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Abstract

While recent research has explored the phenomenon of drug parallel trade in regulated environments such as the European Union (EU), or the European Economic Area, little is known about the mechanisms that explain its origin or the role of the distribution chain in exporting and importing countries in determining its extent. By building on theoretical literature explaining the role of the distribution chain, this paper draws on an empirical specification of a gravity model to examine the determinants of inter-country flows of parallel-traded drugs. In this context, the paper deals with the effect of differences in the regulation of and competition in the distribution chain in the countries of origin and destination. The paper draws on proprietary data from the Intercontinental Medical Statistics database (for the Netherlands and other EU countries that export to the Netherlands) which identify the country of origin of parallel-imported medicines from 1997-2002 for a therapeutic group (statins) for which there is no generic competition. The study reveals that although parallel trade is a specific form of arbitrage, it is primarily a regulation-induced phenomenon. As a result, although the driving force for parallel trade is price differences across countries, the propagation mechanism lies in (a) the way drug prices are regulated across countries and (b) fragmentation and the underlying incentive structure in the wholesale distribution chain in countries where drug prices are regulated. The implications that flow from our study are that a more flexible and competitive and less fragmented (along national borders) distribution chain, particularly at wholesale level, might reduce the extent of and potential for parallel trade.

Key words: parallel trade, arbitrage, pharmaceuticals, economic integration, price regulation, vertical integration and drug distribution.
JEL: I11, I19, L22, L42, O52, F15

Contents

1. Introduction

The development of a single European market and the free movement of goods encourage arbitrage opportunities whereby price differences for particular goods across countries can be reduced or minimised. Due to significant cross country price differences, one such opportunity is parallel trade of in-patent pharmaceuticals[1]. The European Court of Justice (ECJ) has on several occasions ruled on its validity (Kanavos and Costa-Font, 2005), and the principle of regional exhaustion of intellectual property rights supports it (Forrester, 2002). Recent evidence suggests that pharmaceutical parallel trade has risen quite significantly (Kanavos and Costa-Font, 2005), and its extent has been attributed to price differences for in-patent medicines across countries, arising from price regulatory practices (Kanavos and Costa-Font, 2005; Szymanski and Valetti, 2005; Jelovac and Borodoy, 2005 and Peccorino, 2002). Indeed, the regulation of drug prices by national health insurance agencies suggests that price differences will continue to exist long after arbitrage has commenced, thus making this practice an imperfect form of arbitrage.

While the phenomenon of pharmaceutical parallel trade has been analysed both theoretically (Malueg and Schwartz, 1994; Richardson 2002, Chen and Maskus 2005, Maskus and Chen, 2002, Szymanski and Valetti, 2005) and empirically (Ganslandt and Maskus, 2004), and its impact on different stakeholders explored (Kanavos and Costa-Font, 2005), the role of the distribution chain in its proliferation and perpetuation remains under-researched. As pharmaceutical manufacturers cannot sell directly to patients and have to rely on wholesalers and retailers to distribute and dispense medicines respectively, clearly, the degree of vertical control that manufacturers can legally exert over the latter influences the extent to which wholesalers can divert products from one country, where prices are low, to another, where prices (and therefore rents) are higher.

Under a regime of regional exhaustion, such as the one in place within the European Economic Area, intellectual property rights do not confer legitimate control of the product final destination upon sale in one country, and thus if price differences arise,

[1] Parallel trade refers to the movement of a drug from a specific market A to a market B – where the drug is already under circulation through *official* distribution channels – but distributed in parallel distribution channels to official ones.

parallel trade takes place. As expected, parallel trade, as any other form of arbitrage results theoretically from price differences being higher than transport and transaction costs, such as those resulting from obtaining a parallel distribution licence, as well as exchange rate variability (Rose, 2000). Consequently, parallel trade is perceived as a market mechanism to smooth existing price dispersion at a certain point in time that results from discriminatory monopolist strategies across countries (Weigand, 1991) or currency rate fluctuations. However, the case in the pharmaceutical sector is arguably different, given that cross-country price differences in drug prices result from differences in price regulation (Kanavos and Costa-Font, 2005) as well as differences in the regulation of the distribution chain.

This paper analyses the impact that different price regulatory regimes and the market and incentive structures of drug distribution systems across countries are having on the amplitude and extent of pharmaceutical parallel trade. Proprietary data are used to examine the impact of cross border price regulation and the drug distribution system on pharmaceutical parallel imports from other European Union (EU) countries into the Netherlands. Knowing with precision the source countries for such exports has allowed the use of a gravity approach. This is the first time that a gravity model has been employed to evaluate the determinants of bilateral flows of pharmaceutical trade, although gravity models have been employed to evaluate the trade potential of integration processes. As some studies reveal (Egger, 2000; 2002) cross-sectional gravity models might be misspecified given that exporter- and importer-specific effects may well be in place. This paper performs panel data analysis to capture part of the unobserved heterogeneity in measuring specific parallel trade determinants.

Section 2 provides some background information on pharmaceutical parallel trade and discusses the market structure of the distribution chain in different EU countries. Section 3 discusses the theoretical underpinnings of parallel trade and arbitrage in the context of a gravity model. Section 4 presents the methodology, data sources and the approach followed in the analysis, while section 5 presents results and discusses policy implications. Finally, section 6 draws the main conclusions.

2. Parallel trade of medicines and drug distribution

Within the European Economic Area, the development of a single market, the implementation of a community exhaustion of IPR, the removal of nominal exchange rate variability in those countries that have joined the European single currency, together with a number of decisions by the European Court of Justice have fostered the development of pharmaceutical parallel trade, despite the legality of a parallel trade ban having being questioned unsuccessfully by arguing that vertical control should be a natural extension of intellectual property rights (Barfield and Groombridge, 1998). Empirical evidence, however, questions the capacity of parallel trade to achieve price equalisation in the European pharmaceutical market (Kanavos and Costa-Font, 2005). Prior studies on parallel trade have analysed country-specific flows (Ganslandt and Maskus, 2004), but have not taken into account the presence of generic drugs and price and reimbursement regulation both in importing and exporting countries. Previous literature remains inconclusive about the capacity of parallel trade to increase the country's welfare (Mauleg and Schwartz, 1994, Richardson, 2002). Indeed, the normative implications for welfare of increasing parallel trade are ambiguous and tightly dependent on the benefits of a unitary price as compared to a price discrimination equilibrium (Szymanski and Valletti, 2005).

One of the lesser-explored areas in the literature is the structural determinants of parallel imported drugs across countries. On the one hand, retail price differences might not well capture the way drug distributors are reimbursed in each country. On the other hand, price differences at wholesale level across countries are the result of different competitive conditions in drug distribution (e.g. larger number of companies) that, in turn, motivate a lower price in such a country, but those differences alone do not necessarily explain the motivation for parallel trade. Thus, in countries where drug wholesalers are subject to more stringent competitive conditions they have an incentive to ship part of their stock of medicines to another country where the competitive conditions are less stringent. Recent contributions stress the importance of price differences at ex-manufacturer level (Maskus and Chen, 2004; Chen and Maskus, 2005) and point out that the (theoretical) determinants of parallel trade depend on the vertical formation of drug prices. Finally, the analysis of trade flows is based on the specification of a gravity equation (Anderson and van Wincoop, 2003), taking into

account the joint population and economic size of the two areas (since the destination (original) country dimension determines higher potential volume of drugs sales (distribution)) as well as their distance (given that the higher the distance the higher the transport costs, although this very much depends on the specification of the transport costs function). Table 1 provides some descriptive evidence on the differences in the regulation of prices and the wholesaling competitive conditions across European countries. We find that in France wholesaler margins are the lowest in 2005 followed by other southern European countries. Southern European countries show a significantly higher fragmentation in their wholesaling and retailing practices compared to other European countries.

Table 1
Pharmaceutical price structure and distribution chain market structure in selected EU countries, 2005

Country	Ex-Manufacturer[2] (% price)	Number of wholesalers	Wholesaler margin (% price)[3]	Pharmacy density (Population per pharmacy)	Pharmacy margin (% price)[3]
Belgium	56.6	13	8.5	5,200	29.2
France	64.8	12[1]	***3.8***	**2,800**	26.2
Germany	51.2	16	7.7	3,900	27.3
Greece	63.1	130	***5.5***	**1,420**	24
Italy	63.8	95[1]	***6.7***	3,700	20.4
Netherlands	63.4	4	**10.8**	6,100	20.2
Portugal	67.8	18	8.4	4,000	19
Spain	62.7	51	***6.7***	**2,000**	26.8
UK	72.4	10	10.3	4,850	17.3

Note: [1] Excluding regional offices and counting only head offices of the same wholesaler.
[2] Ex-manufacturer price as a proportion of price, assuming price=100.
[3] Margins expressed as a proportion of price, assuming price=100.
Sources: Paterson et al, 2003a; European Association of Pharmaceutical Wholesalers, 2005.

3. Parallel trade: a gravity approach

3.1 Theoretical considerations

Despite parallel trade often being defined as a specific form of arbitrage (Maskus and Chen, 2005; Malueg and Schwartz, 2004), predictions of arbitrage theory do not seem to be backed by empirical evidence (Kanavos and Costa-Font, 2005). One explanation refers to the possibility of an accommodative equilibrium by drug companies (Ganslandt and Maskus, 2004), whilst alternative explanations rest on the incentives

resulting from country-specific regulations affecting both the probability of undertaking parallel trade and the emergence of long-lasting price differences across countries. In pharmaceuticals, regulatory interventions at national level maintain price differences over time (Kanavos and Costa-Font, 2005). Therefore, prices do not necessarily reflect differences in purchasing powers across countries[2].

One of the likely sources of parallel trade in individual countries is the country's 'economic size'. The larger a particular market, the more attractive it is for both pharmaceutical manufacturers and parallel distributors to undertake production and trade respectively. Most European counties, whether parallel importing or parallel exporting, operate with a single payer (national health insurance) who negotiates rates and purchases drugs on behalf of the health care system[3]. Assuming that payers regulate prices of pharmaceuticals (Peccorino, 2002; Mossialos and Mrazek, 2004) then, *ceteris paribus*, the larger a country market size the higher the potential bargaining power of the payer. Manufacturers may follow a dual strategy in this case: they can either *deter* parallel trade by setting a sufficiently low (high) price in a high (low) price country such that it would make it unprofitable to perform parallel trade; or, alternatively, they can *accommodate* parallel trade simply by allowing parallel distribution to take place without necessarily taking action on prices. When arbitrage is unlimited then deterrence is more profitable than accommodation. Conversely, accommodation emerges when the potential volume of arbitrage is small and trade costs are relatively high (Ganslandt and Maskus, 2004).

It may well be the case, however, that pharmaceutical parallel trade results from lack of barriers to arbitrage such as the lack of total vertical control in the pharmaceutical distribution chain by the manufacturer. This lack is not self-imposed, but governed by regulation, so that the most widely-used model of distribution has to be that the manufacturer sells to the wholesaler and the latter to a retailer (pharmacy). However, there are some exemptions to this model, but only relating to the structure of the distribution chain itself, namely, some countries allow a degree of vertical integration between wholesalers and retailers, whereas others allow some horizontal integration

[2] On the other hand, parallel trade might well have an endogenous effect on innovation and, subsequently, on the launch of new products by pharmaceutical manufacturers (Szymanski and Valletti, 2006).
[3] Hence, it may well be the case that country size determines the country's monopsony power in price negotiation.

amongst wholesalers or retailers (Mossialos and Mrazek, 2003). Maintaining vertical restraints implies substantial transaction and information costs and, as a result, weak distribution control, combined with a fragmented wholesaler structure, leads to wholesalers in low-price countries channeling part of their stocks to high-price countries. In addition, exercising a significant degree of vertical control was deemed up until very recently to be illegal by the European Court of Justice[4].

Parallel imports have been modeled as being the result of third degree price discrimination (Mauleg and Schawartz, 1994); however, they may well be the effect of second degree price discrimination, for example resulting from discounts given by parallel distributors to pharmacists in importing countries (Anderson and Ginsburgh, 1999). Empirically, the existence of a mechanism that allows health insurance to retain part of that discount in the UK and the Netherlands, confirms this assumption (Kanavos and Costa-Font, 2005). The motivations behind parallel trade have been modeled in recent theoretical work (Maskus and Chen, 2002; Maskus and Chen, 2004; Chen and Maskus, 2005). Indeed, the theoretical predictions of this stream of literature are that parallel trade takes place due to the lack of vertical control. Parallel distributors tend to be either distributors or agents that purchase from authorised distributors, therefore changes in the wholesaler price and competitive conditions in the distribution chain are likely to determine the profitability of the parallel trade business.

Let us now consider the price of a manufacturer monopolist selling a product (drug) to a set of distinct markets, i, subject to regulation (which can potentially influence the product price), thus p_{ij} is the price in each market for a specific product which we assume is not subject to generic competition, but only subject to potential competition from parallel distributors. Individuals' utility is measured by using a model of vertical product differentiation to represent consumer preferences in each market. Assume

[4] On 6 January 2004, the European Court of Justice dismissed the appeal by the European Commission and others (*Bundesverband der Arzneimittel-Importeure and Commission of the European Communities v Bayer AG*) against a judgment of the Court of First Instance in Bayer (Adalat) (*Bayer AG v Commission of the European Communities*). The ECJ benchmark is the Adalat case ruling which allowed manufacturers indirectly to control their stocks in different countries and, therefore, implicitly monitor the behaviour of wholesalers, so long as such monitoring would not result in explicit agreements between manufacturers and wholesalers restricting the free movement of goods across borders.

further that the manufacturer has access to and sells a drug in two countries[5]. Further assume that the principle of regional exhaustion holds, therefore it is not possible to prevent products from one country being sold to the other, and $t \geq 0$ refers to the transportation and/or transaction costs of any bilateral parallel trade. In both countries sales take place through independent distributors, who purchase from manufacturers and a share of the drug sold in one country can be diverted to the other country, based on price differences between the two. The total volume of the product sold in each country is given by

$$Q_i = nq_i^i + q_j^i \quad (1)$$

which is the addition of the locally sourced product in country i and what is imported from country *j*, and where *n* refers to the number of wholesalers. The manufacturer's marginal cost is assumed to be null and the wholesaler price in each country is

$$p_{wi} = p_{wi}(nq_i^i) \quad (2)$$

Parallel distributors maximise a profit function which can be expressed as the wholesale price difference between the two countries ($p_{wi} - p_{wj}$) and the transaction cost times the volume of parallel trade (q_j^i):

$$\pi_j^i = \left[p_{wi}\left(n_i q_i^i\right) - p_{wj}\left(n_j q_j^j\right) - t\right] * q_j^i \quad (3)$$

and hence if $\frac{\partial \pi_j^i}{\partial q_j^i} \geq 0$, parallel trade will take place until the wholesale price difference in the two countries equals the transport costs t. Given that $\frac{\partial p_{wi}}{\partial n_i} \leq 0$ and $\frac{\partial p_{wj}}{\partial n_j} \leq 0$, the higher the number of wholesalers, theoretically, the higher the

[5] This facilitated by the existence of a pan European licence through the European Medicines Evaluation Agency.

competition in each distribution sector, and the lower the prices in each respective country[6].

3.2 The gravity model

Based on equation (3), bilateral flows of parallel traded drugs can be specified by using a gravity model. The gravity model of international trade flows has been widely used as a baseline model for estimating the impact of a variety of policy issues related to regional trading groups, currency unions and various trade distortions (Bougheas, Demetriades and Morgenroth, 1999; De Grauwe and Skudelny 2000; Glink and Rose 2002). Following Newton's gravity law, a reduced form of spatial flows could be specified, incorporating both demand and supply factors along with trade barriers such as distance and other common preference factors. This predicts that the flow of goods between two locations is *positively* related to their size (or income levels) and *negatively* related to the distance between them, after controlling for a number of other factors which might affect trade through the gravity model (price differences, differences in the competitive pressures of certain regulatory frameworks as promoting parallel trade and the size of the market as an indication of the potential demand and thus profits from parallel trade).

Parallel distributors aim at maximising an expected profit function (Kanavos and Costa-Font, 2005; Szymanzki and Valletti, 2005), such as the one showed in equation (3), and from this they are more likely to ship products to countries that are closer, and have higher prices compared to the countries of origin. Given that the relevant price for parallel traders is the wholesale price prevailing in any of the countries in question, the extent of parallel trade would depend, among other things, on a number of parameters related to drug distributors. The first is the nature of competition prevailing in the wholesale distribution business and the number of wholesalers. The second relates to the economic rents from wholesaling, in terms of margins accruing to each wholesale distributor as part of the product's retail price, which in most European countries, are fixed by government regulation. Therefore, our research questions become: Do spatial determinants, regulation and non-gravity related aspects, such as price differences across countries, exchange rates, etc, explain cross-border bilateral flows of

[6] This would hold, provided the market is unregulated.

pharmaceutical products? Is parallel trade different from conventional (non-regulation induced) trade? How does the model specification determine the magnitude of parallel traded flows?

The model can be specified using a cross-sectional specification. Alternatively, panel data techniques offer more robust specifications. The specification defined raises a number of econometric issues: namely, the extent of inclusion of specific fixed effects, the existence of some endogenous variables, as well as measurement problems for certain regulation effects. In this paper we explore both the pool and the panel data model specification possibilities. An augmented logarithmic version of the traditional gravity equation that would follow from equation (3) to include geographic controls would give the following:

$$\ln M_{ijt} = \beta_o + \beta_1 \ln(p_i - p_j)_t + \beta_2 \tau_{ij} + \beta_3 (Y_i Y_j)_t + \beta_4 \xi_{ijt} + \beta_5 \ln\left[(Y_i / P_i)(Y_j / P_j)\right]_t + \beta_6 \ln(Q_i Q_j)_t + \beta_7 X_{ijt} + \varepsilon_{ijt} \quad (4)$$

where i and j denote the destination country and the country of origin or export country(-ies) respectively. The error term ε_{ij} captures any other random shocks and unobserved events that may affect bilateral trade between the two countries. Gravity-specific determinants include distance (τ_{ij}), the combined GDP $(Y_i Y_j)$ of the two trading countries, the combined GDP per capita of the two trading countries $(Y_i / P_i)(Y_j / P_j)$, and the exchange rate (ξ_{ij}). Given that parallel trade is theoretically conceptualised as a specific type of arbitrage (Ganslandt and Maskus, 2004), it is arguably driven by the existence of a price difference between the two countries $(p_i - p_j)$ and a volume effect in the form of total drugs from the specific therapeutic group of interest $(Q_i Q_j)$. Finally, a number of key determinants are included in X_{ij}. These are as follows: first, the competition environment in the wholesaling sector, defined as the total number of wholesalers in each country and, second, the impact of drug distribution, defined as the difference in the margins of wholesalers and pharmacists between export and import country. Finally, β denotes the vector of coefficients and ε_{ij} measures the set of other influences on bilateral parallel imports.

Table 2
Variables and descriptive statistics

Variable	Description	Mean	s.e
M_{ijt}	Bilateral Import flow of statins (logs) [a]	1.513	0.096
τ_{ij}	Euclidean distance of latitude and longitude (in logs) of the country capitals	6.467	0.034
ξ_{ijt}	Exchange rates in euros (logs)[b]	0.0679	0.037
$\ln\left[(Y_i / P_i)(Y_j / P_j)\right]_t$	Product of per capita GDPs (logs)[b] (Y= DGP) and (P=population)	0.166	0.027
$\ln(Q_i Q_j)_t$	Product of total sales of statins (logs)[a]	21.359	0.045
$\ln(Y_i Y_j)_t$	Product of GDPs (logs)[b]	20.161	0.008
Entry	Dummy variable measuring the entry of a new drug in the parallel trade market[a]	0.283	0.016
$\ln(p_{it} - p_{jt})$	Price difference between Netherlands and source country adjusted by defined daily doses (DDD)[a]	0.323	0.015
$\mathrm{Ln}(N_i + N_j)_t$	Sum of the total number of wholesalers (logs)[c]	1.265	0.022
$\mathrm{Ln}(\eta_i - \eta_j)_t$	Percentage difference in wholesalers' drug margins (logs)[c]	1.439	0.026
$\mathrm{Ln}(\rho_i - \rho_j)_t$	Percentage difference in pharmacist drug price margins (logs)[c]	0.528	0.030

Note: Export Country (i), Import County (j) and time (t).
Sources: [a] IMS data 1997-2002.
[b]OECD Economic Outlook data 1997-2002.
[c] EFPIA, several years (www.efpia.org).

4. Data and methods

We used the Intercontinental Medical Statistics (IMS) database on a quarterly basis over the 1997-2002 period for a set of products that fall in the therapeutic product category of statins and exhibit parallel trade during the study period, resulting in a total sample size of N= 768 observations[7]. IMS collect data on prices and sales for a number of countries, including the Netherlands, and for the selected product group, statins, on a product-by-product (e.g. simvastatin, pravastatin, etc) and product presentation basis (e.g. simvastatin, 20mg, 28 tablets). The accuracy of the database's sources has been validated externally (IMS, 2002). Pricing data are available at public level, i.e. inclusive of all wholesale and retail margins as well as Value Added Tax (VAT). Through official national sources, the relevant margins for wholesalers and retailers (pharmacists), as well as the statutory VAT rates applicable for prescription-only (POM) medicines can be indentified. The group selected for the analysis (statins) accounts for a significant

[7] The number of observations is made up of 24 quarterly observations, 4 products and 8 export countries. Data for each product was made available at dispensation level.

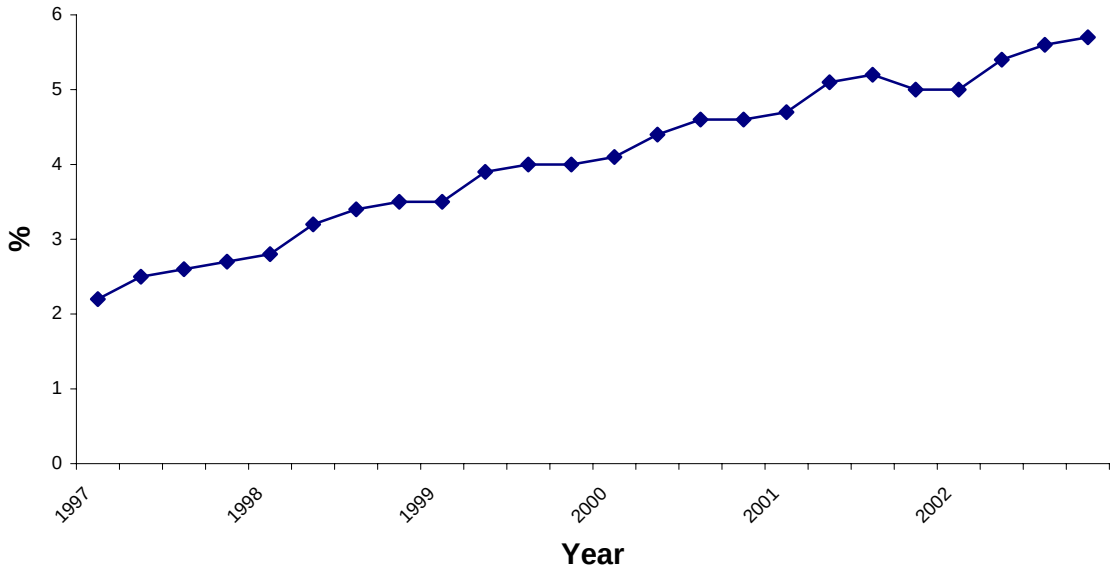
proportion of total retail sales of prescription only medicines in European countries (5.7% in 2002) (**Figure 1**).

Statins are drugs that lower levels of LDL ("bad") cholesterol by 30-50%, and have been increasingly prescribed for the (primary and secondary) prevention of coronary heart disease (CHD), including myocardial infarction (MI). Therefore, they are products whose importance in preventing heart disease is well-documented in the literature and their use has been increasing over time, making them, in turn, desirable targets for parallel trade (Kanavos et al, 2006). All drugs within the group were protected by a patent during the study period, therefore, the effect of parallel trade could be isolated from other effects, such as competition from generic equivalents, and studied without having to account for the competition effect due to generic penetration which may be significant (Kanavos and Costa-Font, 2005; Frank and Salkever, 1991; Grabowski and Vernon, 1992; Ganslandt and Maskus, 2004).

We examined parallel import flows of statins into the Netherlands and were in a position to identify the source country for these imports. In this particular case, and for the above study period, the Netherlands parallel imported statins from Belgium, France, Germany, Greece, Italy, Portugal, Spain and the United Kingdom. We were able to identify with precision the price and quantity differences at any point in time between each exporting country and the Netherlands, and estimate the impact of arbitrage in the Dutch market for each of the products within the statins group.

In explaining trade flows, we consider the influence of price differences, given the arbitrage nature of parallel trade, the nature of competitive forces in the drug distribution system, and the cross national differences in wholesale price regulation. Recent studies (Kanavos and Costa-Font, 2005) already find that some of the gains from parallel trade are invisible because of the incentive structures of different stakeholders that play a key role in the distribution of medicines in general and parallel imported medicines in particular, most notably parallel distributors and pharmacies.

Figure 1
Market share of statins in the retail market in six* European countries, 1997-2002



Source: The authors from IMS, 2004.
*These include United Kingdom, Germany, The Netherlands, Sweden, Denmark, Norway and Sweden.

In estimating the model presented in equation (4), we follow both a pooled (cross-section) and a panel data approach to measure the impact of country-specific or time heterogeneity effects that can be modelled by including country-pair "individual" effects and, accordingly, identifying bilateral trade. Hence, the pooled (cross-section) specification contains a reduced form of equation (4), whilst the panel case refers to a random effects approach consistent with the gravity specification whereby some variables are country-specific (e.g. distance). In using the pooled approach, we are aware that ordinary least squares (OLS) estimation ignores the presence of unobserved heterogeneity resulting from unobserved characteristics related to bilateral trade relationships. Thus, a country would export different amounts of the same product to two other countries, even if their GDPs are identical and they are equidistant from the exporting country. This is due to potential differences in drug regulation, which are not entirely observed, along with the presence of country-specific heterogeneity. Since the cross-section OLS estimates may not be able to account for these heterogeneous factors, the results are likely to suffer from substantial heterogeneity bias[8]. In contrast, a panel-based approach may be more desirable in order to deal with heterogeneity issues because the effects of such determinants can be modelled by including country-pair "individual" effects. In this case, a random effects approach would be more appropriate,

[8] We nevertheless show the OLS results purely for comparative purposes.

whereas a fixed effects approach would not allow for estimating coefficients on time-invariant variables such as distance or common language, though the consistent estimation of such effects is equally important in many situations. Finally, we separate the full model from the restricted model, following a two-part approach, whereby if we group all explanatory variables in $X\beta$ then, the conditional expectation of bilateral trade is:

$$E(M_{ijt} / X\beta) = E(M_{ijt} / M_{ijt} > 0 / X\beta) pr(M_{ijt} > 0 / X\beta) \quad (5)$$

Hence, we can separate the entry decision into a market $E(M_{ijt} / M_{ijt} > 0 / X\beta)$ from the actual penetration of a market $pr(M_{ijt} > 0 / X\beta)$ in order to disentangle potentially different explanatory effects.

The dependent variable is the logarithm of real imports of statins in the Netherlands and the logarithm of total trade volume in the country of origin. First, we use the basic specification and consider the impact of core explanatory variables such as GDP, population and distance. Subsequently, in line with recent theoretical developments (Egger, 2002), we include variables measuring the size of trading countries and other barriers that might explain the development of parallel trade such as distance and exchange rates. The model described in equation (4) contains variables that are potentially endogenous, namely the price difference between the Netherlands and each $pr(M_{ijt} > 0 / X\beta)$ exporting country. We estimate two stage least squares (2SLS) and two stage generalised least squares (2SGLS) models to account for such effects. To instrument price differences between importing and exporting country we employ the difference in pharmacy mark-ups and the number of wholesalers as instruments as neither variable is associated with volume, but both help explain drug prices. Indeed, as discussed elsewhere (Kanavos and Costa-Font, 2005), incentives to purchase parallel traded drugs by wholesalers and pharmacies take place through unobservable discounts which, in the vast majority of cases, remain unaccounted for by health insurance. We use the Hausmann and the Davidson and McKinnon tests to confirm endogeneity in price formation and the Sargan test to check whether the model is over-identified.

The variables employed in the analysis are presented in **Table 2** and are as follows: (a) (M_{ijt}) is the observed volume of each statin imported into the Netherlands from another EU country; (b) (τ_{ij}), represents the distance between two areas and is defined as the

Euclidean distance of latitude and longitude between country capitals; the reason for measuring distance in this way rests on the fact that kilometres are not necessarily a good approximation for distance given alternative and more direct ways of transportation (e.g. air travel); (c) exchange rate (ξ_{ijt}) is an obvious determinant of parallel trade insofar as it impacts price transparency, especially in the context of European integration; (d) following the predictions of a gravity model, our model includes the product of country GDPs (in logs) $\ln\left[(Y_i / P_i)(Y_j / P_j)\right]_t$, and the product of statins sales in € (in logs) ($\ln(Q_i Q_j)_t$) that is the specific therapeutic group in question which has been growing in size during the study period; (e) furthermore, we consider the point of entry of a parallel traded drug or product presentation as a variable to select the sample under consideration. As expected from a model of arbitrage, price differences between countries (in logs) ($\ln(p_{it} - p_{jt})$) should be a key determinant. Finally, (g) a set of variables has been added to measure the aggregate number of distributors, which accounts for the degree of competition in the distribution chain in both countries ($(N_i + N_j)_t$) proxied by the sum of the number of wholesalers in the Netherlands and the exporting country and the (h) difference in the wholesaler ($(\eta_i - \eta_j)_t$) and pharmacy mark-up difference ($(\rho_i - \rho_j)_t$) and account for possible economic incentives for parallel trade.

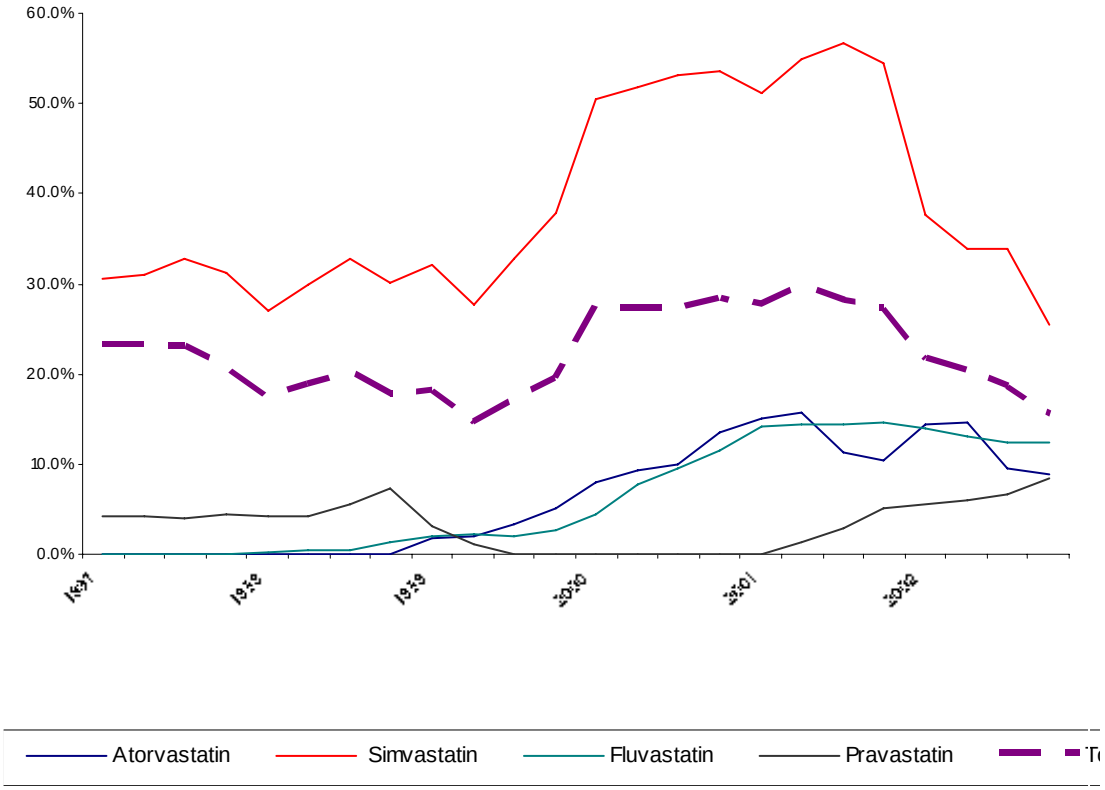
5. Results

Overall, there is evidence of an increase in parallel import penetration to the Netherlands post 1999 (**Figure 2**). Whilst this is initially attributable mainly to a single product (simvastatin), subsequently, other competitor statins increase their share in total statin imports. According to IMS, the market share of parallel imported statins is about 30% over the study period.

Figure 3 reports the patterns of trade from each of the potential countries of origin. The most common country of origin of parallel imported drugs in the Netherlands, at least in the earlier parts of the study period, was France. This is not totally unexpected although France does not have the lowest statin price among exporting countries. Significant exporting activity by France may be due to the fact that France is a large country with a significant capacity to parallel export (Kanavos and Costa-Font, 2005). At the same time, of all the other existing countries that can potentially export, France is, together

with Belgium, closest geographically to the Netherlands. Finally, the wholesale margin in France is the lowest of the countries considered (**Table 1**), and this can be interpreted as an incentive for wholesalers to divert part of their stocks to other countries, seeking higher returns.

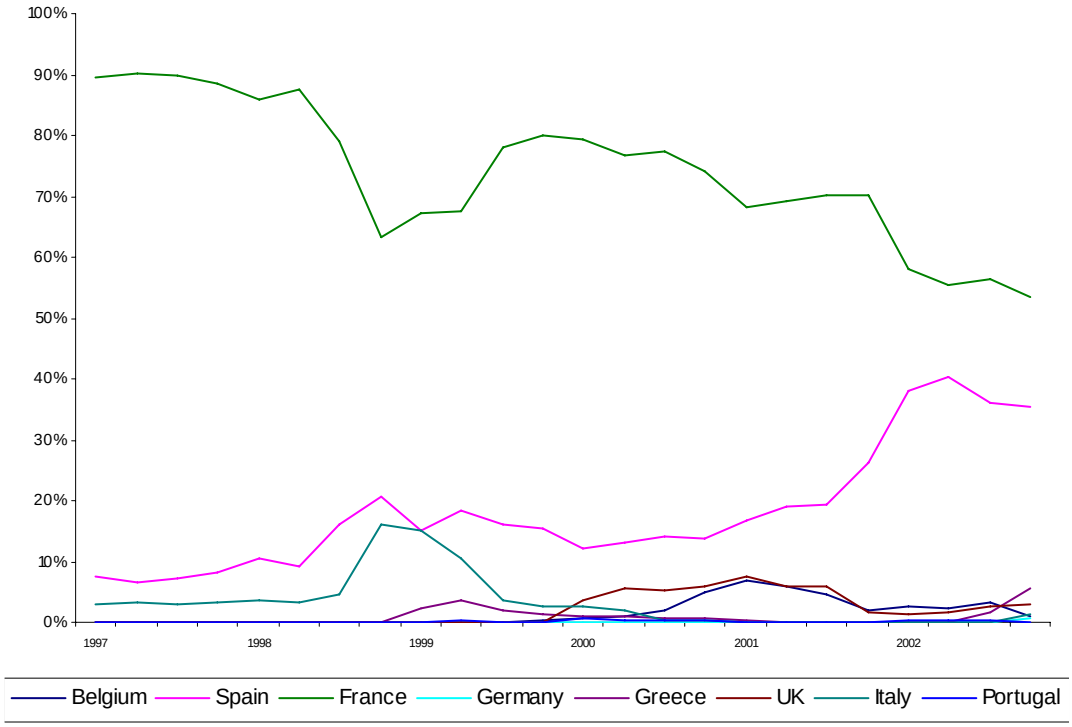
Figure 2
Parallel trade penetration of statins in the Netherlands (parallel imports as a % of total product market), 1997-2002



Source: The authors from IMS, 2004.

The evidence presented in **Figure 3** suggests that although 90% of parallel imported statins into the Netherlands were sourced in France in 1997, Spain's market share has increased significantly since 2000. By 2002 Spanish exports accounted for 40% of all statins parallel imported into the Netherlands.

Figure 3
Origin of parallel imported statins in the Netherlands, 1997-2002



Source: The authors from IMS, 2004.

Table 3
Gravity Equation (OLS)
Dependent variable: bilateral parallel imports to the Netherlands (in M_{it})

	Total sample (3.1)			Restricted Sample* (3.2)			Entry (Probit) (3.3)		
	coeff	s.e	t-value	coeff	s.e	t-value	coeff	s.e	t-value
$\ln(p_{it} - p_{jt})$	0.654[b]	0.259	2.53	2.070 [a]	0.305	6.78	0.313 [b]	0.145	2.15
τ_{ij}	-9.824[a]	2.426	-4.05	-9.15 [b]	3.488	-2.62	-6.50[a]	1.584	-4.1
ξ_{ijt}	0.580 [a]	0.150	3.87	-1.28 [a]	0.165	-7.76	0.484[a]	0.085	5.67
$\ln\left[(Y_i / P_i)(Y_j / P_j)\right]_t$	11.77[a]	3.528	3.34	-2.37	4.567	-0.52	9.902[a]	2.221	4.46
$\ln(Q_i Q_j)_t$	-3.292 [a]	1.164	-2.83	-4.25 [a]	1.533	-2.78	-2.31[a]	0.727	-3.17
$\ln(Y_i Y_j)_t$	-0.350	0.325	-1.08	0.775	0.402	1.93	-0.527 [b]	0.200	-2.63
$(\eta_i - \eta_j)_t$	-1.027	0.382	-2.69	-0.657	0.459	-1.43	-0.83[a]	0.230	-3.64
$(N_i + N_j)_t$	-0.019	0.210	-0.09	0.240	0.230	1.04	-0.085	0.120	-0.71
Intercept	-117.08[a]	30.78	-3.80	26.71	39.76	0.67	-95.69[a]	19.34	-4.95
F-Test (all coeff=0)	0.14			30.8 [a]					
R^2 (Adjusted)	0.11			0.55					
N (No. of observations)	768.0			217.0					
Sargan Test	1.35			1.47					
N (No. of Observations)	768			217			768		
Pseudo R^2							0.10		
Likelihood Ratio χ^2_9							87.06		

*Restricted to the existence of some parallel trade.
Note: [a] denotes significance at 1% level, [b] denotes significance at 5% level.

By undertaking the econometric estimation of the gravity equations following the premises of equation (2) we seek to analyse the determinants of parallel trade entry and penetration. **Table 3** provides the estimates of an OLS model which includes equation (2) along with regulatory variables that influence the decision by local distributors (wholesalers) to sell to parallel exporters. Accordingly, we add the wholesalers' mark-up difference and the number of wholesalers to measure the effect of competitive conditions in the drug distribution system. Column (3.1) presents the determinants of total bilateral parallel trade. Column (3.2) shows the volume of parallel trade restricted to the existence of some penetration and column (3.3) shows the determinants of market entry. Our evidence suggests that total bilateral parallel trade increases with a higher price difference, as expected from a specific form of arbitrage (column 3.1). A 10% increase in the price difference between two countries leads to a 6.5% increase in bilateral parallel trade among them. When we split the sample with entry (probability of some parallel trade) and parallel trade penetration achieving market share for parallel traded statins, we find that the price difference is larger for a restricted OLS sample, and

indicates, for instance, that a 1% increase in the price difference between importing and exporting countries leads to a 2% expansion of parallel imports into the Netherlands.

Parallel trade is explained by monetary barriers to trade – exchange rates – yet there is an apparent difference between the effect of exchange rates over total trade and entry on the one hand, and the effect of exchange rates over parallel import penetration on the other. This has to do with the fact that in some countries such as Spain and France the introduction of the euro has eliminated the exchange rate variability with the Netherlands, whilst some countries that remain outside the Eurozone entered the parallel trade business in the meantime (e.g. the United Kingdom). Transport costs – measured by distance – are responsible for a reduction in both entry and parallel trade penetration consistent with the prediction of a generalised gravity model. Indeed, the higher the distance between two countries, the lower the extent of bilateral parallel trade. The OLS model specification suggests that the economic mass of a country and the size of the therapeutic group are significant parallel trade entry determinants. However, a higher combined income per capita does not seem to influence parallel trade penetration once a product is already on the market. This feature can be explained by the fact that a combined higher income might well signal a higher capacity to restrict parallel trade from taking place. However, as expected, bilateral parallel trade flows increase with the size of the statins market. Finally, the variable measuring the difference in wholesaler mark-ups shows that the differences in the reimbursement of wholesalers amongst countries determines the entry decision to undertake parallel trade (column 3.3), consistent with our theoretical explanation and relevant literature (Maskus and Chen, 2002; Maskus and Chen, 2004).

Next, we tested for endogeneity resulting from the model specification by using the Davidson and MacKinnon (1993) augmented regression test, and found unambiguous evidence of endogeneity (F=15.08). Accordingly, we instrumented the price difference using data on pharmacist margins difference across countries ($(\rho_i - \rho_j)_t$) and the difference in the number of wholesalers across countries (in logs). The theoretical justification for including these variables as instruments lies in the fact that they are strongly associated with the formation of drug public prices given that both pharmacy margins (mark-ups) and the least competitive conditions for drug distribution are responsible for the formation of final public prices, whilst they do not appear to be associated (both in prior correlation analysis and in OLS regression models that include

this variable as a covariate) with parallel trade volume, given the latter is driven by the nature of incentives at wholesale level. On the other hand, parallel trade strongly is associated with price differences. Therefore, an instrumental variables (IV) estimation should provide a consistent estimate of the coefficients of interest and could well correct for any omitted variable bias (Angrist and Krueger, 2001).

A key issue refers to the validity of the instruments. **Table 4** provides the first stage of the models estimated and confirms that price differences depend on exchange rates, the competitive nature of the distribution chain and pharmacy mark-ups. The significance of all instruments indicates their goodness. **Table 5** reports the results of a gravity equation estimated using instrumental variables. When the effect of potential endogeneity of price differences is accounted for, we find that price differences are not significantly associated with parallel trade. This can be explained by the fact that part of the price difference effect results from pharmaceutical market regulation, which in all European countries is significant, hence parallel trade becomes a regulation-induced phenomenon. This applies to both the full sample and the two-part model results.

Table 4
Price difference (*in* $(P_{it}^{M} - P_{it}^{X})$) instrumental equations

	Total sample (A1.1)			Restricted Sample (A1.2)			IV Probit (A1.3)		
	coeff	s.e	t-value	coeff	s.e	t-value	coeff	s.e	t-value
τ_{ij}	0.04	0.04	1.12	0.003	0.066	0.04	0.04	0.04	1.12
ξ_{ijt}	-1.28[a]	0.20	-6.52	-1.035[a]	0.337	-3.07	-1.28[a]	0.20	-6.55
$\ln\left[(Y_i / P_i)(Y_j / P_j)\right]_t$	-0.02	0.04	-0.36	0.024	0.081	0.29	-0.01	0.04	-0.36
$\ln(Q_i Q_j)t$	0.12[a]	0.04	2.75	0.063	0.085	0.75	0.12[b]	0.04	2.77
$\ln(Y_i Y_j)_t$	-0.49[b]	0.24	-2.02	-0.532	0.457	-1.17	-0.49[b]	0.24	-2.03
$(\eta_i - \eta_j)_t$	-0.02	0.01	-1.93	-0.040	0.021	-1.92	-0.02	0.01	-1.94
$(N_i + N_j)_t$	0.005[a]	0.0001	4.89	0.003[a]	0.001	3.82	0.005[a]	0.0001	4.92
$(\rho_i - \rho_j)_t$	0.01[b]	0.00	2.14	0.019[a]	0.005	3.60	0.01[b]	0.00	2.13
Intercept	8.71	4.21	2.07	10.785	7.705	1.40	8.72[b]	4.18	2.08
F Test (all coeff=0)	40.82[a]			17.16[a]					
R^2 (Adjusted)	0.3			0.374					
N (Number of observations)	768			217			768		

Note: [a] denotes significance at 1% level, [b] denotes significance at 5% level.

Table 5
Gravity equation 2SLS
Dependent variable: bilateral parallel imports to the Netherlands (in M_{it})

	Total sample (4.1)			Restricted Sample* (4.2)			Entry (IV Probit) (4.3)		
	coeff	s.e	t-value	coeff	s.e	t-value	coeff	s.e	t-value
$\ln(p_{it} - p_{jt})$	2.41	1.52	1.59	1.782	1.062	1.68	0.44	0.82	0.54
τ_{ij}	0.07	0.35	0.21	-1.311[a]	0.274	-4.79	0.41[b]	0.19	2.08
ξ_{ijt}	-3.33	2.19	-1.52	-5.793[a]	1.708	-3.39	-2.55[b]	1.25	-2.04
$\ln\left[(Y_i / P_i)(Y_j / P_j)\right]_t$	-0.25	0.31	-0.83	-1.275[a]	0.318	-4.01	-0.18	0.17	-1.08
$\ln(Q_i Q_j)t$	0.26	0.25	1.06	1.049[a]	0.294	3.57	-0.07	0.13	-0.49
$\ln(Y_i Y_j)_t$	2.11	1.36	1.55	-2.760	1.458	-1.89	2.41[a]	0.77	3.14
$\ln(\eta_i - \eta_j)_t$	-0.22[b]	0.09	-2.52	-0.099	0.081	-1.23	-0.16[a]	0.05	-3.30
Intercept	-43.30	22.97	-1.89	53.13[b]	23.85	2.23	-47.07[a]	12.91	-3.65
F Test (all coeff=0)	12.68[a]			33.37[a]					
R^2 (Adjusted)	0.06			0.57					
N	768			217			768		
Sargan Test	1.78			1.68					
Wald χ^2_7 $(\nabla\beta_i = 0)$							76.54		
Wald endogeneity test χ^2_1							0.02		

* Restricted to the existence of some parallel trade.
Note: [a] denotes significance at 1% level, [b] denotes significance at 5% level.

When IV estimation is implemented, exchange rates exhibit the expected effects. Distance appears to be reducing the total volume of bilateral parallel trade to the Netherlands and entry into the parallel trade business. However, it exhibits an opposite coefficient for penetration (volume). This has to do with the fact that once parallel traders have established contacts with a potential source, distance does not become a significant barrier and it might well be that relatively distant sources geographically have incentives to become better connected. Yet, whilst richer countries tend to be less likely to parallel export, those countries that have larger market sizes for statins are more likely to ship larger quantities to the Netherlands. The other findings indicate that there is some evidence that economic size explains entry and the difference in wholesaler mark-ups also explains parallel trade as before, although the sign is not as expected. This may be due to the fact that some unobserved heterogeneity might remain, so that the variable captures country-specific effects associated with wholesaler mark-ups, ultimately suggesting the need to explore a specification using panel data.

Table 6
Random effects 2SGLS *(in M_{it})*
Dependent variable: bilateral parallel imports to the Netherlands

	Total sample (5.1)			Restricted sample* (5.2)		
	coeff	s.e	t-value	coeff	s.e	t-value
$\ln(p_{it} - p_{jt})$	5.02	12.52	0.40	-2.108	1.892	-1.110
τ_{ij}	-0.06	2.37	-0.03	0.510	0.477	1.070
ξ_{ijt}	11.10	20.75	0.54	-1.619	4.203	-0.390
$\ln\left[(Y_i / P_i)(Y_j / P_j)\right]_t$	0.87	1.43	0.61	-0.367	0.525	-0.700
$\ln(Q_i Q_j)t$	-0.42	0.29	-1.47	-0.230	0.125	-1.840
$\ln(Y_i Y_j)_t$	5.44	3.40	1.60	3.079 [a]	0.844	3.650
$\mathrm{Ln}(\eta_i - \eta_j)_t$	0.42[b]	0.19	2.15	0.174 [a]	0.046	3.760
Intercept	-114.20[b]	54.74	-2.09	-58.507	14.452	-4.050
N (Number of Observations)	768			217		
Wald $\chi^2_7\ (\nabla\beta_i = 0)$	108.2			3631		
R^2 (Adjusted)	0.02			0.72		

* Restricted to the existence of some parallel trade.
Note: [a] denotes significance at 1% level, [b] denotes significance at 5% level.

Despite the analysis and results so far, it may be the case that some country- and product-specific effects might be in place, or generally speaking, some unobserved heterogeneity might be present. This could be corrected using panel data analysis. By including time-series cross sectional data the results could capture the effect of unobservable variables. We employ a random effect and a fixed effects specification in **Tables 6 and 7** respectively. The Breusch Pagan test does not reveal that a fixed effects specification is more efficient and the Sargan test shows no evidence of over-identification. **Table 6** provides evidence suggesting that economic size does exert an effect in explaining parallel trade penetration, and we find evidence that the difference in the wholesaler mark-ups increases bilateral flows of parallel traded drugs although the fixed effect specification (**Table 7**) reveals additional evidence of income and volume effects, suggesting that whilst total income fosters the development of parallel trade, both total product sales (volume) and per capita GDP do not significantly explain the development of parallel trade. The fixed effects specification drops the distance variable as expected, given that distance does not vary over time and this specification reveals economic size and income per capita as significant, in addition to wholesaler mark-ups which exhibit the expected sign.

Table 7
Fixed effects 2SGLS
Dependent variable: bilateral parallel imports to the Netherlands *(in* M_{it} *)*

	Total sample (6.1)			Restricted sample (6.2)		
	coeff	s.e	t-value	Coeff	s.e	t-value
$\ln(p_{it} - p_{jt})$	-11.30[a]	3.71	-3.04	-0.999	0.826	-1.210
ξ_{ijt}	-9.51	7.21	-1.32	2.731	1.708	1.600
$\ln\left[(Y_i / P_i)(Y_j / P_j)\right]_t$	-93.67[a]	32.09	-2.92	-18.89[b]	7.428	-2.540
$\ln(Q_i Q_j)t$	-0.47	0.44	-1.05	-0.236[b]	0.112	-2.100
$\ln(Y_i Y_j)_t$	89.73[a]	27.85	3.22	19.01[a]	6.405	2.970
$(\eta_i - \eta_j)_t$	0.33[b]	0.13	2.44	0.200[a]	0.034	5.890
Intercept	-58.50[a]	14.45	4.05	-378.4[a]	127.024	-2.980
Wald Test $\chi^2_7 \ (\nabla\beta_i = 0)$	480.9			9503.1		
N (Number of Observations)	768			217		
$F_{31,730}$	19.19[a]			53.5[a]		
R^2 (Adjusted)	0.02			0.05		

Note: [a] denotes significance at 1% level, [b] denotes significance at 5% level.

6. Conclusion

This paper examined the determinants of flows of parallel traded drugs into the Netherlands, by using proprietary IMS data on statins over the 1997-2002 period. As patents protected all statins during the study period, and therefore the only source of competition to a statin was from a parallel traded equivalent. Specifically, the paper approximated the impact that country-specific regulation of the distribution chain in exporting (e.g. Spain, France etc) and importing countries (The Netherlands) has on the proliferation of parallel trade in proprietary medicines. By focusing on in-patent medicines only, the paper examined the effect parallel trade has on the destination country. It also isolated and empirically analysed the contribution of the degree of competition and market regulation in the drug distribution system in both the country of origin and destination. Finally, the paper took into consideration a number of country-specific effects and it can be argued that this unambiguously demonstrates that pharmaceutical parallel trade is a regulation-induced phenomenon, consistent with theoretical predictions in similar settings (Peccorino, 2002).

The paper specified a battery of gravity models and controlled for a number of

econometric issues such as the existence of endogeneity, a two-part process, as well as potential time-series cross-section effects. The results suggest that parallel trade is a specific phenomenon that mainly takes place at the distribution level, and therefore changes in the expected profit of wholesalers stand as a key determining factor in addition to pharmaceutical price regulation. Indeed, even if price differences between two countries are significant, the lack of competitive pressures in drug distribution might inhibit parallel trade between them. This is similar to the finding of Maskus and Chen (2002, 2004), who suggest that parallel trade might be the natural result of the absence of vertical control in the distribution process. An explanation of the expansion of parallel trade from Spain into the Netherlands refers to the regulation of drugs distribution in place in Spain which induces some wholesalers to undertake parallel exporting activities. Indeed, wholesalers' mark-up in Spain is limited to roughly 8% and has declined over time, which in addition to the competitive environment defined by a large number of companies in the market, makes parallel trade attractive to some specialised wholesalers in a number of high volume drugs.

Within the context of the present study, the rationale for the proliferation of parallel trade is exclusively pecuniary rather than promoting access to medicines and distributional equity across or within countries: wholesalers in exporting countries may have small domestic market shares exerting a downward influence on their total mark-up and profit functions. Consequently, they would have an incentive to increase their payoffs by diverting part of the stock purchased for the needs of the country they serve to other countries. They are incentivised to do so because they may be receiving payment on time and from a single source (parallel importer) rather than expecting payment from several sources (individual pharmacies in their domestic market). Consequently, parallel trade is not only the result of significant price differences and differential regulation, but is also determined by the structure of the (wholesale) drug distribution chain in exporting countries, how wholesale distribution is regulated and the overall competitive environment that results from such regulation. It is also dependent on the incentive structure of the distribution chain in the importing country (in this case, The Netherlands).

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