumer surplus ($CS_i = \frac{\bar{\omega}_i \alpha_i}{8}$) and the producer surplus ($\Pi_i = \frac{\alpha_i \bar{\omega}_i}{4} - F$) – is an increasing function of the maximum willingness to pay for such a pharmaceutical product, as well as health need and other non-price determinants.

2.2.2. Drug prices with country specific health insurance price regulation.

Pharmaceutical prices are determined by the presence of an overall regulatory framework, which has been put in place by health insurance organizations in each of the two countries. Health insurance organizations negotiate prices collectively; therefore, they act as a monopsonist, whereas the pharmaceutical manufacturer acts as a monopolist in view of its patent status for the product in question. Following Pecorino (2002), we can reformulate the welfare function in the form of a Nash bargaining process as follows:

$$[CS_i(p_i)]^\gamma [\Pi(p_i)]^{1-\gamma} \quad (2)$$

where γ_i reflects the bargaining power of each health insurer $\gamma = \{1, 0\}$, so that order conditions indicate that:

$$\frac{\Pi(p_i^*)}{CS(p_i^*)} = \frac{\gamma \Pi'(p_i^*)}{(1-\gamma)x(p_i^*)} \quad (3)$$

In the absence of parallel trade, prices will range from a purely competitive equilibrium ($\gamma = 0$) to that of a regulated monopoly ($\gamma > 0$). Differences in prices across countries $i = 1, 2$ result from differences in the price regulatory regimes that are the result of the bargaining process, such that if $\gamma_1 < \gamma_2$, then prices are reasonably free in country 2 but overly regulated in country 1, therefore $p_1 < p_2$.

Assuming now that regional exhaustion of intellectual property rights applies, then parallel trade in pharmaceuticals is allowed between the two countries. Profit maximizing parallel distributors who are able to observe prices and price differentials between the two countries perform this. In the presence of differences in price regulation, a parallel importer might arbitrage price differences and, in so doing, faces certain transaction costs (t)⁹ subject to capacity (supply) restrictions and demand limitations. The latter may be due to a share of the population still preferring the product sourced locally from the originator drug manufacturer to that of the parallel importer (Jelovac and Bordoy, 2005) because of different presentation and packaging, where that preference might be parameterized as $\rho < 1$ in the demand slope, thus reducing the maximum willingness to pay in the importing country (\mathfrak{W}_1).

Considering a new, patented product that enters the market in each of the two countries, then in the presence of parallel trade, a two-stage process can be defined. In the first stage, maximum (list) prices for the originator product (p_i^*) in each country are negotiated and agreed upon with regulatory authorities.¹⁰ These prices are used as benchmark for formulary inclusion, are fixed over a period of time¹¹ and are reimbursed by health insurance organizations, subject to any cost sharing by patients. In a second stage, a parallel importer sets the price depending on competition in this market as well as the availability of product in export countries.

If the market is competitive (and there is some deterrence by the originator) in setting unlimited volume of parallel trade then the equilibrium price for the parallel imported product in the presence of competition and equal preferences between locally sourced and parallel imported product ($\rho = 1$) will be $p^{PI} = p_i^* + t$ where p_i^* is the originator product price in the exporting country. However, given that the originator market price is supposed to be the maximum price, in the presence of some PI product while if there are no competition effects, then the 'accommodation' equilibrium is $p^{PI} \leq \rho p_2^*$.

Finally, the quantity sold by the parallel importer $x^{PI}(p^{PI})$ will depend on the size of potential consumers who are better off paying p^{PI} than p_2^* (Jelovac and Bordoy,

⁹ Those include transportation, storage, fulfilling regulatory requirements in the importation country, and providing discounts to retailers in the importation country.

¹⁰ Whereas strict price negotiation on the basis of a number of predetermined criteria is the rule, in some countries, regulatory authorities do not impose price controls, but may allow manufacturers to set prices having set a restriction, for instance, subject to observing a rate of return constraint, or demonstrating cost-effectiveness in order to justify premium pricing.

¹¹ Standard reimbursement rules suggest that freedom to modulate prices is at best very limited once their reimbursement level has been fixed. Even in countries where manufacturers are allowed to modulate prices, they have to apply for permission from the regulator, outlining the reasons for such an application.

2005) subject to a maximum arbitrage capacity (Ganslandt and Maskus, 2004). The resulting change in welfare effects,

$$\Delta W_i = \Delta CS_i(p_i^*) + \Delta \Pi_i(p_i^*) + \Delta \Pi_1^{PI} \quad (4)$$

depends on the direction of the constituent parts that affect them. Indeed, they will depend on the degree of competition in the market, the magnitude of transaction costs (t) and the extent of market regulation (γ). Other important considerations, are overall reimbursement mechanisms (β), as well as the maximum willingness to pay (ω) for the product in question.

2.3. Competition and efficiency effects of parallel trade

The literature finds a trade-off between arguments in favour of competition and patent protection on the one side and industrial policy on the other. It is also suggested that whether regulating PT is beneficial or harmful to societal welfare is also an empirical issue and depends on parameters such as demand and demand-side policies, regulation, market structure, and innovation (Linomaa *et al.*, 2003; Ganslandt and Maskus, 2001; Jelovac and Bordoy, 2005). Having accounted for the differences between countries in terms of health system (reflected in the level of patient co-payments), and in terms of drug needs (reflected in the patients' valuation for drugs consumed), PT leads to price convergence between countries, makes the individuals of the importing country better off, while making the ones of the exporting country worse off and decreases the profit of the monopoly producer. Recent theoretical work (Rey, 2003; Szymanski and Valletti, this issue) argues that product quality will fall because lower investment will be devoted to those products under PT, and therefore global welfare could fall. In addition, even though PT might contribute to the objective of short-term cost-containment, it might sacrifice profits of manufacturers and thus, arguably, funds devoted to innovation.

3. PHARMACEUTICAL PARALLEL TRADE IN EUROPE: STYLIZED FACTS AND IMPACT ON STAKEHOLDERS

3.1. Stylized facts

Central to pharmaceutical parallel trade activities is the existence of price differences in pharmaceutical products¹² across EU member states.¹³ It is not uncommon for such price differences to be to the order of 100–300%, depending on the product and the country in which it is sold (Table 1). Importantly, pharmaceutical price differences

¹² For the purposes of this analysis, 'pharmaceutical products' is taken to mean 'patented' or/and 'branded' products, although similar price differences across member states exist for generic (off-patent) products.

¹³ The introduction of the euro may have made this a less risky and more transparent venture (Kanavos, 1998, 2000), although quantitative evidence to substantiate this latter point is not available.

Table 1. Unit wholesale prices for 19 products in selected EU countries and Norway; 2002, in €^a

INN name ^b	Norway ^c	Germany	Sweden	Denmark	UK	Netherlands	Spain	Portugal	Italy	Greece	France
Atorvastatin	0.78	1.37	1.04	0.72	1.01	0.95	0.96	0.91	0.63	0.55	0.91
Pravastatin	1.25	1.63	1.00	0.98	1.67	1.04	1.58	1.11	0.91	0.66	1.07
Simvastatin	1.43	1.06	N/a	0.81	1.25	1.12	1.19	0.82	0.74	0.62	0.80
Captopril	0.48	0.28	0.21	0.46	0.58	0.54	0.26	0.56	0.30	0.38	0.61
Enalapril	0.25	0.20	N/a	0.22	0.59	0.30	0.19	0.28	0.28	0.19	0.46
Quinapril	N/a	0.45	0.49	0.37	0.38	0.88	0.19	0.36	0.37	0.27	0.53
Ramipril	0.32	0.48	0.31	0.17	0.60	0.69	0.21	0.28	0.24	0.18	0.40
Losartan	0.83	0.80	0.85	0.63	0.97	0.87	0.63	0.77	0.69	0.58	0.92
Valsartan	0.82	0.80	0.82	0.60	0.88	0.86	0.45	0.72	0.62	0.39	0.87
Clozapine	0.20	0.25	0.18	0.19	0.92	0.28	0.13	0.28	0.29	0.11	0.30
Olanzapine	4.80	5.78	5.37	3.81	5.48	5.19	3.57	3.90	3.60	3.30	4.83
Risperidone	3.98	5.54	4.08	2.68	5.21	5.47	2.87	3.22	2.93	2.25	3.65
Lansoprazole	1.37	1.84	1.15	0.85	1.33	1.93	1.07	0.90	1.53	1.05	1.68
Omeprazole	1.89	1.77	1.83	N/a	1.60	2.09	0.43	1.66	1.50	0.84	1.86
Pantoprazole	1.33	2.32	1.16	0.83	1.33	1.88	1.27	1.34	1.28	1.10	1.65
Citalopram	1.02	1.12	0.66	0.75	0.90	1.18	0.73	N/a	0.75	0.68	0.90
Fluoxetine	0.97	1.16	0.85	0.78	1.51	1.38	0.53	0.69	0.56	0.65	0.93
Paroxetine	N/a	1.16	0.90	0.91	0.93	1.11	0.80	0.86	0.77	0.69	0.90
Sertraline	1.08	1.11	1.12	0.82	0.85	1.31	0.72	0.76	0.87	0.55	0.84

Notes: ^a Wholesale prices include wholesale margins, but exclude retail margins and VAT, where applicable. The prices quoted in this table are per unit (e.g. per pill), and are adjusted by defined daily dosage (DDD) and for pack size.

^b Refers to each product's chemical (not proprietary name). Prices are for the branded product and exclude prices of generics, if these are available, following the originator drug's patent expiry.

^c Norway is not part of the EU, but as part of the European Economic Area (EEA), the same principles of parallel trade apply as in the EU.

Source: Authors' calculations from Intercontinental Medical Statistics (IMS).

are due to differences in regulatory approaches among EU member states (Danzon, 1998; Kanavos, 2002; Mossialos *et al.*, 2004). The pharmaceutical market in Europe is a regulated market. With the exception of Germany and, to a certain extent, the UK, Sweden, the Netherlands and Denmark, free pricing or premium pricing for in-patent pharmaceuticals is not allowed or is allowed subject to satisfactory proof of clinical cost-effectiveness. Health insurers providing universal coverage on behalf of their members, either negotiate a price ceiling with manufacturers, or set prices on the basis of a predetermined pricing formula and a number of additional criteria. Pricing and reimbursement (P&R) negotiation is, therefore, a two-part bargaining process comprising a monopoly (manufacturer) and a monopsony (health insurer) and includes elements such as the extent of product therapeutic benefit, budget impact analysis, prices of the same molecule in other countries, cost-effectiveness, industrial policy considerations and affordability or willingness to pay (Kanavos and Gemmill, 2005). Pricing formulae used in negotiations with national authorities include average pricing, reference pricing, cost-plus pricing, and rate of return on capital among others (Danzon, 1998). Price increases are usually disallowed and may be considered, but are not always approved, by health insurance. Frequently, there is downward pressure on prices by health insurance if the drug budget is exceeded, which can manifest itself by unilateral action in the form of price cuts, price freezes, or payback clauses directly payable by manufacturers. The emphasis on and approach to regulation is not uniform among EU member states and that explains the differences in price levels for reimbursed pharmaceuticals. Additionally, as a result of regulation, prices are least responsive to exogenous pressures.

In this environment, parallel trade has expanded in recent years and has reached a significant proportion of total national pharmaceutical expenditure in many countries (Table 2). Official sources suggest that the total share of parallel imports was almost 20% of the UK market, 14% of the Dutch market, 10% of the Danish and Swedish markets, and 7% of the German market in 2002. By contrast, parallel exports represented 16.7% and nearly 22% of the Greek market in 2000 and 2002 respectively according to official estimates (Kontozamanis *et al.*, 2003). Price fixing and the concomitant price rigidity imply that price equalization or approximation from parallel trade as predicted by the theory of arbitrage are not occurring.

Governments and health insurance organizations in high-price countries are promoting directly or indirectly the use of parallel imported pharmaceutical products in search of savings to their total healthcare budgets. Promotional policies relate to directly encouraging the dispensing of PI products via incentives. Denmark, Germany, the Netherlands, Norway, Sweden and the UK, which are considered to be high-price countries and, therefore, significant parallel importers of pharmaceuticals, have such policies in place (Table 3). Most of these policies aim to directly influence the dispensing behaviour of pharmacies. In most European countries pharmacies are reimbursed on a fixed margin basis and, consequently, would require additional explicit incentives to dispense a PI medicine. The exceptions to this rule are the UK and the Netherlands,

Table 2. Market value of pharmaceutical parallel imports and their share as a percentage of the total prescription pharmaceutical market in selected EU countries, 1997–2002^a

Country	1997	1998	1999	2000	2001	2002
Sweden (SEK m)	270	1,012	1,402	1,732	2,011	2,309
	1.9%	6.2%	7.7%	8.6%	9.3%	10.1%
Denmark (DKK m)	554.6	656.2	700.3	781.4	835.5	917.2
	9.1%	10%	10%	10.2%	9.9%	9.7%
Germany (€ m)	216.7	256.6	331.1	504	800.3	1,296.3
	1.7%	1.9%	2.3%	3.2%	4.7%	7.01%
Greece ^b (€ m)	14.0	107.0	173.7	308.1	514.3	556.7
	0.9%	7.7%	10.7%	16.5%	24.4%	21.6% ^c
Netherlands (€ m)	357	363	374	365	424	456
	14%	14%	14.5%	13.5%	14.3%	14%
UK (£ m) ^c	na	462	633	749	1,076	1,346
	na	9.5%	11.9%	13.6%	17.1%	19.8%

Notes: ^a Data and information are not available for a number of countries as follows: (a) in France, the regulatory framework allowing parallel imports was set up in 2004; data for parallel exports were not available; (b) in Italy, as of June 2003, there were four registrations for parallel imports; data on parallel exports were not available; (c) in Portugal, there are no official data for parallel imports or parallel exports; (d) in Spain, there are no official data for parallel imports or exports; as of 2003, there were two parallel imported pharmaceuticals, one from France and one from Greece.

^b Data for Greece relate to pharmaceutical parallel exports.

^c Official UK data (from the Prescription Pricing Authority) does not identify parallel imported products.

Sources: Direct communication with experts in the following organizations: Sweden: Institute of Health Economics (IHE), 2003; Denmark: Association of the Danish Pharmaceutical Industry (LFN), 2003; Germany: Research Foundation of Social Insurance (AOK), 2003; Greece: Social Insurance Organisation/Hellenic Industrial Research Organisation (IKA/IOBE), 2003; The Netherlands: Foundation for Pharmaceutical Statistics (SFK), 2003; UK: Intercontinental Medical Statistics (IMS) estimates, 2003.

Table 3. National policies favouring parallel importation of pharmaceuticals in EU member states, 2004

Incentive structure	Denmark	Germany	Netherlands	Norway	Sweden	UK
All or most of the visible financial benefit to the health system accrues to health insurance	Y	Y	Y	Y	Y	Y
Clawback or indirect benefit to health insurance	N	N	Y	N	N	Y
Financial incentive to pharmacy (explicit or implicit)	N	N	Y	Y	Y	Y
Penalty to pharmacy	N	Y	N	N	N	N
Other policy towards pharmacy	Y	N	N	N	Y	N
Consumer benefits	Possible	None	None	Possible	Possible	None

Source: Adapted from Kanavos, Gross and Taylor (2005).

where pharmacies receive a fixed fee from health insurance, but the majority of their income comes from wholesaler industry discounts; consequently, they will have an incentive to dispense the product that carries the highest discount.

In all six countries, health insurance benefits directly from the difference between the price in the locally sourced and the parallel imported branded product. For this to take place, parallel imported products must have a market share, that is, they need to be dispensed by pharmacies. This is typically encouraged either explicitly or implicitly. An explicit incentive would be for health insurance to directly share the price difference between locally sourced and PI medicine with the pharmacy. In the Netherlands and Norway, part of the price difference is allocated to pharmacies (one-third of the price difference in the Netherlands and one-half in Norway) as a direct incentive to dispense PI products and favour them over locally sourced equivalents. In Sweden, the county councils, responsible for administering the drug budget, also award a one-off bonus payment to Apoteket, the Swedish pharmacy network, at year-end to compensate them for their work on generics and PI drugs. In 2002 Apoteket received a total of SKr50 million (€5.5 million) extra for their additional work with generics and PI.

In addition to the explicit financial benefits from the price difference between locally sourced and parallel imported drugs, health insurers in the UK and the Netherlands realize indirect financial benefits from what is known as the clawback. The clawback is a mechanism whereby sickness insurers ensure that a share of the discounts pharmacists receive from wholesalers are passed on back to them as savings. In the UK, the Department of Health (DoH) takes into consideration the 'Discount to Pharmacy' given by the wholesaler or parallel distributor to the pharmacist. Chain pharmacies are excluded from the inquiry. The DoH refunds the pharmacist based on the NHS price level minus a clawback, which currently ranges between 6.51% and 13.2% depending of the number of prescriptions dispensed each month. Most pharmacies fall into the 10.44% bracket.¹⁴ Given the flat fee structure of the clawback relative to the number of prescriptions, pharmacies have an indirect incentive to procure more from parallel distributors, or, indeed, obtain the so-called 'price-equalization' deals from official wholesalers, as they can keep a significant proportion of the overall discount given. If pharmacies achieve a higher discount than the clawback, they can keep the difference. Other than discounts given to pharmacies, PI pharmaceuticals do not have an incentive to be priced lower than the list price. By dispensing more PI drugs pharmacies increase their revenue, while keeping the returns to the DoH unchanged through the fixed clawback scales. This, of course, may have an upward knock-on effect on future clawback scales, but this would have prospective rather than

¹⁴ Every pharmacy in the UK, whether it uses parallel-distributed products or not, is subject to the clawback. The exceptions to this case are the 'zero discount scheme' products in the drug tariff. This scheme applies to products that have a high cost for wholesalers in terms of storage and distribution. It affects about 500 products including 300 fridge-lines (e.g. vaccines), expensive items such as betaferon and controlled drugs that require extensive record keeping. For these products the wholesalers do not discount the product to the pharmacist and the DoH reimburses the pharmacist at NHS-price level without deducting the clawback.

retrospective action. According to one source, the Department of Health estimates for 2001–2002 placed savings from this activity at £100 million (€143 million) (Macarthur, 2003), whereas other estimates elevate the impact of the clawback from parallel imports to the sum of £134 million (€192 million) for 2002 (West and Mahon, 2003). In the Netherlands the clawback stood at 6.82% of pharmacies' reimbursement claims until September 2003 and increased to 8% subsequently. This still provides pharmacies with a financial benefit as they achieve discounts on PI medicines in the region of 20% off list prices from parallel distributors. Discounts on PI medicines are substantially higher than those on locally sourced brands (7%). Evidence suggests that total savings to Dutch sickness funds from the clawback amounted to €68 million in 1999.

In Germany pharmacies do not have incentives to dispense PI medicines but they are subjected to penalties if they do not. The sickness funds and the association of pharmacists have agreed upon a PI quota for the latter to dispense in a given year. This quota is based on pharmacies' overall turnover with the sickness funds and describes the share that dispensed, imported pharmaceuticals take of the pharmacy's revenue as a proportion of all non-imported pharmaceuticals. The quota was implemented in April 2002 and was set at 5.5%, but increased to 7% with effect from January 2003. Sickness funds receive all the financial benefits from price differences between LS and PI medicines. If pharmacies fail to meet their quota, they may be penalized and their reimbursement bill is reduced accordingly. If pharmacies exceed the quota they receive a credit, which can be used to settle the pharmacy's bill when the import quota is not reached, but there is no cash benefit to pharmacists.

There also exist other policies towards pharmacies. In Denmark and Sweden, although there has been increased focus on PI and a clear promotion of PI pharmaceuticals, the direct interventions from the perspective of the respective governments toward PI have been focusing on substitution at pharmacy level. In Denmark, pharmacies are legally bound to inform patients of the availability of the cheapest PI drug when savings reach up to 5% on a prescribed product, but all savings from PI dispensing accrue to the Danish health service. In Sweden there exists a substitution policy in place at pharmacy level that includes both generic and PI products. In both cases, this gives pharmacists the right to substitute for a generic or a PI product should either of these be available, in lieu of a branded product.

Finally, in environments that provide comprehensive health insurance coverage (including a prescription drug benefit) with low co-payments and significant exemptions from paying these, patients have no incentive to seek cheaper alternatives for their prescription medicines. Indeed, in Germany, the UK and the Netherlands, patients do not benefit directly, but may benefit indirectly, through savings made by health insurance, provided such savings are used to purchase care more cost-effectively. In Denmark, Norway and Sweden, the direct benefits to patients are marginal. The differences in national cost-sharing policy can explain the respective differences in patient benefits. Flat fee co-payments as they apply in the UK (per prescription item)

and Germany¹⁵ (per prescription item depending on pack size) do not make patients aware of the cost of medicines; therefore, no benefits exist from consuming PI drugs. In the Netherlands there are no co-payments for prescription medicines.¹⁶ In Norway, Denmark and Sweden, patients pay a combination of co-payments, including an annual deductible and a percentage of the cost of their medicines (cost-sharing) up to a limit beyond which health insurance covers the entire cost. There are, however, significant exemptions, on the basis of age and type of illness. In these countries, the financial impact on patients is proportional to the price difference between the LS and PI drug.

While the above policies clearly provide incentives in high price countries to enhance PI consumption, the situation in parallel exporting countries (predominantly Spain, France, Greece, Italy and Portugal) is often perceived to be the opposite, although this is never stated explicitly because it would otherwise be perceived to be a barrier to the free movement of goods, including pharmaceuticals. Countries such as Portugal and Italy have in recent years changed their pricing regulation to explicitly adopt a price for reimbursed medicines which is close to the average European price for these medicines. France has also moved into the direction of allowing free pricing for highly innovative products. Although these movements are not in response to parallel exports, they may influence their extent. Spain and Greece also require wholesalers to register and report the destination of their products, and to keep a stock at 25% more than historical demand, respectively.

Despite the fast rise in pharmaceutical parallel trade in recent years and the adoption of policies encouraging their use, this has not been without barriers. First, a parallel traded product needs to be approved and licensed by national regulatory agencies (or the EMEA for EU-wide distribution) in order to safeguard product safety. The European Court of Justice (ECJ) has simplified procedures and an application for parallel importation can be approved within weeks. Second, the nature of the pharmaceutical distribution chain suggests that obtaining market share requires a minimum scale of operations: parallel distributors (PDs) must be in a position to supply a significant number of products to local retailers and on a sustainable basis from their source countries, otherwise they risk not becoming a preferred wholesaler and increase retailers' costs of compliance. Third, given the fragmented structure of European wholesaling, parallel distribution requires the establishment of a large network of national wholesalers from whom quantities of medicines can be purchased at low prices and imported in high price countries. Fourth, manufacturers are increasingly in a position to control their distribution chain in all countries where they operate¹⁷ and this means that finding extra quantities for parallel exportation is becoming

¹⁵ As of January 2004, co-payment policy has changed in Germany, making it a co-insurance rather than a flat fee per pack. This also changes the likely benefits accruing to patients since the introduction of co-insurance is likely to provide small financial savings to patients per prescription.

¹⁶ Other than patients having to pay the difference between the reference drug and the drug of choice, should the former not be the patient's drug of choice.

¹⁷ The ECJ ruled in favour of implicit control of supplies in January 2004 in the Bayer Adalat case.

increasingly difficult. Fifth, there may be other barriers to entry relating to the perception of parallel imported (PI) products among consumers; while the active ingredient is identical in both cases, the packaging, language and presentation may be different to what consumers are used to. This has led to an eventual simplification of product packaging, labelling and patient insert requirements, which, in turn, facilitate parallel distribution.

3.2. The impact of pharmaceutical parallel trade on stakeholders

Beyond benefits accruing to PDs from this activity, there is widespread perception that pharmaceutical PT can yield significant benefits to statutory health insurers who are responsible for reimbursing the cost of medicines and are interested in macroeconomic efficiency. Yet, little is known about the effect PT is having on key stakeholders (i.e. insurers, patients, pharmacists, PDs and industry).

3.2.1. Data sources. In order to measure the impact of PT on stakeholders, we used data from Intercontinental Medical Statistics (IMS) and focused on six therapeutic (product) categories, (proton pump inhibitors (PPI), HMG CoA reductase inhibitors (statins), ACE I inhibitors, ACE II inhibitors, SSRIs, and atypical anti-psychotics). The selection of these categories was based on the fact that they provide (a) a large number of high-volume and high-price products across several therapeutic categories,¹⁸ and (b) the product mix ensures that there are branded in-patent medicines not subjected to generic competition, branded off-patent medicines subjected to generic competition, products that are subjected to parallel trade, and products that do not face parallel trade at all. For each product and product formulation within these product categories, quarterly data was obtained on market shares, prices, sales, and volumes (in terms of packs) sold. All monetary (price and sales) figures were expressed in euros (€). Our study countries are Denmark, Germany, the Netherlands, Norway, Sweden and the UK. Due to their high relative price levels they are destination countries for parallel imports. We are also in a position to distinguish between market shares of volumes, sales, and prices of LS and PI products respectively in these countries. We also considered prices for the selected products in a number of lower price, parallel exporting countries, namely France, Greece, Italy, Portugal, and Spain. These countries were added in order to capture the price spread between themselves and the destination countries. The selected product mix accounted for 21% of the retail (pharmacy) pharmaceutical market in the study countries. By being able to observe prices in exporting countries, prices for LS products in destination countries, as well as prices of PI products in destination countries, it was possible to calculate the price variability and spread between LS and PI medicines. This further enabled the calculation of savings to health insurance organizations and patients from the

¹⁸ These categories include very widely prescribed life-saving and very effective products for severe chronic conditions, such as (peptic and duodenal) ulcer, depression, hypertension, angina, prevention of heart disease, hyperlipidemia, and schizophrenia.

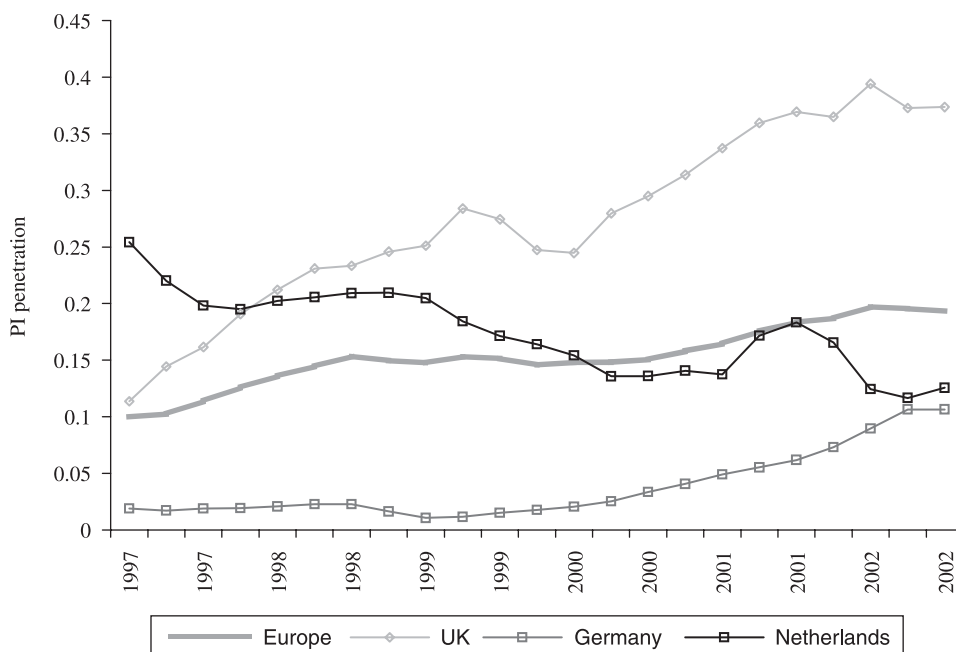


Figure 1. Market share of parallel imports in selected European countries;^{a,b,c} 1997–2002

Notes: ^a The countries included here are: Denmark, Germany, the Netherlands, Norway, Sweden, and the UK.

^b Parallel import sales from 19 high-volume products selected across 6 product categories and expressed as a proportion of total sales for these products.

^c “Europe” comprises the market share of parallel imports of the six product categories in all six countries.

Source: Authors’ compilations from IMS.

prescribing and use of PI products over LS ones. It was also possible to calculate target revenues for pharmacists as well as gross profits for parallel distributors and losses to the pharmaceutical industry. Box 1 outlines the methodology implemented to calculate these effects.

3.2.2. Direct effects of parallel trade on stakeholders. Overall, the share of PI in the six product categories and in all six countries has increased over time, from about 12% for the six product classes in 1997, to just under 20% in 2002 (Figure 1). Variations can be seen within countries, most importantly the UK, Germany and the Netherlands, which have the highest PI potential in Europe. Germany experienced significant increases in PT post-2000, from about 3% of the pharmacy market, to 10% by the end of 2002 (Figure 1). In the UK, the relevant market share is over 35% in 2002 increasing from 15% in 1997, whereas in the Netherlands an overall decline is observed over the study period and for the six product categories from an average of 21.7% in 1997 to 14% in 2002.

The impact of PT on key stakeholders (patients, pharmacies, health insurance, parallel distributors and industry) is summarized in Table 4. Our sample represents

Box 1. Data sources, price differentials and stakeholder effects

Data: Sales and pricing data on six therapeutic (product) categories (proton pump inhibitors (PPI), HMG CoA reductase inhibitors (statins), ACE I inhibitors, ACE II inhibitors, SSRIs, and atypical anti-psychotics), from Intercontinental Medical Statistics (IMS).

Accounting for different prices: of the pricing data provided, the price for each presentation (dosage and pack) was identified and, subsequently, three sets of prices were computed for each product presentation. The first was the price of the locally sourced (LS) original product in the destination country, P_{it}^{orig} , namely the public price used by health insurance organizations for reimbursement purposes, where i denotes product and t denotes (destination) country. The second is the parallel import price of the same product presentation, P_{it}^{PI} , again in the destination country. This is the price that parallel importers sell at in the destination country and is, in the majority of cases, different (and lower) than the price of the locally sourced original. Being faced with several parallel distributors per product presentation, we took the average price of all presentations in order to arrive at the parallel import price per presentation. Differences in prices for the same presentation among different parallel distributors are negligible, suggesting little price competition among parallel distributors for the same product.

Finally, we considered the three lowest prices among potentially exporting countries for exactly the same product presentation as in the destination country for the brand product (P_{it}^{orig*}). These prices would provide a strong indication of the most likely source from which parallel distributors would obtain their supplies. It is assumed that parallel distributors are rational agents acting as profit maximizers and would consequently procure from the cheapest source(s) possible, provided that these sources are of adequate size to cover demand in destination countries and have available product in stock.

Within each destination country, and when comparing the prices of locally sourced product presentations with those of PI presentations, we matched product presentations precisely (dosage and pack sizes); this meant, for example, that the 10mg/56 pack of LS olanzapine, was matched with the same strength and pack of PI olanzapine. In the very few cases (one in Germany and two in Norway) where this was not possible, we recalculated prices by adjusting for the number of pills in each presentation.

Price variability: taking into account LS prices, export prices, and PI prices, enabled the construction of indices of price variability and price spreads (the latter in €). These indices and price spreads were calculated to capture the difference between PI prices and LS prices within each country and the

difference in prices of original products among countries (inter-price variability and spread). Inter-price variability (and inter-price spread) was computed as the difference between the PI price in a country and the prices of the three cheapest parallel exporting countries ($P_{it}^{PI} - P_{it}^{orig*}$). On the other hand, the intra-price variability enables to calculate the absolute (relative) savings to the NHS per pack sold in a specific market ($P_{it}^{orig} - P_{it}^{PI}$).

Savings to health insurance: the price variability indices enabled the precise calculation of direct savings accruing to health insurance organizations as the sum of two effects: first, the effect of price difference (intra-price spread) between LS and PI product for PI volume and, second, the effect of any likely clawbacks arising from governments or statutory health insurance organizations appropriating a proportion of pharmacy benefits from more efficient pharmacy purchasing.

As Denmark, Germany, Norway, and Sweden do not have clawback mechanisms in place, the savings accruing to their statutory health insurance systems would arise purely from the intra-price spread. For the UK and the Netherlands, where clawback schemes are in place, their effect was calculated separately, despite little information being available about the average discounts given to pharmacists for the selected products. For the UK, the calculation of the clawback was based on macro level data collected from government sources. Savings to health insurance are, therefore, given by the formula:

$$S_{it} = q_{it}^{PI} (P_{it}^{orig} - P_{it}^{PI})$$

Total revenues and gross profits to parallel distributors: the total gross turnover of parallel distributors is equal to the volume they sell in the destination country, multiplied by the price they sell at and which, in the majority of cases, is lower than the price of LS original. From the stream of revenues, we were also able to arrive at the likely profits that parallel distributors make from their operations. Prices in the three lowest price EU countries were taken and the analysis was based on the assumption that a destination country was served entirely by either of these countries and that exporting countries had the spare capacity to do so.

The prices taken were at wholesale level, as parallel distributors observe these prices, since they purchase primarily from wholesalers in exporting countries, or are wholesalers themselves. Gross profits were thus calculated by subtracting the total revenues in case the volume of PI drugs would have been served with original products the expenses that parallel importers face when purchasing the drugs in the three cheapest countries. Gross profits (π) were calculated as:

$$\pi = q_{it}^{PI} (P_{it}^{PI} - P_{it}^{orig*})$$

The foundation for this argument lies in that parallel distributors observe and acquire the entire difference between acquisition price (in potential export countries) and selling price (in destination countries). While this remains true, it is also true that they incur certain costs to bring the PI medicines onto the market in destination countries. These are either sunk costs (e.g. regulatory costs incurred once in a product's lifetime, are related to the process of approval and cost on average \$1,200–2,000 per product depending on the country in which an application is submitted), or other costs, especially, transport, relabelling and distribution costs. As European legislation allows PI medicines to be distributed in the packaging of their country of origin, repackaging costs are modest and so are transportation costs for entire consignments of medicines. Warehousing and distribution costs may vary, depending on whether parallel distributors already run distribution networks or piggy back on mainstream wholesalers' distribution networks, or, indeed, need to set up their own.

Pharmacy benefits: margins, the main method of reimbursing pharmacy services, are regulated throughout the European Union, with the exception of the UK and the Netherlands, where pharmacists are paid on the basis of a flat fee per prescription plus revenue from discounts obtained from wholesalers. In the case of pharmaceutical PI, pharmacy benefits are equal to the financial incentives provided to them from government or health insurance organizations to dispense PI drugs plus any discounts which they receive from wholesalers/parallel distributors. When a clawback exists, then the pharmacy benefits from the marginal discount, i.e. the difference between the discount offered by the wholesaler/parallel distributor for each product minus the effect of the clawback, which is the case in the UK and the Netherlands.

Patient benefits: patient benefits from parallel trade are directly related to the price difference between LS and PI products, the type of co-payment in place, and the extent of exemptions. For Germany, the UK, and the Netherlands, as co-payments are not related to the cost of the dispensed medicine*, direct patient benefits are zero, regardless of whether there are price differences between LS and PI products. In the cases of Denmark, Norway, and Sweden, where price differences between LS and PI products are positive and where a co-insurance system exists, among others, direct patient benefits may be positive, although negligible, due to patient exemptions from cost-sharing.

Impact on pharmaceutical manufacturers: manufacturers incur a loss in profitability equivalent to the price difference between export country and destination country (list prices) times PI sales volume in each country. As mentioned above, this is redistributed among health insurance organizations, pharmacies and parallel distributors.

* For Germany this was the case until the end of 2003.

Table 4. Aggregate net benefits from pharmaceutical parallel trade on stakeholders (in € million), 2002

	Norway	Germany	Sweden	Denmark	UK	Netherlands	All 6
Total sales at PPP € million	196.4	2,208.3	353.7	138.7	1,972.3	524.9	5,394.2
Total PI penetration (%)	18.3	13.5	31	28.1	27.4	19	25
Price spread between locally sourced and PI medicines (%)	2.5	6.7	2.2	8.4	0	15.8	Na
Total impact of PT ^a € million	13.6	115.7	22.2	10.4	524.9	68.8	755.6
Parallel distributor maximum revenues € million	12.4	98.0	18.4	7.4	469.0 ^b	43.2 ^b	648.4 ^b
Parallel distributor mark-ups	46	53	60	44	49 ^b	44 ^b	53
Health Service Savings if elasticity of demand is 0; in € million	0.6	17.7	3.8	3.0	55.9 ^b	19.1 ^b	100.1 ^b
Savings as % market if elasticity of demand is 0	0.3	0.8	1.3	2.2	2.8 ^b	3.6 ^b	1.8 ^b
Health service savings when elasticity of demand is -0.33; in € million	0.75	23.6	5.01	4.0	55.9 ^{b,d}	25.4 ^b	113.9 ^b
Savings as % market when elasticity of demand is -0.33	0.4	1.1	1.4	2.9	2.8	4.8	2.1
Pharmacy revenue from parallel distribution; in € million	0.6	0	0	0	Positive	6.4	6.9
Pharmacy revenue as % of market	3×10^{-4}	0	0	0	N/a	1.2	0.13
Patients	N/a ^c	0	N/a ^c	N/a ^c	0	0	0
Ratio of benefits to parallel distributors/health insurance savings	22.66	5.53	4.89	2.46	75.22 (8.4) ^b	4.01 (2.26) ^b	16.01 (6.48) ^b

Notes: ^a Or, equivalently, net loss to pharmaceutical manufacturers (producer loss).

^b Including the effect of the clawback. In the UK these are estimates only.

^c The impact on patients depends on the cost-sharing policy affecting each drug and the type of patient, i.e. whether the latter pays co-payments or is exempt due to age or illness.

^d Savings are unaffected by virtue of the zero price difference between locally sourced and PT medicine. The reported figure corresponds to the clawback.

Source: Authors' compilations from IMS.

21% of the total prescription drug sales in the six study countries at retail (pharmacy) level. Of these sales, PI penetration was 25% of total retail brand sales in 2002. Overall, the price spread between locally sourced and parallel imported products in destination countries is small and is, on average, 6.4% ranging from 0% (UK¹⁹) to 15.8% (the Netherlands). On a product-by-product basis this spread does not exceed 8% in the majority of cases.

With regard to patients, the financial impact is proportional to the price difference between LS and PI drugs. This impact is on average 2.5% in Norway, 2.2% in Sweden and 8.4% in Denmark, while in other countries it is zero (Table 4).

Pharmacists have financial benefits ranging from modest to moderate, first, where incentives exist to dispense PI medicines and, second, where the wholesale/retail market does not operate on the basis of fixed margins.²⁰ The Netherlands and Norway are representative of how financial incentives can provide benefits to pharmacies, but the total income to pharmacies is modest (close to 0% and 1.2% of total prescription drug costs in Norway and the Netherlands, respectively). The UK and the Netherlands are only two examples in the EU of drug distribution markets operating without fixed margins. In both cases, revenues to pharmacies are product-related and difficult to calculate with accuracy because discounts from wholesalers to pharmacies are confidential, but thought to be positive and significant.

The overall savings to health insurance organizations are modest both in absolute and relative terms and amount to €100 million including the effect of the clawback in the UK and the Netherlands, or 1.8% of total brand retail sales in the six countries. Few products generate significant savings to health insurance, and, concurrently, few products yield significant benefits to parallel distributors; three products account for over 50% of savings to health insurers (simvastatin, risperidone, and paroxetine). The total impact of PT on the cost of medicines to health insurance is very modest and ranges from 0.3% in Norway, to a maximum of 3.6% in the Netherlands. It appears that the existence of policies or incentives encouraging the use of PI medicines affects the absolute and relative size of the impact on health insurance. Examples of this are the UK and the Netherlands with the clawback. Of the financial impact of PT on insurance in the UK and the Netherlands, 87.7% and 33.2% respectively is related to the clawback, a national policy allowing government to retain a proportion of the discount offered to pharmacies by wholesalers and parallel distributors. The clawback boosts savings to health insurance in the UK and the Netherlands to 2.8% and 3.6% of the prescription drug market respectively, compared with 0.3% and 2.2% without it respectively.

¹⁹ There is no incentive for PI prices to be different than those of locally sourced products in the UK, as the NHS will reimburse the list price for all products, but will claw back a certain proportion from pharmacy reimbursement due to discounts granted by wholesalers or parallel distributors to pharmacists. Therefore, whereas price differences are zero for list prices of locally sourced and PI products, the latter usually carry a higher discount to pharmacy than the former, making them more attractive for pharmacists to dispense.

²⁰ It should be recognized, however, that even when fixed margins are in operation, there is still an opportunity for informal discounts to take place between wholesalers/parallel traders and pharmacies; these may be quantitative in nature (buy one get one free), which would make the quantification of their impact even more difficult.

We find that the majority of financial benefits from conducting PT accrue to parallel distributors (€648.4 million) with three products accounting for 60% of these benefits (simvastatin, atorvastatin, and olanzapine). The total loss of producer surplus for 21% of the brand retail market in the six country studies was calculated to be €755 million at pharmacy purchase prices (wholesale prices), whereas the total impact on industry of PT was estimated to be between €1.9 billion and €3.8 billion.²¹ Of this, 85% accrues to parallel distributors, 13.2% accrues to health insurance organizations, and the remainder (approximately 1%) to pharmacies.²² The ratio of gross revenues to parallel distributors over savings to health insurance is 6.48.

The above discussion of gains to health insurance organizations is based on the assumption that prices and quantities are unchanged in the presence of PT; therefore, a perfectly inelastic demand curve is assumed. There is increasing evidence on how drug benefits affect the price elasticity of demand for pharmaceuticals. For instance, Mortimer (1997) finds that demand for prescription medicines in the self-paid sector is the least price elastic, despite the fact that patients must pay for the entire cost of drugs. Grootendorst *et al.* (1997) find that, in the Canadian province of Ontario, the elasticity of demand for medicines for persons with lower health status (two or more chronic health problems) was -0.11 to -0.13 . Leibowitz *et al.* (1985) report, on US data, that the demand for prescribed medicines declines with higher co-insurance rates. Although their study did not explicitly estimate the impact of drug prices on demand, it did suggest that insurance affected consumer demand for pharmaceuticals. Patient level studies have revealed elasticities ranging from close to zero up to -0.33 . In a study of Medicare HMO enrollees, Johnson *et al.* (1997) produced an elasticity of only -0.01 for a co-payment increase of US\$1–3 and -0.12 for a co-payment increase of US\$3–5. In a study of retired Oregon public employees, Gardner *et al.* (1997) produced an overall elasticity of -0.23 when the co-payment was increased from US\$5 to US\$8 for generics and US\$10 for brand name drugs. When the co-payment was further increased to \$10 and \$15 respectively, the elasticity was -0.38 . In the UK five studies (Hughes and McGuire, 1995; Lavers, 1989; O'Brien, 1989; Ryan and Birch, 1991; and Smith and Watson, 1990) produced elasticity estimates for prescription drug use between -0.02 and -0.33 .

While it would be impossible to test what might have happened to the demand for pharmaceuticals in our sample in the absence of PT, the results from the empirical patient-based literature suggest that the price elasticity of demand for pharmaceuticals

²¹ In assessing the overall financial impact we have taken into account, first, the extent to which our product sample is over- or under-representative of parallel trade and, second, the weight of the sample in the total prescription medicines market. The latter determines the upper boundary for estimating the total impact of parallel trade, whereas the former determines the lower boundary. With regard to the upper boundary, we arrived at the reported figure by means of linear extrapolation. Estimates for the lower boundary were based on secondary sources and government data in the UK, Germany and the Netherlands. According to these, the six product categories we have analysed account for almost 40% of the total parallel trade in these countries.

²² Excluding, as discussed earlier, the effect of 'differential discounts' in the UK, which form part of pharmacies' income after the clawback has been deducted.

ranges between zero²³ and -0.33 . If we consider the former to be the lower bound for savings accruing to health insurance organizations, then the latter provides the upper bound. We have recalculated the savings to health insurance based on this assumption and included the results in Table 4.

The size of the financial benefit should be commensurate with the volume of PI medicines consumed. However, some empirical evidence from Finland contradicts this (Linnoosmaa *et al.*, 2003) and similar evidence from Sweden suggests that benefits from price competition are product specific and are on many occasions negative (Persson *et al.*, 2003). Both results are consistent with theoretical predictions that the direction of welfare effects from price competition is ambiguous (Malueg and Schwartz, 1994) although there is little empirical evidence on the welfare effects. Moreover, it has been argued that these can be significant and that lower prices due to PT improve patient access (West and Mahon, 2003). The benefits are both direct, through lower co-payments, and indirect, through savings passed on to them by health insurers. Finally, PT might have an impact on the pharmaceutical industry. Proponents of (pharmaceutical) PT have argued that it does not affect the ability of industry to operate profitably and does not harm its innovative capacity because it affects a small part of the market. Standard microeconomic theory also postulates that the loss to producer surplus forces producers (industry) to become more efficient (Varian, 1989a, 1989b). There are, however, suggestions that this may not apply to research-based industries such as pharmaceuticals (Danzon, 1998; Varian, 1989b). Furthermore, in the long run one might well find a trade-off between static and dynamic efficiency, in other words, how the likely short-term gains from parallel trade in medicines are valued vis-à-vis the likely long-term impact of parallel trade on drug R&D (Valletti and Szymanski, 2003).

3.2.3. Price competition from PI within importing countries. In principle, PI should be a competition-enhancing tool given that parallel imported drugs appear as substitutes of locally sourced drugs over the long term.²⁴ In this case, health insurers should benefit over the long term from better price deals in *both* LS and PI pharmaceuticals. From an economic standpoint, this would also imply a rather competitive PI market structure with parallel distributors engaging in competition among themselves and undercutting each other by offering better price deals to pharmacies and, by extension, health insurance. It is also possible that the original manufacturer may engage in price competition as well.

²³ Conceptually, the assumption of an inelastic demand can be explained as follows: the comprehensive nature of insurance coverage for prescription medicines means that patients are either unaware of the cost of medicines, or face marginal cost-sharing with generous exemptions and are, therefore, insensitive as to price variation. Similarly, physicians, responsible for all prescriptions cannot explicitly favour PT drugs and have, in most cases, no incentives to save money on prescribing budgets. While this suggests a very inelastic demand for pharmaceuticals as to price, the fact remains that this cannot be validated robustly; therefore, the estimates produced in the previous sections should be considered as (upper) bounds on the gains from trade.

²⁴ Assuming that patients' perception of a locally sourced and a PI pharmaceutical is exactly the same. This may not be the case, if the PI product has not been repackaged in the destination country, or the colour (or shape) of the pill/capsule may be different between export and destination country.

Under the assumption of homogeneity, (pharmaceutical) PT would be expected to result in price competition in destination countries, which may lead to an overall price reduction in (pharmaceutical) prices, and which, in turn, may have measurable and positive impact on payers and consumers over the longer term.

In order to examine whether parallel trade has any impact on prices in importing countries, we first of all analysed the competition patterns in five of the most selling PI products in each of the UK, the Netherlands and Germany, which are considered to be mature PI markets. In an environment where the top selling PT products have seen their market shares over locally sourced equivalents rise over time, this would provide an indication of the extent of price movements. Subsequently, having accounted for the mix of products in each of the six countries, we estimated the relative price changes for all products between the base year in our sample (1997) and the final year (2002). This would enable us to consider the (price) effects of parallel imports in each of the study countries.

By analysing competition patterns in five of the most selling products in three study countries, we find that, in the majority of cases, the difference between the highest and lowest parallel distributors' price does not exceed 7%, with the sole exceptions of simvastatin and risperidone in the Netherlands, where the spread between highest and lowest PI price is 11% and 13.3% respectively (Table 5). In the majority of cases, the distributors with the largest market share are those with prices towards the lower end of the spectrum, or those with the lowest price in the range. Prices of LS equivalent products have nevertheless increased over time in each of the three countries shown in Table 5, except for molecules affected by patent expiries and generic market entry despite seeing their domestic market share declining in the presence of parallel imports. Small price differences between LS and PI drugs, combined with the significantly lower acquisition prices by parallel distributors (as shown in Table 1) suggest that there may be little competition in products subjected to intensive parallel distribution. This, however, is by no means conclusive evidence that arbitrage has little or no effect on prices of locally sourced drugs; indeed, it may suggest that arbitrage is keeping prices and price increases within a certain range. Empirical evidence across a wide range of pharmaceutical products in Sweden and Finland, suggests that the average price change of parallel-imported goods and the original manufacturer's price is the same, (Ganslandt and Maskus, 2001; Linnosmaa *et al.*, 2003), indicating that there is a co-movement in prices, in the presence of parallel trade.

The question still remains, however, whether PT has any effect on prices of locally sourced products. In order to determine this, we performed a comparison between products that are subject to competition from PIs and products that are not. Furthermore, knowing which products are patented and for which the patent has expired between 1997 and 2002, we were able to make comparisons between prices of patented drugs and prices of non-patented drugs subjected to generic competition. For this purpose, we calculated the relative price change for all products between 1997 and 2002. The relative price change is defined as the price in euros in 2002, divided by

Table 5. Price spread among parallel importers for the most widely parallel-traded products in Germany, the Netherlands and the United Kingdom, €^a, 2002

	Number of parallel importers	Price of locally sourced product 1997	Price of locally sourced 2002	Highest PI price, 2002	Lowest PI price, 2002	Relative spread between highest and lowest PI price (%)
Germany						
Simvastatin	11	218.4	223.4	221.7	212.6	4.2
Risperidone	7	449.4	512.3	496.7	467.1	6.3
Olanzapine	9	130.2	175.4	157.8	155.6	1.4
Fluoxetine ^f	5	230.2	182.7	128.2	119.8	7.1
Paroxetine ^f	5	64.8	56.9	55.1	52.9	4.1
The Netherlands						
Simvastatin	11	55.2	50.4	50.2	45.3 ^{b,c}	11
Risperidone	10	92.2	96.9	89.6 ^d	79.1	13.3
Olanzapine	4	64.2	74.2	66.5 ^c	62.5	6.5
Fluoxetine ^f	8	67.5	47.1	40	39.5	1.3
Paroxetine ^f	9	67.8	63	55.8 ^c	55.6	0.4
UK						
Simvastatin ^f	N/a	60.9	55.6	55.4	49.9	0
Risperidone	N/a	101.6	106.8	98.8	87.2	0
Olanzapine	N/a	70.8	81.8	73.4	68.9	0
Fluoxetine ^f	N/a	74.4	51.9	44.1	43.5	0
Paroxetine ^f	N/a	74.8	69.5	61.6	61.3	0

Notes: ^a Euro exchange rate as of 31 December 2002 for sterling and prices are per pack for the most common presentation of the product imported. Different countries may import different presentations of the same product.

^b Most common price is the lowest.

^c In the Netherlands we could identify some differences in prices among the same company depending on the origin of the product and the supplier (e.g., Euromedica sells simvastatin 20mg 20 pills at 45.40 and 45.35 originating from Spain).

^d Most common price is the lowest.

^e Most common price is the highest.

^f Subjected to generic entry prior to 2002, Quarter 4.

Source: The authors from IMS.

the corresponding price in 1997, minus 1 (Ganslandt and Maskus, 2004). We calculated the change for the average price including PIs as well as the change for locally sourced original products and generics. The results are shown in Table 6. It appears that the prices of (locally sourced) originals facing PT increase slower or decline faster than the prices of originals not facing PT in Norway and Sweden respectively; this is what one would expect the effect to be, but it is quite the opposite in the remaining countries, namely, that prices of originals subjected to PI rise faster or decline slower than those that are not. The analysis does not include generics. We tested whether the observed differences are significant, by performing a *t*-test, assuming unequal variances, of the hypothesis that the mean change is the same. The hypothesis that those original products' price changes for those subjected to PIs and those not facing PIs are the same could be rejected at the 5% level. However, the situation is different when we examine the behaviour of originals facing both PIs and generics. In this case, prices of originals decline significantly in the presence of generics as well as PIs and this change, when performing a *t*-test, is significant at the 5% level.

Table 6. Relative price change (1997–2002) of originally sourced and parallel imported drugs facing (or not facing) both parallel imports and/or generic competition

	Norway	Denmark	Germany	UK	Sweden	Netherlands
Price of originals (not facing PI)	0.02 (0.002)	-0.13 (0.02)	0.02 (0.05)	N/a	-0.03 (0.07)	0.04 (0.04)
Price of originals (facing PI)	0.01 (0.09)	-0.07 (0.07)	0.04 (0.11)	0.05 (0.10)	-0.14 (0.12)	0.06 (0.09)
Price of originals (facing PI and generics)	-0.30 (0.15)	-0.33 (0.12)	-0.43 (0.23)	0.01 (0.02)	-0.57 (0.60)	-0.57 (0.70)
Price of PI (not facing generics)	0.057 (0.06)	-0.02 (0.01)	0.10 (0.03)	0.03 (0.02)	-0.18 (0.19)	0.05 (0.07)
Price of PI (facing generics)	-0.32 (0.18)	0.56 (0.07)	-0.34 (0.43)	0.06 (0.06)	-0.60 (0.13)	-0.26 (0.22)

Note: The products which are subjected to generic competition during the period 1997–2002 are Omeprazole, Clozapine, Captopril, Enalapril, Citalopram, Fluoxetine, and Paroxetine. Figures in parentheses are standard deviations.

Source: Authors' compilations from IMS.

It appears, therefore, that generic competition has an impact on prices of locally sourced originals – more so than competition from PIs. This can be explained in a number of ways. First, prices of locally sourced pharmaceutical products are not sensitive to the presence of parallel-distributed products and, therefore, maintain their structure over time, despite the loss of market share to equivalent imported drugs. The economic rationale in this case is that if prices were driven downwards, revenues would also suffer due to both smaller market shares and lower prices. Second, by reducing prices, local manufacturers would accept that PT poses a threat to their commercial interests; instead, LS products can still maintain market share by offering the so-called ‘price equalization deals’ to their own distributors and, by extension, to pharmacists. This implies that whereas the list price remains as is, there can be significant discounts to pharmacists. In this case, the latter may also benefit financially but these benefits are invisible. Third, manufacturers are aware that there may be exogenous pressures affecting product supply to parallel distributors, and, therefore, affecting their ability to operate successfully over time. These pressures may relate to the intensity of the regulatory procedure, the coverage of the market by the parallel distributor, the overall market size for certain products, transportation costs, product availability in source countries, and transaction costs where they apply, such as repackaging, relabelling, reboxing and inserting new patient leaflets.

Perhaps the most significant factors influencing the behaviour of parallel distributors is product availability. It is not always guaranteed that product will be available, or that it will become available from the cheapest possible source; in fact, there is evidence of product shortages in some countries that parallel-export intensively. Conceptually, therefore, it is questionable whether PT leads to (downward) price convergence over time; by decomposing our product sample into in-patent and off-patent drugs and examining the effect of PT in each group, we have shown that generic competition leads to a

downward price adjustment, whereas the effect of price competition from PT is ambiguous. This would require more robust analysis, which we pursue in the following section.

4. PARALLEL TRADE ENTRY, PENETRATION AND PRICING

4.1. Conceptual framework

The descriptive analysis of aggregate parallel trade poses several questions as to what determines market entry by a parallel distributor and whether, following such entry there are any price competition effects in destination countries, and, if so, what determines these. If we consider a model comprising destination ($j = 1$) and exporting countries ($j = 0$), and a linear demand function ($q_j(P) = \alpha - \beta P_j$), then the behaviour of parallel distributors follows a two-stage game.

In the first stage the parallel distributor makes a decision on whether they should or should not enter a particular destination country and a product market, whereas in the second stage they are in the market in a destination country and their pricing decisions are triggering price reactions from the product originator. In the first stage, the decision to engage in parallel trade activities depends on price differences between export and destination country. If $P_0 < P_1$, there could be a parallel distributor that engages in parallel trade activities if the expected profit from such activity is positive. In the second stage, the manufacturer in the destination country may adjust its price depending on the behaviour of the parallel distributor. Therefore, if parallel trade leads to price competition in destination countries, then prices should fall as parallel trade intensifies, as predicted by standard oligopoly theory (Tirole, 1989).

Consequently, the first issue that needs to be analysed empirically is the determinants of market entry and penetration. This is consistent with the assumption that parallel trade is tantamount to arbitrage, given that market penetration of parallel imported drugs should in principle increase as price gaps between export and destination countries increase. From a pure arbitrage perspective, parallel distributors will import a product as long as the price difference between exporting and destination country exceeds transportation and transaction costs (Ganslandt and Maskus, 2004). Thus, the expected profit ($\pi = [(P_j - P_k) - t]q_j^{PI}$) of parallel distributors increases as the price difference between the destination and the exporting country $P_j - P_k$ increases, declines with transaction costs (t) that include transport costs (τ), measured by the distance between destination and exporting country, and the exchange rate. Finally, parallel distributors' expected returns should be higher in those countries with a larger drug market (Q_j) because in principle they can exploit scale economies and minimize unit transaction costs. Generics (G_j), inpatient beds (B_j) and number of physicians (D_j) influence the total volume of drugs prescribed by affecting the demand for drugs. Overall, market penetration S_j is determined by the parallel distributors' expected profits as follows:

$$s_j = \arg \max(\pi(s_i) = \pi^{PI} \{(P_j - P_k), Q_j, t, G_j, B_j, D_j\}) \tag{5}$$

In the absence of price regulation (therefore under free pricing) the manufacturer in a destination country might wish to deter parallel trade by temporarily reducing the price for the locally sourced product so that parallel importation becomes unprofitable. Once this happens the manufacturer could raise prices to the previous level. However, as price differences between locally sourced and parallel imported drugs result from differences in the drug regulation across countries, and, therefore, are certain to persist over time,²⁵ there would be limited scope for a reduction in drug prices in the destination market, and the parallel distributor can benefit depending on (a) its capacity to source adequate supplies for parallel exportation,²⁶ (b) the existence of psychological barriers to parallel traded products related to their perception by consumers, (c) the product specific competitive market and, finally, (d) the degree of competition in the exporting market (Maskus and Chen, 2002, 2004). Finally, regulation affecting pricing and discounts to pharmacy may affect the extent of parallel distributors' profitability.

The second step in the game that we examine is the extent to which originator drug prices in destination countries are affected by a larger penetration of parallel traded drugs. As discussed earlier, drug prices of locally sourced drugs are obtained from a bargaining process as follows:

$$P_j = \arg \max((CS(P_j))^\gamma (\pi(P_j) - \pi(s_j))^{1-\gamma}) \quad (6)$$

From (6), the empirical model will examine whether there is evidence of competition in the market for parallel imported drugs as well as the determinants explaining prices in destination countries. In doing so we consider whether patent expiry of originator drugs, and the ensuing generic market entry, has any impact on the prices of branded medicines and whether or not it affects the extent of parallel trade in drugs whose patents have expired. Although there exists evidence in the literature that prices of branded medicines increase rather than decrease with generic competition (the so-called 'generic competition paradox') (Grabowski and Vernon, 1992),²⁷ this feature is found to depend on the extent of insurance coverage (Frank and Salkever, 1992) and is influenced by the country specific regulation. Indeed, empirical evidence suggests that the entry of new generic competitors reduces the price of the originator drug (Hudson, 1992), although other elements of regulation may be at play. Other determinants of the prices of originally sourced drugs are: exchange rate fluctuation, changes in purchasing power parity, country specific regulation and

²⁵ It would not be in the manufacturer's best interests to reduce prices over the long term in a high-price country. This would not only have a knock-on effect on price levels in the destination country, but it would also affect pricing of medicines in low-price countries, the reason being that prices in these countries are partly determined by taking into account or explicitly referencing prices from a basket of countries, including prices in high-price countries.

²⁶ An extreme equilibrium under limited penetration of parallel imports is the accommodative equilibrium. For a sufficiently small arbitrage capacity the originator company might not deter parallel trade but accommodate it (Ganslandt and Maskus, 2001).

²⁷ This could be explained, first, by the fact that the originator (branded) product has built significant brand loyalty over time and, second by the fact that physicians continue to prescribe brand name products even when the drug goes off-patent, unless there is mandatory generic substitution at pharmacy level. This, too, can be circumvented, and a physician can usually tick a box on a prescription advising the pharmacist to 'dispense the product as written' or, simply, by switching his/her prescribing habits towards new products.

the market size of the country. The latter implies that, in large countries, insurers may have greater monopsony power in determining price levels if prices are regulated.

4.2. Econometric specification

We used the same IMS price and sales database for six therapeutic categories (19 products) across six destination countries (Denmark, Germany, the Netherlands, Norway, Sweden, and the UK), over the 1997–2002 period on a quarterly basis to analyse (a) parallel trade entry decisions and penetration and (b) whether there is evidence of price competition in destination countries following parallel importation. The variables employed were: (a) the total market size, defined as sales for all 19 products across the 6 therapeutic categories (Q_{ij}); (b) prices of locally sourced products for each product and each destination country (P_{ij}); (c) the price gap between destination and exporting country ($P_{ij} - P_{ik}$); (d) the market share of generic drugs in each product and country (G_i); and (e) the market share of parallel imported medicines in each of the study countries (s_{ij}). OECD-released data on nominal euro-exchange rates (E_{ik}), and PPP indices (PPP_i) were also used for each study country. The underlying assumption behind the use of exchange rates was that exchange rate uncertainty and variability could have an impact on the extent of PT, bearing in mind that four of our six importing countries for PT lie outside the euro-zone (UK, Sweden, Denmark, Norway), while the majority of exporting countries lie within. Therefore, the price gap between importing and exporting country ($P_{ij} - P_{ik}$), and, consequently, the extent of parallel trade, could be affected by exchange rate variability.²⁸ The model incorporates a proxy for transport costs defined as the distance between destination and exporting countries (τ_{ik}) (Rose and Wincoop, 2001; Rose, 2000).

In order to determine whether the structure, organization or finance of the health-care system affected the extent of PT through prescribing, we included three health system-related variables: (a) the number of physicians per thousand inhabitants (D_i) as a proxy for the demand for pharmaceuticals; there is evidence that the larger the number of physicians per capita, the greater the potential supplier-induced demand, which is manifested in the number of prescriptions written (Van de Voorde *et al.*, 2001; Grytten and Sorensen, 2001; Calcott, 1999), (b) the number of hospital beds per thousand inhabitants (B_i), is an indicator of overall healthcare utilization, and is a predictor of consumption of medicines in hospitals; and (c) the impact of the regulatory regime for pharmaceuticals, which might encourage the extent of PT was included by means of two drug policy-related dummy variables, namely, the existence of price regulation and the clawback. A list and brief description of all variables included in the empirical analysis is provided in Box 2.

²⁸ Because drug dosages and pack sizes might differ for the same product across our study countries, we standardized to defined daily dosage (DDD) as established by the World Health Organization (WHO) methodology. In addition, we adjusted prescription packs using simple regression analysis within each drug category. DDD- and pack-size adjustment enabled us to express prices in units, comparable across all countries in our sample.

Box 2. Variables and their definitions for panel data analysis, 1997 Q1–2002 Q4

Variable	Definition	Mean	SE
P_{ij}	Price of each locally sourced product (j) in each importing country (i), measured in logs and in levels; prices are in euros; quarterly	0.31	0.29
$P_{ij} - P_{\bar{k}}$	Price gap between each importing country (i) and the average price of exporting countries (k) for each product (j) measured in logs. The existence of parallel trade implies that the difference as defined needs to be positive; in euros; quarterly	0.39	0.01
Q_j	Total market size, defined as sales for all 19 products across the six product categories; in euros; quarterly		
s_{ij}	(Volume-based) market share of each parallel imported product within each product market (j) and each importing country (i); quarterly	0.15	0.007
τ_{ik}	Average Euclidean Distance of latitude and longitude between each importing (i) and exporting country capitals (k) measured in logs; quarterly	2.95	0.02
E_{ik}	Nominal exchange rate between the currencies in each of the six importing countries (i) and the €; the rate is 1 for Germany and the Netherlands; quarterly	4.582	0.06
PPP_j	Purchasing Power Parities (index) in importing country in logs (i); quarterly	1.00	0.02
Generic penetration (G_{ij})	Market shares of generics consumption in a country (i) on quarterly basis; seven branded products (j) had patent expiries between Q1, 1997 and Q4, 2002: omeprazole, clozapine, captopril, enalapril, citalopram, fluoxetine, and paroxetine.	12.25	0.46

Clawback	Dummy variable for introduction of the clawback; the dummy takes the value of 1 in the UK and the Netherlands over the 1997–2002 period, and 0 in the other four countries; clawback operates in identical manner in the UK and the Netherlands and is part of government policy of retaining part of the discount provided from wholesalers to pharmacists; quarterly	0.50	0.009
Price regulation	Dummy variable for price regulation; price regulation defined as the intervention of third party payer (national insurance company) or the government in terms of setting price of each product (j); price regulation takes value of 1 in Norway, Sweden and the Netherlands from Q1, 1997 onwards; and to Denmark from Q1, 2001 onwards; quarterly	0.44	0.009
Number of Physicians (D_i)	Total number of physicians working in the health system per 1,000 inhabitants in each of the six import countries in our sample; the greater the number of physicians, the greater the potential for supplier-induced demand, including demand for pharmaceuticals; in levels; quarterly	2.9	0.08
Number of inpatient care beds (B_i)	Total number of hospital beds per 1,000 inhabitants in each of the six import countries in our sample; the ratio is an indicator of health care utilization; in levels; quarterly	4.38	0.04

Notes: Time subscripts omitted for simplicity.
 $j = 1, \dots, 19$, for the 19 products in our sample.
 $i = 1, \dots, 6$; the countries are: Germany, UK, The Netherlands, Sweden, Norway, Denmark.

The data has allowed the construction of a panel containing data for 19 products in 6 countries over 6 years on a quarterly basis ($N = 2,736$). In order to analyse both the determinants of PT volume and the impact of PT on prices in import countries, our econometric strategy employed several alternative model specifications: two stage least squares (2SLS), two stage generalized least squares (2SGLS) for panel data analysis both for fixed effects and random effects and an IV-Tobit model to examine whether there are effects resulting from the censored nature of the data. After testing whether there are significant differences associated with country specific effects by using the standard Breusch–Pagan test (Baltagi, 1995) a fixed effects specification was employed as a general model although the results of a random effects model with regulatory specific dummies are also included for comparison.

4.3. Parallel trade entry decision and market penetration

Parallel trade entry and market penetration (s_{ij}) may be influenced by the price gap ($P_j - P_i$) between destination and exporting country. Following the arbitrage hypothesis, the higher the price gap the higher the extent of parallel trade should be. After confirming endogeneity empirically, this variable was always treated as endogenous.²⁹ In addition to regulatory variables, we also used τ_{ik} and PPP_j as identification instruments for the price gap equation. The theoretical underpinning for this is that distance, expressed by τ_{ik} , is a proxy for transportation costs and the price level, expressed by PPP_j is a proxy for price discrimination applied by drug manufacturers when they set or negotiate prices in different jurisdictions, but is also a factor considered by regulatory authorities when negotiating prices of pharmaceutical products with manufacturers. We use total sales (Q_j) as a proxy for each destination country's market size and we expect a larger market to contribute to greater returns for parallel distributors. Following the prediction of gravity models, distance (τ_{ik}) should be a determinant of parallel trade volume. A number of health system-related variables were also included in the analysis, namely, the number of doctors per thousand population in each country (D_i), the number of hospital beds per thousand population in each country (B_i). The model was tested for over-identification by using the Sargan test. The test indicated no evidence of over-identification at the 5% significance level. Finally, given that for some product categories the data might be censored, a Tobit model was employed that corrected for endogeneity as well as accounted for the censoring nature of the data (IV-Tobit).³⁰ The advantage of using this model is that it takes into account the fact that for some products there is no parallel trade. Indeed, it has been shown that parallel trade occurs on a limited number of products rather than all

²⁹ Indeed, by testing for endogeneity of the price gap, we find that the Wu–Hausmann test rejects the H_0 of exogeneity (at 1% significance level) consistently with the theoretical prediction. As a result, we specified a 2SLS model, with one equation in market share and one equation explaining the price gap between importing and exporting countries. The equation explaining the price gap can be seen in the Appendix.

³⁰ Several specifications taking into account attrition in the panel model provide similar results, but are not reported here.

(Ganslandt and Maskus, 2004). Although our dataset contains a large number of products that register parallel trade, our results might still suffer from a censoring problem.³¹

The resulting model is shown in Equation (7):

$$q_{ij} = \beta_0 + \beta_1(P_{ij} - P_k) + \beta_2Q_j + \beta_3\tau_{ik} + \beta_4G_{ij} + \beta_5B_j + \beta_6D_j + Trend + \varepsilon_i + \varepsilon_{ij} \quad (7)$$

where ε_{ij} is the error term and ε_i is a fixed effect. Regulatory variables could, in theory, have a direct effect on quantities, either through changes in physician prescribing behavior (proxy-demand), or through changes in the demand patterns of patients due to cost-sharing. Changes in prescribing behavior due to regulatory interventions would occur only if physicians were directly responsible for their prescribing budgets and accountable to health insurance for any excesses in prescribing, provided that clinical guidance would allow such changes to occur. However, there is no evidence that physicians changed their prescribing patterns because of changes in pharmaceutical price regulation in our study countries (Mossialos and Legrand, 1999; Mossialos *et al.*, 2002). There is also no evidence that patients in the study countries changed their demand for medicines because of changes in pricing regulation; this may have been the case either because cost sharing is not related to price (fixed fee in the UK and Germany), therefore patients are unaware of the cost of medicines, or where it is related to price (co-insurance), statutory health insurance provides comprehensive coverage and exemptions, and covers patient co-payments beyond socially acceptable levels (Denmark, Norway, Sweden), or because there is no cost-sharing in place for prescription pharmaceuticals (the Netherlands) (Kanavos, 2002; Kanavos and Gemmill, 2005).

Table 7 summarizes the determinants of parallel trade entry and market penetration. Consistently with our hypothesis, the price gap between destination and exporting country explains entry and market penetration of parallel traded drugs except when the cross-section time series approach is specified. Indeed, after testing for the convenience of a fixed effects model using the Breuch–Pagan test, we find that only the total pharmaceutical market size and inpatient beds explain parallel trade penetration. Therefore, although the coefficient measuring the effect of the price gap always displays the correct sign, it is sensitive to the empirical specification and, particularly, to the presence of country and product fixed effects. Variables measuring the effects of transaction costs such as distance to the importing country, did not display a robust coefficient and were excluded from the cross-section time series specification due to multicollinearity problems. Interestingly, a greater concentration of physicians increases parallel trade penetration although again its statistical significance is affected by the inclusion of country-specific fixed effects. The existence of a positive and significant association between the concentration of physicians and parallel trade

³¹ An alternative to this model would be the sample selection model. However, no evidence of selectivity was found when running such a model.

Table 7. The determinants of parallel trade penetration (s_{ij})

	2SLS		2SGLS-FE		IV-Tobit		2SGLS-RE	
	Coeff	SE	Coeff	SE	Coeff	SE	Coeff	SE
$P_j - P_k$	0.318**	0.101	-0.20	0.51	0.55**	0.17	0.33	0.98
Q_j	0.214**	0.043	0.31*	0.13	0.39**	0.073	0.34	0.24
τ_{jk}	-0.15*	0.006	-	-	-0.40	0.691	-	-
Trend	-0.002	0.002	-0.009	0.0137	0.003	0.004	0.012	0.025
G_{ij}	0.004**	0.002	0.001	0.002	0.008**	0.002	-0.001	0.001
Inpatient beds	-0.015*	0.006	-0.011**	0.004	-0.008	0.011	0.002	0.005
Physicians	0.171**	0.040	0.238	0.19	0.184**	0.06	0.331	0.437
Price regulation	-	-	-	-	-	-	-0.171	0.416
Clawback	-	-	-	-	-	-	0.003	0.030
Intercept	-3.791**	1.062	-3.792**	0.909	-5.99**	1.53	-6.42	6.156
R ²	0.14							
Sargan Test	0.69		1.82					
Wald Test					97.2			
Breuch-Pagan			13,445					
χ^2 test								

Notes: The auxiliary equation for price gap contains two observational variables, namely exchange rates and PPP.

* significant at 5% level.

** significant at 1% level.

penetration results from a demand effect which can be explained by the presence of some supplier-inducement and the fact that pharmacies are in a position to substitute for a cheaper product (e.g. a parallel traded one) in place of what the physician prescribed in the first place. Generic penetration (measured by market share of generics) appears to be positively associated with the parallel trade penetration although the size of the coefficient is very small. The same coefficient is close to zero when both fixed effects and regulatory dummies are introduced. Clearly, the timing of this effect is important, as parallel trade may have preceded product genericization, given that, of the products that went off-patent, nearly all went off-patent after they had been subjected to parallel importation. Finally, when the effects of two regulatory variables (the clawback and price regulation) were considered in a random effects specification, these were found to be non-significant.

4.4. Does parallel trade promote price competition in destination countries?

Given that parallel trade is a specific form of arbitrage, in this section we examine whether a surge in parallel trade (and an increase in the market share of parallel traded products [s_{ij}]) has any impact on pharmaceutical prices in the importing country (P_{ij}), or/and whether the latter are affected by total volume of drug sales (Q_{ij}), exchange rates (E_{ik}), distance (τ_{ik}) and drug regulatory dummies when estimating the model using a random effects model. Again, there is the possibility of endogeneity in that in a price equation, the market share may be endogenously determined. Therefore, we use OLS, 2SLS and 2SGLS to empirically examine the model as shown in (8):

$$P_{ij}^{orig} \text{ or } \Delta P_{ij} = \gamma_0 + \gamma_1 s_{ij} + \gamma_2 Q_j + \gamma_3 PPP_j + \gamma_4 E_{ik} + \gamma_5 \tau_{ik} + \gamma_6 G_{ij} + Trend + \mu_i + \mu_{ij} \quad (8)$$

where μ_{ij} refers to the error term and μ_i to a fixed effect. Given the results from the previous section, parallel trade market share (s_{ij}), consistent with the arbitrage hypothesis, is endogenously determined. Indeed, by testing for endogeneity of the market share, we find that the Wu–Hausmann test rejects the H_0 of exogeneity (at the 1% significance level). Therefore, we proceed as previously, by estimating the parallel trade market share separately (this auxiliary equation can be seen in the Appendix). As competitive elements might show an effect on price changes rather than on price levels, we also estimate the effects of competition on the price change (ΔP_{ij}).

With regard to generics, although they are bio-equivalent to the originator drug, they compete on price among themselves, rather than with the original. The latter may maintain its price due to brand loyalty (Grabowski and Vernon, 1992), but this effect would be dependent upon other elements of reimbursement regulation in destination countries. We would expect, for instance, that regulatory measures such as reference pricing would affect prices of originator branded products in the off-patent sector.³² Reference pricing was in operation in five of the six countries in our sample (Denmark, Germany, the Netherlands, Norway and Sweden). We would expect the generic market share to have a negative effect on the originator drug prices in destination countries.

Similarly, when estimating a random effects model we include two regulatory variables: the clawback, which has an indirect impact on prices of locally sourced original products and price regulation. Furthermore, we used the number of physicians per 1,000 inhabitants and inpatient care beds per 1,000 inhabitants as identification instruments for the market share of parallel trade. We expect both these variables to influence primarily the number of prescriptions and, consequently, drug consumption, rather than drug prices. Physicians prescribe from a predetermined list of medicines (positive list or formulary) and their prescribing behaviour affects the volume of prescriptions and not prices; the latter are predetermined by government and are usually rigid upwards. Similar is the case in hospitals, where the latter procure medicines directly from manufacturers and may engage in international parallel import tendering. Consistently with other studies (Ganslandt and Maskus, 2004) we included nominal exchange rates (E_{ik}) to account for possible effects associated with currency movements in the attractiveness of parallel trade.

Table 8 shows that, regardless of the empirical specification, there is no evidence of competition effects. Although the sign is the expected one, it fails to provide

³² By setting an upper reimbursement ceiling, which is close to the average generic price, health insurance is willing to pay for a generic rather than the branded product. If consumers wish to acquire the branded product, they have to pay out-of-pocket the difference between the branded product and the generic. Empirical evidence suggests that consumers are unwilling to do so and, as a result, the prices of originator drugs converge downwards towards the generic (Selke, 1994).

Table 8. Impact of parallel trade on the prices of destination countries

	P_{ij}							
	2SLS		2SGLS-FE		IV Tobit		2SGLS-RE	
	Coefficient	SE	Coefficient	SE	Coefficient	SE	Coefficient	SE
S_{ij}	-0.742	0.81	-0.112	0.100	-0.73	0.58	-0.161	0.115
Q_j	-0.012	0.093	-0.005	0.033	-0.02	0.07	0.004	0.035
PPP_j	-0.297	0.229	-0.628**	0.120	-0.60**	0.16	-0.628**	0.123
E_{ik}	0.298	0.217	-0.196**	0.034	-0.65**	0.157	-0.200**	0.035
τ_{ik}	-0.221	0.750	-	-	-0.58	0.53	-	-
G_{ij}	-0.022**	0.001	0.0001	0.0001	-0.009**	0.001	0.01	0.01
Price regulation	-	-	-	-	-	-	0.008	0.010
Clawback	-	-	-	-	-	-	-1.605**	0.415
Trend	0.012	0.007	0.001	0.001	-0.005	0.005	0.001	0.001
Intercept	0.134	1.228	0.623	0.476	-3.04*	1.344	3.455	4.196
R ²	0.08							
F test	56.64		7,463.67					
Wald test			43,612.13		171		353.73	
Sargan test	0.32		0.75					
Breusch-Pagan			29,183					
χ^2 test								

Notes: The observational variables were inpatient beds and the concentration of physicians which had overall 5% of the market share variability. The auxiliary equation can be seen in the Appendix.

* significant at 5% level.

** significant at 1% level.

evidence of a significant effect on prices in destination countries. Interestingly, PPP and exchange rates are significant and display the expected coefficient in affecting prices. These results suggest there is some evidence of price discrimination along with an effect of currency depreciation in the drug prices. The effect of generic drugs was sensitive to the intra-product variability as the models that include the cross-section time series variability (2SGLS in Table 8) display no significant effects from generic competition while both the Tobit and the 2SLS model show a negative and statistically significant effect. This is compatible with both economic theory and the practice of health policy in that generics are cheaper than the branded originals, including their parallel imported versions. Generic penetration, therefore, leads to a reduction in originator drug prices, which, in turn, means that parallel imported originals may not have a significant price advantage in destination markets.

The total size of the market does not affect prices significantly. Finally, the random effects model includes two regulatory effects, which indicate that the existence of the clawback (in the UK and the Netherlands) offers an incentive to pharmacists to purchase more cost effectively and therefore has a downward impact on prices. By contrast, price regulation did not affect prices significantly.

Table 9 summarizes the results of the determinants of price changes in importing countries. Again for comparative purposes we report the four different specifications, including cross-section time series models. Interestingly and consistently with previous

Table 9. Impact of parallel trade on the price change of destination countries

	ΔP_{ij}							
	2SLS		2SGLS-FE		IV Tobit		2SGLS-RE	
	Coefficient	SE	Coefficient	SE	Coefficient	SE	Coefficient	SE
s_{ij}	-0.05	0.07	-0.11	0.090	0.431**	0.152	-0.11	0.08
Q_{sj}	-0.031**	0.007	-0.004	0.033	-0.087**	0.019	-0.09**	0.02
PPP_{ij}	0.04*	0.019	0.63**	0.11	-0.011	0.042	-0.12	0.08
E_{ik}	-0.09**	0.018	-0.19**	0.03	-0.124**	0.039	-0.09**	0.03
τ_{ik}	-0.18*	0.063	-	-	0.066	0.141	-	-
G_{ij}	-0.0005**	0.00001	0.0001	0.0001	0.0001	0.0001	-3.23×10^{-5}	0.0001
Price	-	-	-	-	-	-	-0.008	0.008
regulation								
Clawback	-	-	-	-	-	-	-0.34**	0.16
Trend	0.0002	0.0006	0.001	0.0005	0.005**	0.001	0.001	0.001
Intercept	1.115**	0.15	0.91*	0.47	1.125**	0.333	1.82**	0.37
R ²	0.18							
F test	87.4							
Wald test			656.5		343.2		323.4	
Sargan test	0.85		0.545					
Breusch-Pagan χ^2 test			10,430					

Notes: The observational variables were inpatient beds; and number of which had overall 5% of the market share variability.

* significant at 5% level.

** significant at 1% level.

results, there is no evidence of price competition and, even when we account for the censored nature of the data, we find that parallel trade market share is positively associated with the change in drug prices. Thus, the market share of parallel imports does not seem to affect prices of locally sourced originator products in destination countries. From the results attained, we can conclude that the significant and robust variables are those that measure the effect of transaction costs, particularly exchange rates. When the cross-section time series variability is accounted for, we find that normalized drug price changes to the first observation are associated with purchasing power. Overall, generic penetration displays little effect on price changes, and when it does the sign is negative as expected. The weak generic effect could be due to (a) the variability in the application of generic policies and (b) the extent to which additional measures accompany generic policies. It is frequently the case that prices of generics are regulated upwards as a proportion (usually 80%) of the originator drug price.

This means that there is a price effect initially, but, overall, price regulation in generics provides little incentive for price competition in the patent-expired segment of the market (both among generics and between generics and the originator brand); the outcome is that prices in the off-patent sector fail to decline further over time. Similarly, availability of a generic product does not necessarily imply that it will be prescribed by a physician or dispensed by a pharmacist. For this to occur, physicians

need to be trained to prescribe generically and for generic prescribing to be mandatory, and for pharmacists to be able to have extensive substitution rights as well as financial incentives to dispense generically.

4.5. Summary of results

Overall, we find that the key determinants of parallel trade penetration are the price difference between destination and export country and the overall pharmaceutical market size of a country. Other important determinants include the number of physicians, and generic penetration. On the other hand, we find that the extent of parallel trade does not influence prices downwards in destination countries and that exchange rate movements, purchasing power parities and generic penetration may be responsible for a downward effect on prices rather than parallel trade.

5. POLICY IMPLICATIONS

PT has generated considerable interest about its welfare implications and the impact on the various stakeholders. Few studies exist to date examining its impact on stakeholders as well as the impact on price competition. We find that there are significant potential financial gains from pharmaceutical parallel trade, solely on the basis of price differences between export and destination countries. However, financial gains to health insurance and patients are very modest both in absolute terms and as a share of total prescription drug spending; the loss to producers is significant, whereas those who are involved in the distribution chain realize important gains. At first glance, these results may come as a surprise given that all the destination countries in our analysis were found to be implementing policies that, directly or indirectly, encourage PT, by intervening in the incentive structure of health care professionals. Yet, it is important to realize that some of the gains from parallel trade are invisible because of the incentive structures of different professional groups (parallel distributors and pharmacies) that play a key role in the distribution of medicines in general and PI medicines in particular. Health insurance is partly responsible for this. By reimbursing a negotiated 'list price' it leaves a substantial room for gains in the distribution chain. Thus, instead of gains accruing to health insurance, they accrue to the distribution chain.

In terms of competition, our results indicate that the assumed effect of PT on prices in destination countries is questionable, as the latter are more likely to be affected by domestic drug policy parameters (such as regulation and generics) rather than PT *per se*. By extension, this result seems to suggest that if national governments wish to further control their drug spending through supply-side (price) measures, PT probably offers a second-best solution.³³ Although PT does appear to have a volume

³³ Even if we consider the impact of parallel trade on the change of prices (ΔP), it appears that there is no effect of parallel trade in changing prices.

effect in many products, it does not appear to have a price effect, either because there is no incentive to do so, or because product shortages in export countries imply that distributors frequently need to obtain stock on less favourable terms.

The allocation of gains raises further important issues for both destination and export countries, notably public health, industrial policy and health policy in the pharmaceutical sector. With regard to public health, PT involves a destination country and at least one exporting country. If the impact on patients is neutral in the destination country as we have shown this to be, then the next question is what happens in the source country. As pharmaceuticals become commodities, the process of arbitrage implies that parallel distributors will have an incentive to maximize the quantities they acquire in the exporting country for re-sale elsewhere. Wholesalers in the source country may also have an incentive to supply parallel distributors with maximum quantities (and provide them with a discount for that), rather than supply their own market, because they reduce their overall distribution costs as they sell to a single buyer rather than to several buyers (pharmacies).

Consequently, whereas the distribution system in the export country favours parallel trade (or has few available stops to prevent its extent), an important question arises as to what happens to the availability of medicines to patients in that country. Evidence suggests that the end result can be shortages in drugs that are exported intensively. This has been documented in Greece (To Vima, 2002), a country that parallel exported 22% of its total market in 2002 and explicitly raised questions of shortages; there is also some evidence of shortages in Spain and France. In both Greece and Spain, the issue of shortages is reflected in recent regulatory interventions by the respective national governments, essentially placing a requirement on wholesalers to declare the destination of the product they acquire from manufacturers (Hellenic Republic, 2001a, 2001b, Kingdom of Spain, 2003; Costa-Font and Puig-Junoy, 2004). One would, of course, argue that drug manufacturers should increase production in exporting countries to meet demand, but, given the incentives to domestic wholesalers discussed above, it is not guaranteed that increased production will satisfy this demand.

The second issue concerns industrial policy, and suggests that if a strong research-based industry that invests in R&D and discovers new molecules is a policy objective in both exporting and importing countries, then sales and profit erosion through PT do not contribute to this objective. Understandably, the marginal returns to R&D investment have been falling over the past few years, raising questions about the effectiveness of the resources used. But in a competitive environment, where nations compete on the basis of comparative advantage, PT may act as an additional disincentive to an industry that has over the past decade or so increasingly relocated some of its activities in North America from Europe.

Finally, the health policy argument refers to the savings from PT to individual healthcare systems and links with the industrial policy argument. Cost containment is indeed a key policy objective in all EU member states and any savings realized on drug budgets are welcome. The question is whether the modest savings realized

through PT could not be realized with an agreement between insurance and drug companies thereby meeting the objectives of health policy (lower cost of drugs or lower growth in drug spend) and industrial policy (maintaining industrial structure and a healthy industry).

There are two obvious questions at this juncture, the answers to which could be further researched upon in the future. The first is whether governments are interested in maximizing their benefits from PT and whether less regulation might achieve this; the second relates to the trade-off between static and dynamic effects. In this respect, the financial gains to health insurance and patients would need to be weighed against the dynamic impact of PT on industry in terms of lower profitability, R&D investment, competitiveness and location of activities.

6. CONCLUSIONS

This paper has empirically examined the phenomenon of parallel trade in the European Union. We have found that the gains from parallel trade accrue mostly to the distribution chain rather than to health insurance and consumers. On the other hand, although we demonstrate that, within the context of the EU, pharmaceutical parallel trade is a specific form of arbitrage, it does not produce statistically significant price competition effects in destination countries given that parallel traded drugs are priced just under originally sourced drugs. Accordingly, instead of a convergence to the bottom, the evidence points at 'convergence to the top'. This is explained by the fact that drug prices are subjected to regulation in individual countries.

Discussion

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Over the past 7 years, the growth rate of pharmaceutical products in Europe has been around 8% per year, much above the economic growth rate in the Union over the period. At the same time, increased deficits of national health insurance programmes raised concerns, which induced many states to implement strategies to curb spending. The introduction of substitutable generics, the setting of price caps for drugs and the judicial decisions that allow parallel trade must be examined in this context. Allowing parallel trade is expected to reduce drug prices in countries facing high prices. The main aim of the paper by Panos Kanavos and Joan Costa-Font is to test this hypothesis.

There is no doubt that most drugs sold under the protection of patents are priced above their marginal cost. If these drugs are paid directly by consumers, this yields some allocative inefficiencies that can be reduced by influencing prices downwards. However, the pharmaceutical industry incurs large fixed costs associated with R&D

activities. The economic logic of associating a monopoly power to patents is to provide good incentives for investing in research, and attempts to limit this monopoly power may reduce incentives below their efficient level. So, the efficient level of drug prices must be a compromise between *ex-ante* efficiency (incentive to invest in R&D) and *ex-post* (allocative) efficiency. Interestingly enough, most drugs considered in this paper are covered by insurers, so that drugs are paid by the collective budget. This implies that the *ex-post* allocative problem due to the price being larger than marginal cost is irrelevant here. Therefore, there is no explanation for why states should want to reduce drug prices. In fact, low-price countries (such as Spain and Greece) free-ride on R&D efforts made by high-price countries (as Germany, the Netherlands and the United Kingdom), and the race-to-the-bottom on drug prices that seems to go on in the Union is inefficient. If pharmaceutical companies anticipate that they will not be compensated for their R&D efforts, they will undertake less research, and that will have adverse long-term effects on public health.

If the patent holder were able to prevent parallel trade from occurring, it would impose prices that are larger in countries with a low price elasticity than in countries with a high price elasticity. If arbitrage is allowed for a competitive fringe of cost-free parallel trade, traders will take advantage of these price differences, and prices will converge to a unique price. In particular, local producers of the drug in high-price countries will have to match their price downwards. Malueg and Schwartz (1994) have shown that the increased consumers' surplus in the Union will exceed the loss in profits, yielding an overall increase in welfare. Of course, this analysis does not take into account the effect that these changes in prices have on the incentive to invest in R&D.

The striking result obtained by Kanavos and Costa-Font is that the introduction of parallel trade does not influence prices in high-price countries downwards. I am not sure I believe in this empirical finding. More importantly, I am frustrated both by the absence of an economic analysis of this finding, and by the inability of the authors to identify the determinants of this apparent price rigidity. Many explanations can be given. A potential explanation is that the local manufacturer actually matches the price of the importers by using hidden discounts to distributors rather than reducing the list price. If this is true, we can raise some doubts about the empirical findings of the paper. Another explanation is that the local manufacturer colludes with importers to maintain a high price. A third explanation is that pharmacists do not have enough incentives to select the cheapest distributor. Finally, a fourth explanation is that importers are capacity constrained. This may be due to the actions of the patent holder which can impose barriers in order to control parallel trade. These barriers can take various forms, from repackaging, relabelling, reboxing, product liability, to product availability (random rationing in the exporting country). A more structural model would be necessary to identify the relevant explanation for this apparent price rigidity. Without such information, it would be heroic to make any policy recommendation about parallel trade.

For example, it would be useful to analyse how parallel trade affects exporting countries. The presence of drug rationing in these countries would be compatible with

the explanation relying on the active barriers organized by the patent holder. The modest size of parallel trade documented in the paper in spite of large price differences reinforces the idea that local producers in high price countries prefer to accommodate entry by traders, knowing that their impact on market shares will remain under control.

Panel discussion

The paper sparked off a lively discussion, concerning parallel trade in a range of industries as well as econometric and theoretical issues directly related to the paper. Paul Seabright was curious about the number of firms involved in parallel imports and asked what, if there are only a few, the barriers to entry are. The authors replied that in the pharmaceuticals industry, there are few firms doing parallel importing, for instance with the largest trader in Germany having a 60% market share. The main barrier to entry is finding the products; they are often scarce as regional supply is fixed. Furthermore, a parallel trader must build up a wide portfolio of products as otherwise a pharmacy may prefer to supply from a full-time wholesaler. Stefan Szymanski confirmed that there are tightly controlled distribution networks, and a pharmaceutical firm may prefer to do its distribution in-house rather than use an external and untrustworthy distributor. He also suggested that two other barriers to entry are the requirement to make a declaration of imports and obtain a licence, and secondly, the language barrier means that importers must relabel packaging. He related the small volume of parallel trade to the main findings of the paper; that parallel trade has little downward effect on prices.

Hans-Werner Sinn suggested that it is not a surprise that parallel trade does not reduce the prices of pharmaceutical products. This can be explained by the law of supply: if parallel trade adds more suppliers without driving away the high cost (price setting) suppliers, then the price will remain at the same level. The authors elaborated on this to say that there is considerable price fixing in low price countries so prices cannot change. In high-price countries, prices are easier to change, but manufacturers know that even if there is a relatively large supply of parallel imports into the country, it is not in their interest to lower prices. The manufacturers interact with the importers along the lines of a Stackelberg game, as the leaders.

Pierre-Olivier Gourinchas suggested that there may be other costs involved in outlawing parallel trade activities that have not been included in the welfare analysis of the paper. He pointed out that as most of the gains of illegal parallel trade go to the arbitrageurs, this profitable activity would have an impact on law enforcement and deterrence, and potentially could allow arbitrators to use returns from parallel imports to cross subsidize other illegal activities.

As Pierre-Olivier Gourinchas pointed out, the paper segments the market along geographical lines. However, heterogeneity in willingness to pay within countries may be just as large as between countries. As third-degree price discrimination within

countries would have significant implications, such (excessive) focus on the geographical dimension may be unwarranted.

Lans Bovenberg pointed out that *ex post* and *ex ante* efficiency had different implications for welfare through their impact on total tax revenues and the distribution of tax revenues. Pierre-Olivier Gourinchas suggested one should consider government interventions to subsidize drug research and development that does not involve intervening in prices.

Szymanski highlighted some of the confusion in government policy in dealing with parallel trade – for example, on the one hand the UK Government encourages parallel trade with clawback policies, and on the other hand, the UK Department of Trade and Industry discourages it as it wants to promote UK pharmaceutical firms. The authors also said that there is a discrepancy between national policy and supranational (EU) policy. The European Court of Justice issued a ruling in January 2004 whereby manufacturers are allowed to monitor their supply chain and can implicitly limit supply. The manufactures can also apply differential pricing rule and apply a single pricing rule with rebates.

Several panel members questioned the identification of the model. Andrea Prat started the discussion by asking why the instruments were chosen. He suggested that the presence of language differences within Europe (as applied to drug packaging) may be used as an identification device. Carlo Favero had similar doubts, and worried about endogeneity in the model and a suspiciously high *R* squared. The authors responded that beds and doctors were the only instruments available without using prices. In response to comments about sample selection, the authors explained that they selected the countries on the basis of available data. Of the 18 European countries, they chose the countries where more than 90% of parallel trade is concentrated. Giuseppe Bertola, however, would argue that information from countries with little or zero trade is also valuable. The authors also explained that there were measurement issues with the gains of parallel trade, in particular it was difficult to fully take account of transaction costs.

APPENDIX

Table A1. Auxiliary equations

	s_{ij} Coeff (s.e)	$P_j - P_k$ Coeff (s.e)
Q_j	0.09 (0.02)	-0.06 (0.06)
PPP_j	-	-0.62 (0.19)
E_{ik}	-	0.70 (0.27)
τ_{ik}	0.194 (0.05)	0.19 (0.51)
Inpatient beds	-0.02 (0.05)	-
Physicians	0.33 (0.06)	-
G_{ij}	0.04 (0.03)	-0.02 (0.01)
Trend	0.03 (0.01)	0.07 (0.05)
Intercept	-0.99 (0.57)	0.97 (2.27)
R^2	0.09	0.14
F test	32.55	52.69

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