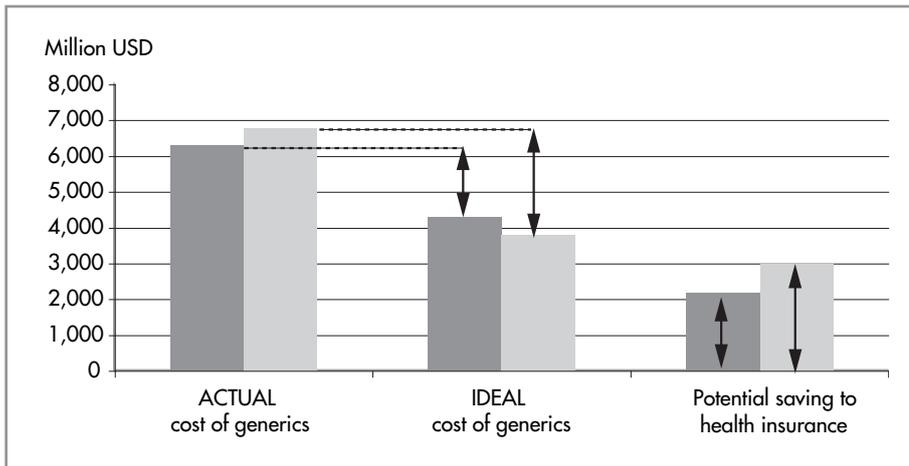


Figure 4: Total effect of efficient generic purchasing in EU-G5, Canada and USA



greater generic penetration, generic prescribing should be encouraged further through financial and non-financial incentives that target physicians, and cost sharing strategies that target patients, such as co-payments. Finally, in terms of further encouraging generic entry, regulatory

hurdles such as price setting and capping should be eliminated, so that the generics market can acquire depth. Where eliminating regulations appears difficult for several reasons a system of 'managed competition' could help to achieve price reductions over time.

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Does pharmaceutical parallel trade serve the objectives of cost control?

Panos Kanavos and Stacey Kowal

Summary: The extent to which pharmaceutical parallel trade can contain pharmaceutical costs has been debated intensely. Although parallel import penetration is significant in many EU countries, parallel trade generates at best moderate savings to health insurance, is not necessarily associated with sustainable long-term price competition and can lead to product shortages in exporting countries and, recently, a higher probability of counterfeiting. Parallel distributors emerge as the key beneficiaries from this practice. The high transaction costs associated with parallel trade, the lack of sustainable long-term price competition and the lack of tangible benefits to patients make this practice an inefficient means of containing costs.

Keywords: pharmaceutical parallel trade, efficiency, cost containment, single market

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Background

Parallel trade refers to 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 authorisation of the patent holder".¹ Therefore, it

constitutes a form of arbitrage, or the purchase and sale of identical products from different markets for the purpose of gaining a profit from unequal prices.² While parallel trade is illegal in many parts of the world, it is legal within the European Union (EU) after the move to a single market for phar-

Table 1: Policies to promote the use of parallel imported drugs in key importing countries in the European Union (2004)

Policy to promote use of parallel imported drugs	Denmark	Germany	Netherlands	Norway	Sweden	United Kingdom
Pharmacy required to inform patient of availability of parallel imported products	X	X			X	
Pharmacy quota on parallel import dispensing rates		X				
Financial incentives for pharmacy to dispense parallel imported drugs			X	X		X
Financial incentives for dispensing lower-price drugs in general, including parallel imported drugs				X	X	

Source: Kanavos P, Gross D, Taylor D, 2005.¹³

maceuticals. Within the single market, key changes in the harmonisation of regulation under the EU's mutual recognition procedure, and Articles 28–30 governing the free movement of goods have fostered an environment where parallel trade can capitalise on pharmaceutical price differences across countries.^{3,4}

“Views on the impact of parallel trade in the EU are highly polarised”

Parallel trade comprises a growing share of the pharmaceutical retail market and a significant share of pharmaceutical expenditure. Its presence is the result of differential country regulation and weak control over the pharmaceutical distribution chain.⁵ Community exhaustion within the EU dictates that a drug approved for human use in one EU member state must be granted authorisation in all other member states unless the concerned member state objects through a formal process. However, drug companies must still negotiate with individual countries over pricing and reimbursement.

Parallel trade in the EU is further fuelled by the structure of the distribution chain (wholesale and retail). The large number of players in the pharmaceutical distribution chain prevents total vertical control by any one stakeholder.⁴ In the presence of pharmaceutical price differences across countries, parallel distributors, who are

themselves registered wholesalers, increase their profit potential by acquiring products from low priced countries and selling such goods to pharmacies in countries with higher drug prices.

Views on the impact of parallel trade in the EU are highly polarised. Proponents claim that parallel trade offers savings to health insurers and patients by increasing the affordability of high priced drugs.⁶ They also claim that affordability may be further increased by manufacturer responses to parallel trade, suggesting that the threat of parallel trade may cause manufacturers to lower prices.⁷ Conversely, opponents claim parallel trade will have long term negative implications in discouraging research and development, thus potentially reducing product quality and impairing future research.⁸

How are individual stakeholders affected?

The implications of parallel trade, however, are contingent upon the viewpoints of the stakeholders involved, namely health insurers, pharmacy, parallel distributors, patients and the pharmaceutical industry.

Health insurance has the potential to benefit from parallel trade if the retail prices of parallel traded drugs are lower than the locally sourced identical products.⁹ In order to increase savings, it is in the interest of health insurance to encourage pharmacies to dispense parallel imported medicines. Given this perception of potential savings, many health insurance organisations have been either directly or indirectly promoting the use of parallel

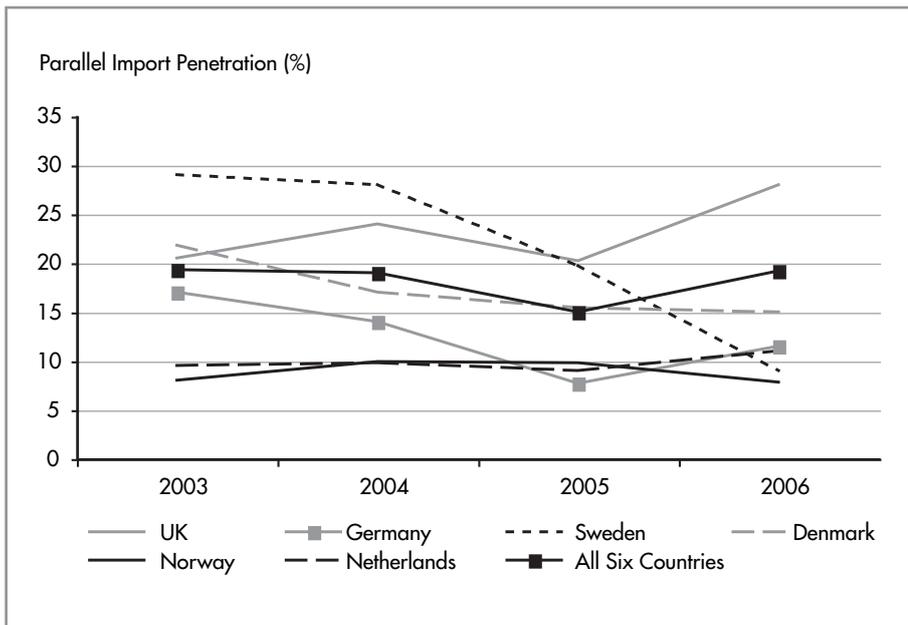
traded goods. Table 1 outlines policies used to promote the use of parallel imported drugs in key destination countries. The table illustrates that most countries aim at influencing the behaviour of pharmacies to some degree.

Despite the proliferation of policies promoting the use of parallel imported medicines, empirical work suggests that these savings are very small in relation to the size of the pharmaceutical market and disproportionately small in relation to the penetration of parallel imports in individual countries and product markets. Ganslandt *et al* empirically demonstrated that parallel imports were associated with a reduction in prices for the top fifty selling drugs in Sweden.² Kanavos *et al* discuss the potential savings to health insurance but empirically find that little savings were gained by health insurance for nineteen high volume, high cost drugs in Germany, Sweden, Norway, Denmark, the UK and the Netherlands between 1997 and 2002.¹

In addition to incentives from health insurance, pharmacists may have reimbursement related incentives that promote the use of parallel imported goods. Many pharmacies are reimbursed on a fixed margin, which offers no additional incentives to dispense parallel traded goods. However, policies rewarding the use of lower priced drugs may lead to benefits for pharmacists for the dispensing of parallel traded goods where parallel imports are less costly than locally sourced products.

Several countries offer explicit incentives, such as sharing the savings from the price

Figure 1: Parallel trade penetration in destination countries



Source: The authors from IMS.

difference between the locally sourced and parallel traded goods with pharmacies. In Norway savings are split equally between health insurance and pharmacies and the Netherlands offers a similar practice but with a 66-33 split.¹ Finally, some countries may penalise pharmacists if parallel import quotas are not met. While these incentives may encourage the use of parallel traded products, the continued use of a fixed margin for reimbursement may not translate into the use of cheaper drugs and subsequent savings to health insurance.

Parallel distributors, as licensed wholesalers, are profit maximisers and are interested in acquiring drugs at the lowest possible prices and selling them at the highest price in the importation country. Given increasing product homogeneity under the harmonisation of EU drug regulations and allowances for the sale of parallel imported goods in packaging from the source country, it is suggested that many of the potential barriers to moving products across countries are negligible. However, a pervasive concern is the sustainability of supply for parallel distributors. In order to maintain purchasing relationships with pharmacies, parallel distributors must ensure a sustainable supply of parallel imported goods.

Sustainability is complicated as parallel distributors are reliant on locating sufficient supplies of desired products in low priced countries. This has often led to product shortages in source countries, such as Spain and Greece, as available quantities to service the local market are siphoned off for exportation.

The effects of pharmaceutical parallel trade on patients are contingent upon a country's co-payment structure and extent of exemptions. In many countries, universal coverage shields patients from the full cost of pharmaceuticals. In the UK and the Netherlands, co-payments are not related to the cost of the dispensed medicine and therefore patients do not gain direct benefits from price differences between the cost of the parallel import and the locally sourced product.

Germany uses a structured payment system which blends co-insurance with a pre-determined minimum and maximum range for patient contribution, creating the potential for benefits to patients within the co-insurance range, although this may be limited. Finally, Denmark, Norway, and Sweden have, among others, co-insurance for out-patient pharmaceuticals up to a maximum ceiling, which theoretically enables patients to gain a marginal benefit

from using lower priced parallel imports. However, price differences between parallel imports and locally sourced drugs in destination countries are generally very small, suggesting that, even in those cases, savings to patients are negligible.^{1,2}

For the pharmaceutical industry, the growing presence of parallel trade presents a challenge as it reduces potential profits and mitigates the ability of manufacturers to recoup research and development costs.⁴ Parallel trade is most pervasive in the on-patent market given limited competitors and high drug prices. However, manufacturers rely on the market exclusivity granted under patents to recoup their research and development costs.¹⁰ The movement of parallel imported goods from low price countries to high price countries causes a reduction in manufacturer profits as the volume of higher priced products in destination countries decreases. Pharmaceutical manufacturers have taken steps to reduce the potential for parallel trade by working to improve control over the distribution chain.³ However, these efforts require additional resources which may also reduce profits.

Is parallel trade an effective method of pharmaceutical cost control?

When addressing the question of whether pharmaceutical parallel trade is an effective method of cost control one needs to consider (a) entry and penetration, (b) competition in markets characterised by parallel imports, (c) savings to payers, and (d) safety and quality of parallel imported medicines.

Entry and penetration

Eighteen products across six therapeutic categories* were used to investigate the overall penetration of pharmaceutical parallel trade in key importing countries (UK, Germany, Sweden, Denmark, Norway and the Netherlands) and, in particular, to identify the benefits accruing to health insurance from this practice over the period from 2003–2006. This builds on previous work conducted in this area, up to 2002.¹

The penetration of parallel imports in the six destination countries under investigation is depicted in Figure 1. The overall

*Namely, statins (atorvastatin, pravastatin, simvastatin), ACE (angiotensin-converting enzyme) I inhibitors (captopril, enalapril, quinapril, ramipril), ACE II inhibitors (losartan, valsartan), atypical antipsychotics (clozapine, olanzapine, risperidone), proton pump inhibitors (lansoprazole, omeprazole, pantoprazole), and selective serotonin reuptake inhibitors (SSRIs) – citalopram, paroxetine, and sertraline.

Table 2 Competition in parallel trade markets (Number of parallel importers and price differentials)

	Number of parallel importers	Price of locally sourced drug 2002 (€)	Highest parallel import price 2002 (€)	Lowest parallel import price 2002 (€)
Germany				
Simvastatin	11	223.4	221.7	212.6
Olanzapine	9	175.4	157.8	155.6
Fluoxetine	5	182.7	1282.1	119.8
Netherlands				
Simvastatin	11	50.4	50.2	45.3
Olanzapine	4	74.2	66.5	62.5
Fluoxetine	8	47.1	40.0	39.5
United Kingdom				
Simvastatin	n/a	55.6	55.4	49.9
Olanzapine	n/a	81.8	73.4	68.9
Fluoxetine	n/a	51.9	44.1	43.5

Source: Adapted and amended from Kanavos P, Costa-Font J, 2005.¹

market share of parallel imports in Europe (as approximated by the six destination countries) remained relatively stable, changing from 18.44% in 2003 to 18.40% in 2006. The most marked changes were observed in Germany and Sweden. In Germany, the percentage of parallel import penetration in the market fell from 17.62% in 2003 to 11.22% in 2006. Conversely, Sweden demonstrated an increase in the parallel trade retail market share, growing from 8.40% in 2003 to 26.66% in 2006. Slight increases were also observed in Denmark and the UK while slight decreases were present in the Netherlands.

Competition

Much of the debate on pharmaceutical parallel trade has focused on the extent to which it creates sustainable price competition over the longer term. By examining competition patterns in three high selling products across three countries, it is shown that in the majority of cases, the difference between the highest and lowest parallel distributors' price does not exceed 7%, with the sole exception of simvastatin in the Netherlands, where the spread between highest and lowest imported price is 11% (Table 2).

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 locally sourced equiv-

alent products have nevertheless increased over time in the three countries, despite seeing their domestic market share declining in the presence of parallel imports.

Small price differences between locally sourced and parallel imported drugs, combined with the significantly lower acquisition prices by parallel distributors suggest that there may be little price competition in products subjected to intensive parallel distribution. In addition, the uncertainty of a sustainable single source of product acquisition by parallel distributors is unlikely to fuel sustainable downward price competition over the longer term.

Pecuniary benefits to stakeholders and savings to health insurance

Existing evidence points at modest to moderate savings to health insurance from parallel importation of medicines.^{1,9,11} More recent evidence updating previous analysis also confirms this.¹⁴ Overall, the savings to health insurance in imported countries range between 0.4% and 2.2% of the retail prescription drug market. Other stakeholders also benefit from this practice, as discussed previously. For instance, the benefits to pharmacy were approximately 0.09% of the pharmaceutical retail market costs.^{1,14}

By contrast, exporting countries may be

faced with shortages of parallel trade products. The larger the market for a particular product, the greater the probability it will be traded intensely and, thus, the greater the likelihood it will result in shortages in export countries. The rents accruing to parallel distributors, however, are a multiple of the rent accruing as saving to health insurance. Evidence suggests^{1,14} that parallel distributor rents were between 2.5 and twenty times higher than savings to health insurance. While it is true that more than one distributor may be involved in the movement of medicines across countries, the fact remains that all distributor parties benefit from this practice.

Safety and quality of parallel imported medicines

Until recently, the arguments surrounding the safety and quality of parallel traded medicines were unproven. The theoretical risk existed that so long as parallel traded medicines could be re-packaged and re-boxed, this could lead to counterfeiting. Yet, parallel distributors are obliged to notify the regulatory authorities as well as the manufacturer of any changes made to the product concerned, thus, making themselves liable in case counterfeit medicines enter the distribution chain from this source.

In 2007, however, there were several recalls of counterfeit medicines that had entered

the UK supply chain via a parallel distributor. Several thousand packs of three medicines were seized or recalled by the UK Medicines and Health Care Products Regulatory Agency (MHRA). The counterfeit medicines, made in China and shipped to Singapore, entered the EU in Luxembourg, where they were re-sold without being checked to UK and Belgian wholesalers. This situation raises concerns about the safety and quality of medicines entering the EU and raises further questions about re-packaging and re-boxing.

Shortages in exporting countries

Whereas the pricing structure and the distribution system in exporting countries favour parallel exportation, an important question arises as to what happens to the availability of medicines to patients in exporting countries. Evidence suggests that the end result can be shortages in drugs that are exported intensively. This has been documented in Greece and Spain, both of which have explicitly raised questions of shortages. This is reflected in recent regulatory interventions by the two respective national governments, essentially placing a requirement on wholesalers to declare the destination of the product they acquire from manufacturers. One would of course argue that drug manufacturers should increase production in exporting countries to meet need, but, this does not provide a long-term solution to the problem.

Overall welfare effects

Given a range of complex stakeholder considerations and the current brevity of empirical evidence on welfare implications, the overall welfare effects for parallel trade are at best ambiguous.^{2,11} Perceived short term benefits in increasing affordability may support possible welfare increases but such gains are arguably at the expense of potentially negative long-term implications. Furthermore, despite the perceived benefits from increased affordability claimed by proponents of parallel trade, current and previous empirical work found that parallel trade did not lead to aggregate and sustainable price reductions in key destination countries.¹

In regards to long term implications, it is argued that short term gains in potential savings will be erased by the long term implications of a reduction in product quality from losses to research and development.^{4,12} Furthermore, it has been suggested that parallel trade reduces global welfare by creating an environment where

manufacturers have no incentive to choose to serve countries with lower drug prices.¹³

Conclusions

Pharmaceutical parallel trade has been a controversial practice enabled by the European single market. Much of the debate surrounding parallel trade in pharmaceuticals has focused on the economic impact it has on stakeholders and whether it facilitates patient access to medicines. While proponents and opponents to the practice may disagree on the precise pecuniary effects of parallel trade on individual stakeholders, the fact remains that, overall, its impact on health insurance budgets in importing countries is very small and the effect on patients negligible. By contrast, patients in exporting countries may be faced with significant shortages and access problems. Those who perform the practice also gain significantly from it. Importantly, however, it is likely that parallel trade results in misallocation of resources and may have a significant long-term welfare effect in terms of investment in innovation.

"Savings from parallel trade are very small relative to the size of the pharmaceutical market"

Finally, in recent months, the ability of parallel trade to procure safe medicines has been called into question; the fact that re-packaging and re-boxing can take place, increases the probability of counterfeiting; on the other hand, the meticulous checking of all parallel traded packs of medicines increases transaction costs significantly and may result to poor allocation of resources. On balance, although the practice of parallel trade is still legal in Europe, it is associated with little actual pecuniary benefits and high transaction costs to health insurers, regulators and patients, in both importing and exporting countries, making it an undesirable cost containment tool.

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