

Parallel Importation of Pharmaceuticals in Finland

Effects on Markets and Expenditures

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Abstract

Background: Parallel importation of pharmaceuticals is illegal in many countries. In the European Union it is allowed, as it is consistent with the principles of free trade and the community exhaustion of intellectual property rights. Parallel importation is assumed to affect pharmaceutical expenditures in two ways. First, parallel imported pharmaceuticals are typically priced lower than brand-name pharmaceuticals, which may reduce pharmaceutical expenditures. Secondly, parallel imported pharmaceuticals may trigger price competition, which might also reduce prices of brand-name products and pharmaceutical expenditures.

Objective: To measure reductions in pharmaceutical expenditures due to the entry of parallel imported pharmaceuticals in Finland.

Methods: Both realized reductions in expenditures (realized savings) and potential reductions (potential savings) were estimated. Savings were estimated using a method that measures differences in pharmaceutical expenditures when prices of pharmaceutical products differ as a result of price differences between parallel imported and brand-name pharmaceuticals (direct effect) and the effect of parallel imported products on the prices of brand-name products (competitive effect). Potential savings were estimated under different assumptions concerning the price development of pharmaceutical products. It was assumed that prices of brand-name pharmaceuticals would decrease either by 22% or 10% as a result of competition from parallel imports.

Results: Realized savings due to parallel importation were approximately €294 000 in the years 1998–2001. The savings remained low since parallel imports have not intensified price competition in Finland. Potential savings for the period between March 2000 and March 2001 were estimated to vary in the range of €3.4–10.2 million depending on the assumptions made on the price development of pharmaceutical products.

Parallel importation of pharmaceuticals is receiving increasing attention among policy makers and researchers.^[1-3] Parallel imported pharmaceuticals are imported into a country without the authorization of a manufacturer. Parallel importation from one country to another occurs when a parallel importing firm or a distributor purchases a brand-name pharmaceutical from a local distributor or wholesaler in the exporting country and imports it to the importing country in parallel with the official distribution network of the manufacturer. Parallel trade is profitable only if the price of the parallel imported pharmaceutical is cheaper in the

exporting country than in the importing country. Thus, parallel importers essentially engage in exploiting arbitrage opportunities.

There are various reasons for the price differences observed in the pharmaceutical markets between different countries. One explanation arises from market structure. Pharmaceutical firms typically obtain a patent for novel innovations, and the patent protects the firm from competition by providing a monopoly position for a specified period of time. Economic theory suggests that a profit maximizing pricing strategy of the monopoly firm is to set different prices in different markets, with prices reflecting the price

sensitivity of market demand.^[4] Price discrimination provides one explanation for price variation in different geographical markets. Another reason for varying price levels of the same pharmaceutical in different market areas is differing price regulation practices. This applies in particular to European countries where prices of pharmaceutical products are subject to price regulation rules that vary between different European countries. One rationale to regulate pharmaceutical prices arises from the special features of the health sector. Typically, in the pharmaceutical market, there exist third-party payers in the form of insurers. The presence of insurance may lead to overuse of covered services, which gives a reason for insurers to control the amount of services they reimburse and the prices they pay.^[5,6]

The parallel importation of pharmaceuticals within the EU has its legal basis in the principles of free trade and the community exhaustion of intellectual property rights. The exhaustion of intellectual property rights at an international level means that property rights are exhausted upon the first sale of a product anywhere, after which parallel trade between countries can take place.^[7] The European Court of Justice has applied this principle in some legal cases concerning parallel trade in pharmaceuticals in Europe, and has confirmed that pharmaceuticals must be allowed to move freely within the European Economic Area the same way as other goods can.^[8] However, parallel importation from outside of the European Economic Area is not allowed.

Parallel importation is seen to intensify price competition in markets protected by patents and, therefore, to create pressure towards uniform pricing across different geographical markets. Uniform pricing is consistent with the idea of the single market; parallel importing is seen as an important driving force for market integration.^[9] This also suggests that pharmaceutical expenditures with parallel imported pharmaceuticals may be lower than that without parallel imported pharmaceuticals.^[3] It is worth mentioning that practices of pharmaceutical price regulation in different member states have not been harmonized at the EU level, which may make the formation of a single market in pharmaceuticals difficult.

Finland joined the EU in 1995 after which time parallel imports became legal. The first parallel imported pharmaceutical products entered the Finnish pharmaceutical market in October, 1996, and currently there are more than 100 brand-name pharmaceutical products with a parallel imported substitute in the market. Currently, there are two parallel importing firms in the Finnish pharmaceutical market. Their market share of the total pharmaceutical

sales was approximately 0.2% in 2001. This figure is low compared with corresponding market shares ranging from 2–15% in Sweden, UK, Denmark, and the Netherlands.^[3]

This study had two objectives. The first one was to define and evaluate the reductions in pharmaceutical expenditures (hereafter referred to as realized savings) at a national level due to the entry of parallel imported pharmaceutical products into the Finnish pharmaceutical market. The realized reductions in pharmaceutical expenditures were estimated over the period from March 1998–March 2001. The second objective was to estimate potential reductions in pharmaceutical expenditures (hereafter referred to as potential savings) under different assumptions concerning the price development of pharmaceutical products for the period of March 2000–March 2001. In addition, possible factors that might explain the low market shares of parallel imported pharmaceuticals are discussed.

Data and Methods

Data

The numerical analysis was based on sales data of brand-name and parallel imported pharmaceuticals in Finland. The annual data covered 4 years from 1998–2001. The data set contained 169 pharmaceutical products, for which both the number of packages sold and the sales revenue were recorded. It is worth mentioning that in our data set, some of the parallel imported pharmaceuticals were not in the market for all 4 years. Sales data were obtained from the Finnish Association of Parallel Imported Pharmaceuticals.

Methods

The estimates of realized and potential savings due to parallel imported pharmaceuticals in Finland were calculated using the method developed by Persson et al.^[3] According to this method, the gross expenditures (E) in a pharmaceutical market can be defined as the sum of expenditures on a brand-name product (E_t) and a parallel imported product (E_p) as follows (equation 1):

$$E(p_t, p_p) = E_t(p_t, p_p) + E_p(p_t, p_p) = p_t D_t(p_t, p_p) + p_p D_p(p_t, p_p)$$

where p_t and p_p refer to prices of the brand-name and the parallel imported products, respectively, and D_t and D_p are the demands for brand-name and parallel imported products.

A parallel imported product may influence gross expenditures in two ways. First, prices of parallel imported products are lower than prices of brand-name pharmaceuticals. Thus, the amount of money consumed on parallel imported pharmaceuticals is reduced compared with the case in which parallel imported products are sold at the prices of brand-name products. This effect (direct effect) can be measured as the difference in expenditures as follows (equation 2):

$$E_p(p_t, p_t) - E_p(p_p, p_t) = (1 + \varepsilon_p)(p_t - p_p)D_p(p_t, p_p)$$

where $p_p < p_t$, and ε_p is the price elasticity of the demand for parallel imported pharmaceuticals. When calculating the direct effect, we compared the current price of the parallel imported pharmaceutical with the current market price of the brand-name product.

Secondly, parallel trade may trigger price competition, lowering the price of the brand-name product and expenditure on the brand-name product compared with the price of the brand-name product before it encountered competition from parallel imports. This effect (competitive effect) can be measured as the difference in expenditures as follows (equation 3):

$$E_t(p_t^0) - E_t(p_t^1, p_p) = (1 + \varepsilon_t)(p_t^0 - p_t^1)D_t(p_t^1, p_p)$$

where p_t^0 and p_t^1 ($p_t^1 < p_t^0$) are the prices of the brand-name product before and after the entry of the parallel imported product, respectively, and ε_t is the price elasticity of the demand for the brand-name pharmaceutical. Total savings due to parallel imports was computed as the sum of the direct and competitive effects. To simplify the calculations of competitive effect we assumed that the price reduction of brand-name products did not have any influence on the demand for parallel imported products. A 10% decrease in the own price of the pharmaceutical was assumed to increase the demand for the pharmaceutical by 2%. This assumption was also made in a similar study by Persson et al.^[3] Realized and potential savings were first calculated for the individual products and then the savings were added up to obtain the total savings due to parallel imports. There are some extra costs associated with parallel imports (i.e. increased work at pharmacies) which in principle should be deducted from savings. This was not done since no reliable data concerning these costs were available.

The sales data used in the calculation of potential savings were expressed using wholesale prices, but for some estimates, retail prices exclusive of value added tax were also calculated. This was done to reflect the fact that increased use of cheaper pharmaceuti-

cals would also lower the absolute profits (however, for higher priced pharmaceuticals the profit margin is lower) to pharmacies leading to further savings from the consumers' perspective. In Finland, retail prices are regulated by law and defined on the basis of wholesale price.^[10] Table I presents the formulae used to calculate the Finnish retail prices of pharmaceuticals.

Computation of Realized and Potential Savings

Realized Savings

The calculation of changes in pharmaceutical expenditure was based on a comparison of the current market structure and prices with a hypothetical market structure in which no parallel importation occurred. Realized savings were measured using information on price differences between direct and parallel imported products, quantities sold, and demand elasticity. Since we had no information on the price of the brand-name product in the case that no parallel imports occurred, realized savings were based on two possible cases. In the first case (direct effects), the market price of the manufacturing firm without parallel imports was assumed to be the one realized currently in the market. Any changes in the market price of the directly imported (brand-name) product were due to changes in the basic conditions (due to changes in technology, demand, regulation, or the entry of a therapeutic substitute) of the market and not due to competitive effects introduced by the parallel importing firm(s). In the second case (direct and competitive effects), it was assumed that any changes in the price of the directly imported product are the result of increased competition introduced by the parallel imports. In the calculations the realized price of the manufacturer was compared with the price of the same pharmaceutical before competitive entry from parallel imports. If parallel imports took place in 1998, the prices of the same year were used because no price data concerning the year 1997 were available.

Table I. Determination of retail prices of pharmaceuticals in Finland

| Wholesale price (WP) [€] | Retail price (€) |
|--------------------------|------------------|
| 0.17–9.24 | 1.5 WP + 0.5 |
| 9.25–46.24 | 1.4 WP + 1.43 |
| 46.25–100.90 | 1.3 WP + 6.05 |
| 100.91–420.47 | 1.2 WP + 16.15 |
| >420.47 | 1.125 WP + 47.68 |

Table II. Anatomical Therapeutic Chemical (ATC) groups selected for savings estimation

| ATC group | Type of pharmaceutical in the group |
|-----------|--|
| C10A | Cholesterol- and triglyceride-lowering preparations |
| N06A | Antidepressants |
| C07A | β -Blocking agents (not combination products) |
| A02B | Anti-ulcerants |
| C08 | Calcium channel blockers |
| G04B | Other urological preparations |
| M01A | Anti-inflammatory and anti-rheumatic products |
| R03B | Other drugs for obstructive airway diseases, inhalants |
| N05A | Antipsychotics |
| C09A | ACE inhibitors (not combination product) |
| L03AB | Interferons |
| G03A | Hormonal contraceptives, systemic |
| R03A | Adrenergics, inhalants |
| N03A | Anti-epileptics |
| A10B | Oral antidiabetics |

Potential Savings

We estimated how large the savings would be if price competition had intensified after the entry of parallel imported pharmaceuticals. Price competition was not expected to intensify in each pharmaceutical market, but for selected products that fulfilled criteria concerning the size of a market and the market share of parallel importing firms. It is argued that price competition is more likely in large markets in which parallel importing firms have a high market share than in small markets with low market shares of parallel imported products.

The size of the market was measured using the Anatomical Therapeutic Chemical (ATC) classification of pharmaceuticals used in our study. Only those ATC groups for which the fraction of sales to total outpatient sales in the Finnish pharmaceutical market exceeded 1.5% (March 2000–March 2001) were selected. Selected classes represented 49.8% of the total sales volume of the Finnish pharmaceutical market (see table II).

Among these classes, those brand-name pharmaceuticals with parallel importation were selected, and then potential savings were estimated under optimistic and moderate price scenarios. Under the optimistic price scenario, prices of both parallel and directly imported (brand-name product) pharmaceuticals were assumed to

decrease 22% due to price competition introduced by parallel imports. This figure was applied because it approximates the price development of Losec®¹ (omeprazole) in Denmark, Sweden, and Norway after the entry of the parallel imported substitute.^[3] Since the price development of Losec® has been quite extreme, we also evaluated potential savings under another, more moderate price scheme. In the moderate price scenario, the prices of both parallel and directly imported products were assumed to decrease by 10% due to competition introduced by parallel imports. These savings figures were then estimated using all selected products and the subset of pharmaceuticals selected satisfying the condition of the market share of the parallel imported product.

Results

Realized Savings

In the first case (direct effects), we calculated realized savings due to lower prices of parallel imported pharmaceuticals. Total savings for the 4 years 1998–2001 are presented in table III. The total savings in that period equalled €293 825.

In the second case, both direct and competitive effects were included in the realized savings estimate. Estimates of realized savings for the years 2000 and 2001 are presented in table IV. Annual estimates were significantly higher than the estimates for direct effects (section 2.2). Estimates of realized savings were significantly higher than the ones in the first case.

Are There Any Competitive Effects?

The natural questions that arise from the above analysis are: Which assumption concerning the pricing pattern of the brand-name products is closer to the realized price development in the market? Are price changes of the brand-name products mainly due to competition introduced by parallel imported products or to some other exogenous factors changing the prices of brand-name products? We sought to answer these questions by using the following linear model (equation 4):

$$BPRICE_{it} = \alpha_i + \beta PIPRICE_{it} + \gamma YEAR_t + \mu_{it}$$

where $BPRICE_{it}$ and $PIPRICE_{it}$ are the prices of the brand-name product i and the parallel imported product i in year t , respectively, and μ_{it} is the statistical error term, and α_i , γ , and β are unknown parameters. The idea was to test if price changes of the parallel imported products have caused any changes in the prices

1 The use of tradenames is for product identification purposes only and does not imply endorsement.

Table III. Realized savings due to direct effects

| Year | Savings (€) |
|----------------------|----------------|
| 1998 | 48 102 |
| 1999 | 73 498 |
| 2000 | 73 835 |
| 2001 | 98 390 |
| Total savings | 293 825 |

of corresponding brand-name pharmaceuticals. The time trend was added to the model as an independent variable to control for possible time trends in data. We estimated the fixed and random effects specifications of the above model using the available data. Results of the estimation are presented in table V.

The price of parallel imported pharmaceuticals was not a statistically significant variable in either model specification. We found no evidence to support the hypothesis that price changes of brand-name pharmaceuticals would have been reactions to price changes of the parallel imported products. We take these results to show that there has been no strategic interdependence in the pricing behavior of manufacturing and parallel importing firms. Competitive effects have not been realized in Finland and the assumptions behind the calculation of the direct effects are closer to the true price development in the market. We therefore estimate that the realized savings due to parallel imports have been €293 825 over the 4 years from 1998–2001.

Potential Savings

Potential savings were calculated using the sum of equations 1 and 2. In equation 2, however, prices of directly imported pharmaceuticals were also those realized during the year in question. Table VI presents the obtained estimates on potential savings. The first row of the table shows potential savings under optimistic and moderate price scenarios for all pharmaceuticals selected on the basis of the largest ATC classes. The second row displays the potential savings calculated only for those markets for which the parallel imported pharmaceuticals had a market share larger than 1%. The latter saving estimates are lower because there were fewer products used in the estimation. However, we believe that it is more likely that price competition occurs in these markets because of the larger market share of parallel imported products. The estimated potential savings ranged from €3.4 million to 10.2 million in 2001 (0.4–1.3% of the total pharmaceutical expenditure in outpatient care).

In order to test how sensitive the above estimates are with respect to the selection criteria, we also calculated the same estimates by using a different measure of market size. The largest pharmaceutical products in Finland, when measured by current sales, were chosen. Their cumulative market share covered approximately 50% of the total outpatient sales. The potential savings ranged from €4.2 million to 11.5 million (€6.2 million to 17.3 million in retail prices). These estimates are slightly but not much higher than the ones obtained using the ATC classes. This was because a different set of parallel imported pharmaceuticals was included in the estimation. This allows us to conclude that the estimates did not change significantly when different selection criteria were applied.

Discussion

In our study, the market for a particular pharmaceutical product was defined to comprise a brand-name pharmaceutical and a parallel imported substitute(s) for the product. This definition may have its drawbacks since it may ignore some substitutes for a pharmaceutical product. The strength of the definition is that it is directly applicable. Information on price elasticity of different products in the Finnish pharmaceutical market would have been needed in order to use some other, and simultaneously a broader, market definition. Since no such data were available, the workable market definition was used.

The estimated realized savings due to parallel imports (see Results section, Realized Savings) are low compared with estimates obtained in other countries.^[3] Low estimates in Finland may be explained by small price differences between brand-name and parallel imported products or by low market shares of parallel imported products. A third possible explanation is that manufacturing firms have not reacted to the increased competition from parallel imports by decreasing their prices. This last explanation was supported by the empirical analysis.

Market shares of parallel imported pharmaceuticals may have a crucial role in the process of price competition and the resulting

Table IV. Estimated realized savings due to direct and competitive effects in Finland

| Year | Savings due to price change of _____ | | Total (€) |
|------|--------------------------------------|---------------------|-----------|
| | brand-name product (€) | parallel import (€) | |
| 2000 | 1 791 201 | 104 781 | 1 895 982 |
| 2001 | 4 695 639 | 211 076 | 4 906 715 |

Table V. Results of estimation for fixed and random effects models^a

| Variable | Fixed effects estimates | Random effects estimates |
|----------|-----------------------------------|-------------------------------------|
| Constant | ^b | 38540.4598 ^c (12899.784) |
| PIPPRICE | 0.0005980 (0.002272) | 0.00051448 (0.0022292) |
| Year | -24.36556 ^c (6.668703) | -19.150478 ^c (6.4500915) |

a Standard errors are presented in parentheses.

b Fixed effects estimates are available on request from the authors.

c Statistically significant at $p < 0.01$.

PIPPRICE = price of the parallel imported product.

formation of realized savings. Regulatory measures, laws concerning the pharmaceutical market, pricing of pharmaceuticals, and institutional features of healthcare may be factors affecting market shares. The institutional feature which differentiates pharmaceutical markets from a typical demand model^[4] is that the utilization of pharmaceutical products in pharmaceutical markets is affected not only by decisions made by patients but also by choices of prescribing physicians and dispensing pharmacists.

Whether this institutional feature in healthcare has any economic importance has been studied in the recent economic literature.^[11-14] These studies came to the conclusion that physicians' habits and consumers' preferences are factors explaining prescription behavior.^[12,13] Evidence also suggests that relative prices of pharmaceuticals do not affect prescription choices.^[14] Although these studies have concentrated mostly on generic substitutes, they can be useful in interpreting the results of this study. The papers demonstrate that the behaviors of physicians and patients are determining the way a demand in a pharmaceutical market is formed. If the demand for a pharmaceutical does not react to the price differences present in the market, it is certainly possible that a low priced substitute ends up with a low market share. This seems to be the case with parallel imported pharmaceuticals in Finland.

At the time of the study, pharmacists were obliged to dispense the pharmaceutical whose brand-name was mentioned in the

prescription (i.e generic substitution was not allowed if the prescription was written using a brand-name). It is worth observing that this rule did not prevent dispensing of the parallel imported pharmaceutical because the alternatives in the market were of the same brand-name. According to Finnish regulations during the study period, a pharmacist should have dispensed the cheapest pharmaceutical available or the one whose price differed only slightly from the lowest price.^[15] What a 'slight price difference' means was not clearly defined and therefore, this policy rule could not be enforced strictly. Pharmacies in Finland have the authority to dispense the cheaper parallel imported version instead of a prescribed and more expensive brand-name pharmaceutical. An economic factor which influences the pharmacists' choices between pharmaceuticals is the unit profit that a pharmacy is earning on a drug, and one reason that might prevent pharmacists from dispensing parallel imported pharmaceuticals is that these products cause extra storage costs for pharmacists.

There may also be commercial impediments to parallel trade that influence the penetration of parallel imports in the market. These include actions taken by manufacturers to make the parallel importation of pharmaceuticals more difficult. For example, it is possible that manufacturers use different brand-names for the same product in different countries. In this case the parallel importer has to demonstrate that the proposed import with a different brand-name is identical to the pharmaceutical already licensed on the market. Thus, different brand-names for the same product make it more difficult to get an import license. Furthermore, different brand-names increase the work of the parallel importer in repackaging or relabeling, and it can cause pharmacists' and patients' anxiety about the parallel import.^[16]

Differences in presentation, packaging, labeling, and instructions for use between various countries may also exist. These differences may appear, for example, in the color of tablets, in the number of tablets in one package, or in the strengths of a pharmaceutical. Obviously these kinds of differences make parallel importation more difficult. In Finland, for example, The National

Table VI. Estimated potential savings in selected pharmaceuticals in Finland, 2001

| | Price scenarios (€; millions) [wholesale price/retail price] | |
|---|--|-------------------------|
| | optimistic (22% decrease) | moderate (10% decrease) |
| A. Pharmaceuticals in the largest Anatomical Therapeutic Chemical groups (covering 50% of total outpatient sales) with a parallel imported substitute | 10.2/15.6 | 4.6/7.1 |
| B. Subset of A: market share of parallel imported products >1% | 7.5/11.4 | 3.4/5.2 |

Agency for Medicines rejected an application for a sales permit for a parallel imported pharmaceutical on the basis of the different number of tablets in a package compared with the directly imported product. This decision was later invalidated by the Supreme Administrative Court since the basis for the decision mentioned in article 30 of the Treaty Establishing the EU did not exist.^[17]

Moreover, restrictions of supply may form an impediment for parallel trade; parallel importers may be unable to obtain the quantities they want at the time they need them.^[16]

Conclusions

The aims of this study were to describe the market for parallel imported pharmaceuticals in Finland and to assess reductions in pharmaceutical expenditures due to parallel imported pharmaceuticals.

Savings were estimated in two cases. The first case assumed that parallel importing firms have no impact on the prices of the manufacturing firms. Any changes in the prices of brand-name products are due to changes in the basic conditions of the market, such as regulation and/or technology. In this case, the realized aggregate savings in the period 1998–2001, with the introduction of parallel imported pharmaceuticals, were estimated to be €293 825. The second case assumed that any changes in the price of the directly imported product are due to a competitive effect introduced by parallel importing firms. The estimated annual potential savings for the years 2000 and 2001 were €1 895 982 and €4 906 715, respectively. Our statistical analysis showed that parallel imports did not change the pricing behavior of the manufacturing firms. Therefore, the estimated savings in the first case were closer to the realized development of the market than what the second case assumed. We conclude that realized savings due to parallel imports were €293 825 in the 4 years under consideration.

The calculated estimates of savings are low compared with the Swedish estimates. A potential explanation for low saving estimates is that, in Finland, parallel imports have not intensified the price competition. The potential savings in a hypothetical case were also assessed. It was assumed that the firms importing directly decided to react to the lower prices of parallel importing firms. Estimates for potential savings ranged from €3.4 million to 10.2 million, depending on assumptions made on the price development.

When assessing the results on potential savings, it is important to note that we applied the price development scheme from other

Nordic countries. Basic conditions of pharmaceutical markets in Finland (e.g. regulation, market shares of parallel imported pharmaceuticals) may differ from the other Nordic countries, which may lead to different pricing behavior of firms. It may also be that, in Finnish markets, optimal pricing behavior of firms differs across markets and does not follow the assumed pattern. Finally, in order to assess how realistic the assumed price reductions are, one would need to know more about price-cost margins in pharmaceutical markets. Such information was not available to us in this study. Further research on factors influencing the price setting behavior of pharmaceutical firms in Finland is needed in order to obtain more reliable estimates of the potential savings due to increased competition.

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