

**THE EUROPEAN ASSOCIATION OF
EURO-PHARMACEUTICAL COMPANIES**

**Benefits to Payers and Patients
From Parallel Trade**

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INVESTOR IN PEOPLE

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Executive Summary

- The total direct savings from the parallel trade of pharmaceutical products in 2002 were estimated as:

UK	€342m
Germany	€194m
Sweden	€47m
Netherlands	€32m
Denmark	€16m ⁽²⁰⁰¹⁾
Total	€635m

- The study finds evidence that parallel imports have indirect competitive effects by forcing down the price of their domestically sourced counterparts.
- Direct and indirect savings from the parallel trade of pharmaceuticals have helped contain mounting public healthcare expenditure in many European countries.

1. INTRODUCTION

The European Association of Euro-Pharmaceutical Companies (EAEPC) commissioned the York Health Economics Consortium (YHEC) in July 2002 to produce a report assessing the benefits from parallel-distribution of pharmaceuticals and to whom these benefits accrue.

The report focuses on the financial benefits available through savings from products that fall under some form of public health insurance. It also considers the indirect benefits that arise from increased competition on national distribution chains.

The report looks in detail at five European countries that have significant markets for parallel-distributed products, namely:

- Denmark;
- Germany;
- Sweden;
- The Netherlands;
- United Kingdom.

To provide an impartial view of the benefits possible through parallel-distribution, the analysis in the report is mostly empirical in nature, with data originating where feasible from independent sources. To aid in an understanding of the savings available and to whom they accrue, an overview of each country's pharmaceutical market and patient reimbursement system is provided.

2. FINDINGS

The key findings for each country are summarised below:

Denmark

- Direct savings of 120 million DKK (€15.7 million) in 2002 from the use of parallel-sourced products - these savings were split roughly 60/40 between the government (i.e. taxpayers) and patients respectively.
- Denmark has one of the highest penetrations of parallel-distributed pharmaceuticals in Europe - around 10% of the total drugs bill.
- Statistical evidence of competition from parallel imports forcing pharmaceutical manufacturers to lower the prices of the products concerned.
- There is evidence in the nature of the market that the manufacturers limit supply in the countries from which parallel imports into Denmark are sourced.

Germany

- Direct savings of €194 million from the purchase of parallel distributed goods – most savings directly benefit the sick funds (i.e. patients).
- Direct savings on the contraceptive pill alone of over €10 million and on insulin products of approximately €6 million.
- The German market for parallel-distributed products has grown rapidly in recent years and experienced exponential growth over 2002 as new measures were introduced to encourage pharmacists to substitute parallel for domestically sourced products.
- Evidence of parallel-distribution resulting in reduced prices for certain domestically sourced equivalents.

Sweden

- Direct savings of SEK 424.3 million (€46.7 million) to the Swedish reimbursement system (PBS) and to patients in 2002 - approximately 78% of this saving is reaped by the government, as a result of a reduced drugs bill for the PBS, and 22% go to the patients through lower levels of co-payment.
- Statistical evidence that prices set by pharmaceutical manufacturers are lower when there is competition from parallel imports than when there is no competition - manufacturers are reluctant to raise prices when they face competition; in other cases, lower prices are due to a price-cutting strategy of the manufacturer to undermine parallel trade.
- From October 2002, a legal obligation has been placed on pharmacists to offer parallel- distributed products. Despite little incentive to dispense these products

beforehand, growth in the parallel-distribution market has been substantial in recent years.

- As in Denmark, the nature of the market suggests supply limiting behaviour by manufacturers. Potential savings could be higher if these limitations were removed

The Netherlands

- Direct savings of €31.6 million from parallel trade - €4.6 million savings to pharmacists and €27 million savings to sick funds (i.e. patients).
- These figures are likely to be lower than actual savings, as there are un-quantifiable savings that pass to pharmacists that are not deducted in the clawback.
- The Dutch market has the longest history of parallel-distributed pharmaceuticals in Europe. It also is one of the least concentrated.
- New policies and pricing regulations that are being introduced are likely to present parallel traders with both challenges and opportunities.

United Kingdom

- The UK market for parallel-distributed pharmaceuticals is one of the largest in Europe - in 2002 it represented around £1,300 million (€2,000 million).
- Direct saving from parallel trade are estimated at up to £228 million (€342 million) or 17 per cent of medicines expenditure.
- Much of the saving passes to government in lower hospital medicine prices and through the clawback mechanism applied to pharmacies.
- With an average clawback of 10% by government, significant savings remain with the pharmacies.
- Indirect benefits from increased competition are difficult to quantify due to lack of data but there is qualitative evidence pointing to their existence.

3. CONCLUSIONS

In 2002 the total estimated direct savings from the five EU countries analysed amounted to €335 million. These savings can be broken down to €342 million in the UK; €194 million in Germany; €47 million in Sweden; €32 million in the Netherlands; and €16 million (2001 figure) in Denmark.

Parallel trade also generates indirect savings by creating competition, where otherwise there is none, and thus forcing pharmaceutical manufacturers to reduce the prices of domestically sourced products. These indirect savings are difficult to quantify but they could be larger than the direct savings.

Finally, these direct and indirect savings from the parallel trade of pharmaceuticals have played a major role in holding down the spiralling public healthcare bill in many European countries.

Section 1: Introduction

1.1 INTRODUCTION

The European Association of Euro-Pharmaceutical Companies (EAEPC) commissioned the York Health Economics Consortium (YHEC) to produce a report highlighting the benefits from parallel-distribution of pharmaceuticals and to whom these benefits accrue. The report focuses on the financial benefits available through savings from products that fall under some form of statutory health insurance.

1.2 WHAT IS PARALLEL-DISTRIBUTION?

Parallel-distribution is the legal movement of identical products between nation states without the explicit consent of the original manufacturer. Opportunities for parallel-distribution exist when the price difference of an identical product in two countries is greater than the costs of transporting a good from the cheaper to the more expensive country. Parallel-distribution has been accused of being the exploitation of a pure arbitrage opportunity, although this is not the case. Even if the transaction was considered to be costless, which it never is, there will always be elements of risk that either the product will not sell due to either consumer resistance or the domestic supplier modifying their selling price leaving the parallel distributor with unsold stock. As it can take many months to gain a licence to distribute a product, there is also the risk of price reductions occurring even before the parallel distributor can legally supply a product.

The legality of parallel-distribution of pharmaceuticals is enshrined in the Article 3 (1c) of the Treaty of Rome:

In the EC there should exist "...an internal market characterised by the abolition, as between Member States, of obstacles to the free movement of goods, persons, services and capital"

Legislation resulting in the exhausting of intellectual property rights once the product has been marketed in one member state has also been essential in legally underpinning the activities of parallel-distributors.

Parallel-distribution of pharmaceuticals within the EU has occurred because the products are essentially identical and large price differences are maintained through a combination of price setting activities of individual member states and perhaps more importantly through the desire of manufacturers to profit maximise through the use of differential pricing.

1.3 THE EUROPEAN REIMBURSED PHARMACEUTICAL MARKET - AN OVERVIEW

Under patent protection, a pharmaceutical company that develops a new chemical entity (NCE) has a monopoly over its production. Conversely, each country in Europe, either through the State or through sick funds, acts as a virtual monopsonistic purchaser within their borders.

Prices for pharmaceuticals are therefore not decided by market forces, but rather through the negotiation of the single purchaser and single producer. For some markets the manufacturer is free to set the price as they see fit, whilst in others stringent pricing regulations such as pricing at or below the European average are in place. However, even in free pricing countries such as the UK, there are still indirect limitations on the price of products through such methods as profit monitoring by Governments.

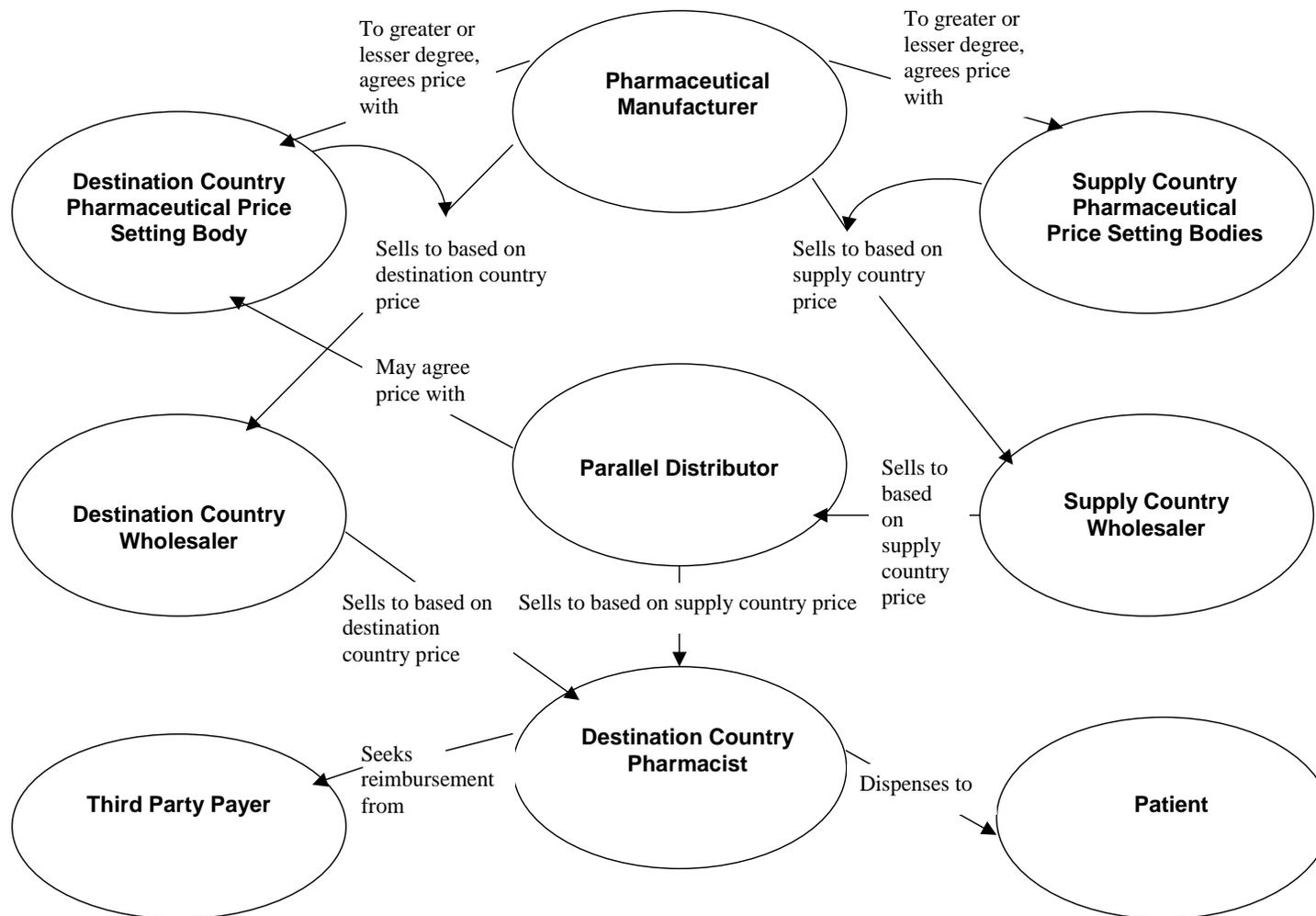
In a monopolistic market with many buyers of the product, a profit maximising manufacturer will exploit his position to reduce supply and increase the price. Faced with several countries with different characteristics and demand curves, it is also profit maximising for the manufacturer to maintain different prices in the different countries.

In a monopsonistic market with many producers, the buyer will try to exploit their position to purchase at a lower price than under market conditions. Each country to a greater or lesser degree tries to exploit their monopsonistic position to achieve what they declare to be a fair price for a product.

Figure 1.1 overleaf provides a general summary of the price setting and supply chain of parallel-distributed pharmaceuticals for a typical European country.

Following the distribution in Figure 1.1 through, although the final consumer of the product is the patient, the pharmacist acts as an intermediary between the wholesaler and the customer. The price a pharmacist can charge for a prescription product is determined in each country individually. Either the patient pays a co-payment proportional to the price of the product or a fixed tariff of anywhere between zero and one hundred percent.

Figure 1.1: A Generalisation of the Reimbursed Market for Parallel-Distributed Pharmaceuticals



1.4 THE ROLE OF THE PHARMACIST

Given the distribution chain in Figure 1.1, why should pharmacists choose to purchase products from a parallel-distributor rather than the domestic wholesaler?¹ The answer to this question lies in the fact that parallel-distributors offer a discounted price compared to the domestically sourced product and so therefore a saving is produced.

However, incentives in the system are crucial if any of the potential savings available from parallel trade are to be realised. Pharmacists need to be given the incentive to source parallel traded alternatives to domestically sourced goods. This may be a financial incentive allowing pharmacists to keep a proportion of the profit generated from purchasing parallel traded goods. Alternatively, a financial penalty could be imposed on pharmacists who do not parallel substitute or a legal obligation on pharmacists to dispense parallel sourced products could be enforced.

Either way, the success or otherwise of benefiting from parallel trade is largely dependent on the pharmacist as the buyer in the industry. The incentives and obligations on pharmacists to dispense parallel substitutes are therefore highlighted throughout this report.

The price an individual pharmacist pays for a drug is usually based on the price agreed between the third party payer and the pharmaceutical company. A wholesaler will normally be involved as an intermediary between the producer and pharmacist, and may be able to negotiate with the manufacturer to secure a better deal.

However, the savings that may accrue may be entirely realised by the pharmacist and not passed onto the third party payer. For this reason, third party payers either reimburse pharmacists at different rates for domestically sourced and PT goods or clawback some of the price difference by reducing the actual reimbursement.

1.5 POTENTIAL BENEFITS TO EXPORTING COUNTRIES

Parallel-distribution in Europe has tended to move products from lower priced countries in the South such as Spain and Greece to Northern Europe. For historical and political reasons, the price of pharmaceuticals in Southern Europe has been lower than that in the North. Whilst this generates savings for the North, it raises questions on how this impacts the supplying countries.²

¹ In some instances, the parallel-distributor may sell direct to the wholesaler who then sells both a domestically and parallel sourced version of the same product to the pharmacist

² It is noted that it is ambiguous to now talk about low price supplying and high price destination countries as parallel-distribution occurs both into and out of most EU countries.

A major concern is whether the supply of some products in countries such as Spain will be diminished through parallel-distribution to such an extent that patients in the supplying country suffer. This can be quickly dispelled by the over-riding condition placed by governments on pharmaceutical companies, and especially wholesalers, to ensure that there is sufficient supply to meet the demands of the domestic market.

Related to this issue is the question of whether parallel-distribution affects the price of a product in a supplying country, thereby increasing the country's drug bill? However, with regulated prices it is not necessarily easy to raise the price of an individual product. Given a monopolists' desire for differential pricing it is not clear that raising the price would in any case be a profit maximising strategy for a pharmaceutical company looking for maximum profits.

The wholesale margin allowable in Spain has been reduced in recent years to act as a brake on a growing drugs bill. At the same time, the number of Spanish wholesalers supplying parallel distributors has risen dramatically. It is possible that the cuts in the wholesaler margins are directly attributable to the profits that can be made from parallel-distribution. As such, the Spanish healthcare system is being subsidised by parallel-distribution out of Spain. Whilst this is a reasonable proposition, without further data it is impossible to prove or disprove this case.

1.6 POTENTIAL BENEFICIARIES IN IMPORTING COUNTRIES

The potential beneficiaries of the savings that can be realised from parallel-distribution within a country are:

- The Government or insurance company as the pharmaceutical reimbursers;
- The pharmacist;
- The patient.

The savings could be direct: the difference in the price between a domestically and a parallel sourced product. Alternatively, savings could be indirect, through the erosion of prices that the competing parallel-distribution brings to products that are often under patent and so have a monopolistic position in the market. The bulk of this report focuses on these savings and attempts to allocate them to the three potential groups of beneficiaries.

1.7 METHODS AND DATA

The analysis of savings focuses on the five largest pharmaceutical markets receiving parallel sourced products in Europe:

- The UK;
- Germany;
- The Netherlands;
- Sweden;
- Denmark.

The major problem facing any price analysis of pharmaceuticals in Europe is the lack of knowledge of the prices actually paid. Whilst official prices are usually readily available, discounting is commonplace, either directly or through so called “brand equalisation” deals, giving indirect discounts on multiple purchases. The actual prices paid for products may vary from pharmacy to pharmacy, so this information is largely unattainable. The savings calculated are therefore, based on the difference between reimbursed prices for domestic and parallel-distributed products unless otherwise stated.

Where possible, data sets were taken from independent sources such as national statistics agencies or pharmacy bodies. If this was not possible, then data was requested from parallel-distributing companies and verified as far as possible. All the results are replicable.

Where time series data on prices was present, statistical analysis was used to isolate a competition effect by looking at both the average price changes and price variance over time for both products, with and without parallel-distributed competition.

Euro exchange rates used in the analysis were those prevailing as at 14 February 2003 and were as follows:

1 GBP = €1.50

1 SEK = €0.11

1 DKK = €0.13

The format of the following sections for each country considered is as follows:

- An overview of the pharmaceutical market in each country;
- A description of parallel-distribution in each country and identification of the potential beneficiaries;
- The sources of data and methods used;
- Results of the data analysis and conclusions.

Section 2: Denmark

2.1 PRICING AND REIMBURSEMENT MECHANISM

Denmark exhibits a relatively free pricing system for pharmaceuticals that enter the reimbursement list. Subject to a few notable interferences from the Government, companies have been free to set the price of their products as they see fit. However, the price at which a product will be reimbursed is heavily regulated, and so indirectly the actual manufacturers' price is also regulated.

For pharmaceuticals that are no longer under patent protection, the price is subject to the lowest price of other pharmaceuticals that have the same active ingredient.

For patent protected pharmaceuticals, in early 2000 an agreement was reached between the Government and pharmaceutical companies that product prices should be no higher than the "European average" without special dispensation from the Government. This rule was introduced in an effort to curb the growth in the Danish drugs bill. Although the agreement expired in June 2001, manufacturers are still required to notify the Danish Government of European prices for their product. New chemical entities are still subject to being priced at the European average price at launch.

Wholesalers are allowed to add a profit margin negotiated for each individual product before selling on to the pharmacist at the Pharmacist Purchase Price (AIP). The pharmacist then marks up the AIP by a fixed percentage and charges a dispensing fee. This gives the pharmacy retail price (AUP) and it is for this amount that a patient may seek reimbursement. The mark up and dispensing fee add about 40% to the AIP, but the actual amount is on a sliding scale depending on the price of the product.

As a baseline case reimbursement of pharmaceuticals to patients is proportional to the amount of reimbursed pharmaceuticals in a given year, with a patient co-payment being made for the difference. There is optional health insurance that covers the cost of the co-payment. Full reimbursement is given to those with chronic conditions where spending exceeds a certain limit within a 12 month period and for the terminally ill where reimbursement is 100%.

2.2 PARALLEL-DISTRIBUTION

Prices for all pharmaceutical products are published fortnightly. Unless instructed otherwise by a physician, pharmacists must offer the cheapest form of the drug on a prescription slip

unless the proprietary brand is less than 5DKK different in price for products under 100 DKK, 5% lower for products between 100 DKK and 400 DKK and 20 DKK over 400 DKK. The cheapest alternative may be a generically manufactured drug or a parallel sourced substitute. However, if the patient chooses, they may have the branded, domestically sourced good. As there is co-payment, there is an incentive by patients to take the cheaper form of the drug, and as the pharmacist has to offer the cheaper alternative, there is a legal obligation for the pharmacist to distribute parallel sourced goods. Despite pharmacists in Denmark receiving a lower level of profit for dispensing parallel-distributed pharmaceuticals, the legal obligation has ensured that parallel-distribution accounts for approximately 10% of pharmaceutical supply in Denmark.

2.3 POTENTIAL BENEFICIARIES OF SAVINGS FROM PARALLEL-DISTRIBUTION

Table 2.1 below shows spending in billions (1,000 million) of Danish Krone on domestically and parallel sourced products in the primary health care sector for the years 1997-2001.

Table 2.1: Split of Danish drugs bill between domestically and parallel sourced products

	1997		1998		1999		2000		2001	
	B.DKK	%								
Domestic	7.1	89.5	7.4	87.9	7.7	88.4	8.3	88.1	8.9	88.7
Parallel	0.8	10.5	1.0	12.1	1.0	11.6	1.1	11.9	1.1	11.3
Total	7.9	100	8.4	100	8.7	100	9.4	100	10.0	100

Source: Danish Ministry of Health

As can be seen, the absolute value of parallel-distributed products has risen some 35% between 1997 and 2001. This is in line with the growth in the Danish pharmaceutical market as a whole, reflected in the fact that the proportion of products domestically sourced has fallen only slightly over this period.

Whilst the beneficiaries of savings from parallel-distribution are not hard to identify, the exact allocation of the savings is. Beneficiaries will either be the Government reimbursing patients, the insurance company covering the co-payment or the patient themselves; due to the sliding scale of reimbursement, it is hard to isolate the levels of reimbursement and co-payment for particular products.

Data from the Danish Medicines Agency splits the drugs bill in primary health care between reimbursement and co-payment for the years 1997-2001. This information is summarised in table 2.1 overleaf.

Table 2.2: Split of Danish drugs bill between co-payment and reimbursement

	1997	1998	1999	2000	2001
Reimbursed	58.8%	58.9%	58.4%	54.2%	57.7%
Co-payment	41.2%	41.1%	41.6%	45.8%	42.3%

Source: Danish Medicines Agency

Whilst this does not split the co-payment between insurance company and patient, it gives an indication of where the savings accrue.

2.4 METHODS AND DATA

2.4.1 Data Sources

Information and data used in the analysis of Denmark was taken from four sources:

- The Danish Medicine Agency (Laegemiddel Styrelsen) website provided price data on every pharmaceutical licensed for sale in Denmark from 25 August 1997 to 10 June 2002;
- The Danish Ministry of Health (Indenrigs-og Sundhedsministeriet) provided the breakdown of the reimbursed drugs bill, taken from the Danish Ministry of Health;
- DLI (Dansk Lægemedel Information) provided sales figures for five years between 1997-2002 via PFL (Parallelimportørforeningen af Lægemedler) and PFL provided a calculation of savings from parallel trade for 2001.

1,392 different pharmaceutical entities have been available to Danish patients at some time over the five years under consideration. It is not viable to individually examine each product in isolation. Analysis therefore focuses on the top selling products and a random sample of 150 products.

The data available allows examination of the two identified areas of potential savings from parallel-distribution in Denmark:

- Direct savings from verification of the PFL calculations;
- Identification of any “competition effect” that may be driving prices down.

2.4.2 Direct Savings

The methodology of the savings calculation from PFL, a simple multiplication of sales by price differential, was verified and the figures used were confirmed.

2.4.3 The Competition Effect

Analysis of individual product lines of the top selling drugs was conducted to search for evidence of competition effects by simply examining time plots of domestically sourced goods and their parallel-distributed competitors. Particular emphasis was placed on those product lines where parallel-distribution had only been in place for a portion of the five-year period under consideration, to isolate the behaviour of the incumbent as competition enters or leaves the market.

Although there has been evidence presented of price competition between parallel-distributors, particularly for the product Spirocort, the time plot analysis is concerned with the competition effect between parallel and domestic suppliers. As such, the time plots show the price movement of the domestic supplier coupled with the parallel-distributor who has been in the market for the longest time for a particular product. Exceptions to this will be where the first parallel-supplier drops out of the market but a different supplier remains. In this case both suppliers prices will be shown.

To examine any competition effect on the market as a whole, a random sample of 150 chemical entities were chosen and separated into groups depending on whether they were subject to competition from parallel distributors, generic manufacturers or both. A final group was formed for those entities with no competition. Only chemical entities that had been available in the market for the whole of the five-year data period were considered for the analysis. This reduced the sample to 114 chemical entities. Only one product line was considered for each entity, and to remove any noise from changes in pharmacist profit margins, the AIP was used.

Average price changes over the whole five-year period were taken for each group and a hypothesis test was conducted to see whether the averages were statistically significantly different from each other. The averages were also compared to the reduction in the Danish Medicines Agencies' AIP price index over the same period.

If a competition effect exists as a result of parallel-distribution forcing prices down, the average price change of the group with parallel-distribution competition both with and without generics competition will be lower than that of the other groups and of the total change in the index.

2.4.4 Limitations of the Analysis

Care must be taken when interpreting time plots with special consideration given to the following factors and confounding issues:

- Looking at one individual chemical entity and pack size can only tell the story for that particular product- it is dangerous to use the results to infer the situation for the whole market.
- Individual products will have many idiosyncratic factors affecting their price that could be misinterpreted as resulting from competition.
- Competitive price-cutting by firms could occur well before a parallel-distributor enters the market, and may even occur pre-emptively to stop a parallel-licence being sought. A time plot analysis will struggle to isolate such behaviour.
- Competition may not result in price-cutting but in a failure to raise prices, which will not be picked up by looking at individual time plots.
- Price movements are recorded fortnightly. Relative price movements between parallel and domestic suppliers may have occurred during this fortnight but who moved first will not be recorded.

The conclusions reached from time plot analysis, whilst useful, must be interpreted on a product-by-product basis and with an understanding of price behaviour being a function of many factors.

For the reasons given above, the examination of the market as a whole will carry much more weight as evidence of the existence of a competition effect.

2.5 RESULTS

2.5.1 Direct Savings

The calculations from PFL were technically sound. The top ten selling parallel-distributed products accounted for some sixty-eight percent of the market for parallel-sourced goods in 2001. The sales and price figures for these ten products were confirmed and so it was concluded that their figures were indeed accurate. The list of the top ten selling products and the savings accrued is given in Table 2.3 overleaf.

Table 2.3: Direct savings in Denmark in 2001 from use of parallel sourced products

Active Ingredient	Product Name	Saving DKK	% of Total Savings
Budesonid	Spirocort	40,030,484	33.2%
Terbutalin	Bricanyl	15,089,160	12.5%
Simvastatin	Zocor	7,401,953	6.1%
Insulin (human)	Insulatard	5,346,931	4.4%
Terbinafin	Lamisil	3,671,268	3.0%
Pravastatin	Pravachol	2,441,328	2.0%
Felodipin	Plendil	2,161,441	1.8%
Zolpidem	Stilnoct	2,098,167	1.7%
Paroxetin	Seroxat	2,054,975	1.7%
Oestrogen	Nuvelle	1,893,928	1.6%
All Other Products	-	38,399,766	31.8%
Total	-	120,589,402	100.0%

Source: PFL

Savings from the two asthma products Spirocort (“Pulmicort”) and Bricanyl alone, from use of parallel-sourced products over 2001, amounted to some 55 million DKK (€7.15 million). Discussions with PFL as to why the savings were so great for these two products suggested that this was because these products could be easily sourced and that this had resulted in price competition between parallel-distributors.

Total savings for all products were estimated to be 120.6 million DKK (€15.7 million).

Using the information on Table 3.2, an estimate of where the benefits from these savings accrued can be calculated for 2001. This is given in Table 2.4 below.

Table 2.4: Division of savings from parallel-distribution in Denmark in 2001

	Proportion	DKK million	€million
Government (Reimburer)	57.7%	69.6	9.1
Patient/Insurance Company	42.3%	51.0	6.6

2.6 COMPETITION EFFECT

2.6.1 Top 25 Selling Products

Table 2.5 below lists the 25 top-selling drugs in Denmark for the calendar year 2001.

Table 2.5: Top 25 selling pharmaceuticals in Denmark in 2001

Active Substance	2001 Sales (M.DKK – pharmacy retail price)	Sales Rank			
		2000	1999	1998	1997
Citalopram	280,2	2	3	3	3
Omeprazol	272,5	1	1	1	4
Amlodipin	233,9	4	4	6	6
Paracetamol	254,9	5	5	5	5
Budesonid	194,4	3	2	2	1
Simvastatin	177,2	7	7	7	9
Olanzapin	173,1	9	11	24	100
Sumatriptan	148,4	6	6	4	2
Nicotin	171,2	8	8	9	10
Sertralin	113,7	13	14	16	25
Lamotrigin	108,9	11	15	15	21
Fluticason	106,2	10	9	10	12
Atorvastatin	101,4	20	32	89	469
Mirtazapin	95,4	21	31	55	112
Aspirin	115,1	12	10	8	7
Fenoterol	98,2	16	19	13	17
Losartan	90,4	14	13	14	23
Tramadol	100,5	17	17	29	27
Metoprolol	91,5	26	23	17	11
Venlafaxin	79,4	27	35	53	90
Rofecoxib	80,2	40	574	-	-
Lanzoprazol	77,4	19	18	23	28
Salmeterol	76,5	15	12	11	13
Fentanyl	72,9	28	34	45	81
Bendroflumethiazid	83,5	25	27	28	26

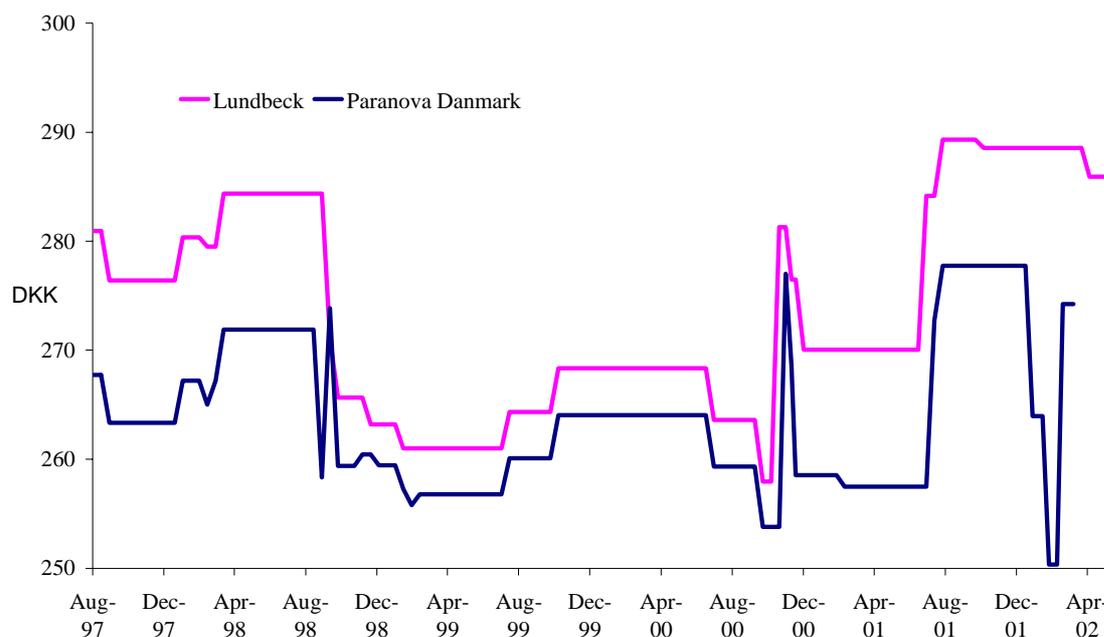
Source: Danish Medicines Agency

Provided the product in the above list had a parallel-distributed competitor, time plots were drawn to examine price movements. A sample of individual products is discussed below.

2.6.2 Citalopram

The proprietary manufacturer of citalopram is Lundbeck who produce the drug under the brand name “Cipramil”. Citalopram is no longer under patent and had generic competition from 2002 onwards. The time plot for 20mg of Cipramil in packs of 28 for both Lundbeck and Paranova is given in Figure 2.1 overleaf.

Figure 2.1: Citalopram (“Cipramil”) 20mg (28)



As can be seen from the above graph, there is no clear indication that Lundbeck is influenced by the presence or activities of Paranova, and for most of the period the prices mirror one another. At the start of August 1998, Paranova lowered their price and it appears that Lundbeck may have responded by cutting their price shortly after. This would be evidence that Paranova’s presence was competitively forcing the price of the proprietary manufacturer down. However, in October 2000 Lundbeck increased the price by almost 10% with Paranova shortly after following suit. Time plots of other strengths and pack sizes showed almost identical price behaviour.

Correspondence with PFL suggested that Lundbeck had consistently lowered their price to within the 5% limit for pharmacists to be legally obliged to offer a parallel-sourced alternative. Parallel-distributors were therefore reluctant to compete on price for this product, as they would be consistently undercut. Whilst this was not picked up in the analysis this may be due to the discrete nature of the data set picking up only fortnightly declared changes in prices.

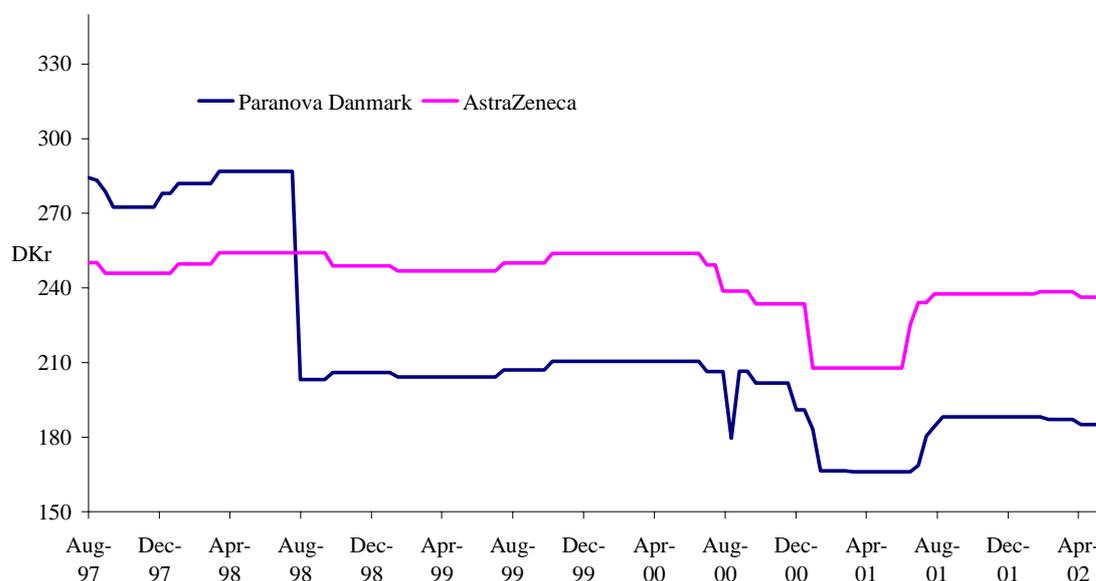
2.6.3 Spirocort

AstraZeneca is the proprietary manufacturer of Spirocort, the active ingredient of which is Budesonide. The product also goes by the name Pulmicort.

Budesonide was off patent, and subject to parallel-distributed competition for the whole time period.

A variety of strengths and pack sizes are available from both AstraZeneca and the parallel-distributors, the price path of all of which are all broadly similar over the sample period. An example is given in Figure 2.2 below.

Figure 2.2: Spirocort (“Pulmicort”) 200 mikg (100)



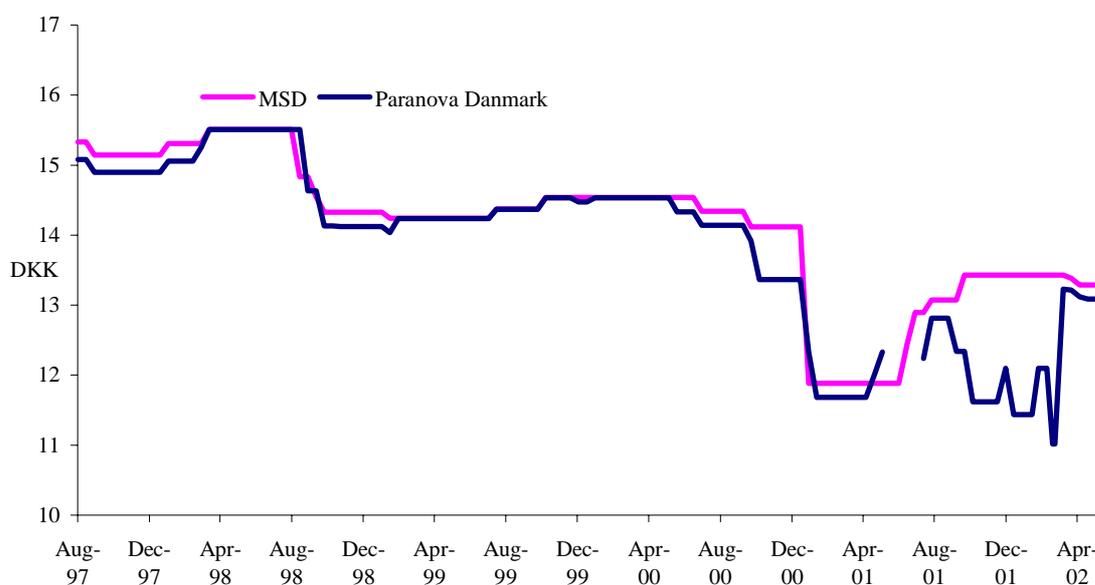
Spirocort accounts for over a third of the total savings from parallel-distribution in Denmark. Over 40 million DKK (€5.2 million) is diverted away from AstraZeneca to patients and reimbursers for this product alone. If AstraZeneca therefore competed on price as a strategy against parallel-distribution, it would be logical to think that it would do so with this product. The graph above provides no evidence that this is the case. In fact, it appears to indicate that AstraZeneca are oblivious to the activities of the parallel-distributors.

However, PFL has pointed out that prior to 1997 Astra Zeneca had engaged in serious price cutting behaviour for products that were targeted by parallel-distributors, particularly Losec. Unfortunately the data set does not go as far back as this period, but there may be evidence of the residual effect of this behaviour in the fact that Astra Zeneca’s price was much lower than Paranova’s during 1997.

2.6.4 Simvastatin

Simvastatin is produced under the proprietary name “Zocor” by MSD. The plot in Figure 2.3 below examines 20mg strength in pack sizes of 100 (parallel-distributor) and 98 (domestic supplier) tablets. The price has been standardised per tablet to allow comparison.

Figure 2.3: Simvastatin (“Zocor”) 28 mg (100/98) per tablet



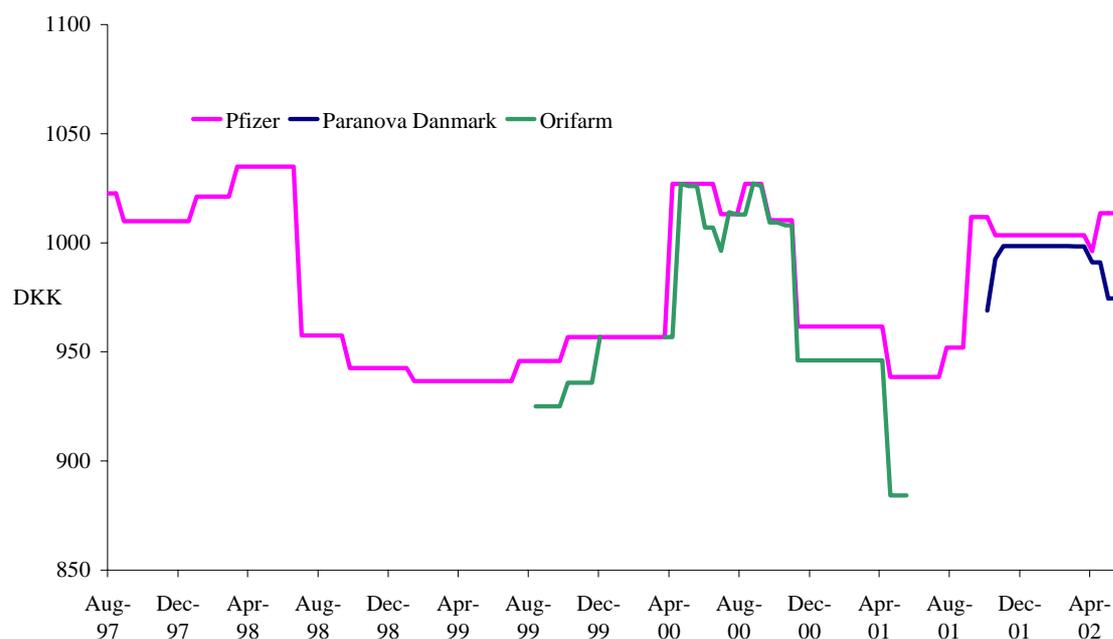
Again, the prices of the proprietary manufacturer and the domestically sourced goods seem to move in parallel for most of the period considered. A sustained price reduction at the end of 2000 to August 2001 may be an attempt by MSD to compete the parallel distributors out of the market, but more evidence would be required to prove this.

2.6.5 Sertralin

Pfizer is the proprietary manufacturer of Sertralin and produce it under name “Zoloft”. No generics manufacturer made Sertralin over the period under consideration. It is not known whether this is due to patent protection still applying or for some other reason. The only competition to Zoloft arises from parallel distributors. Zoloft provides an interesting case for analysis, as parallel-distribution did not begin until mid way through 1999.

Figure 2.3 overleaf shows the movement in price of Zoloft 50mg 98 tablets between 1997 and 2002.

Figure 2.3: Sertraline (Zoloft) 50mg (98)



The above plot provides no evidence that there was any effect on the price of Zoloft when Orifarm or Paranova enter the market. However, Orifarm have indicated that when their authorisation to supply the product in 1998 was issued, Pfizer reduced the price of Zoloft to deter Orifarms' entry. There is certainly evidence in this plot that in April 1998, the price of Zoloft was cut, but more evidence would be needed to directly attribute this to Orifarms' authorisation.

2.6.6 Venlafaxin

Wyeth manufactures venlafaxin under the proprietary name "Efexor". Again, the product appears to be under patent protection over the period of the price data. Efexor is available in various strengths and pack sizes, some of which are under direct competition from parallel-distribution and some indirectly (taking more weaker tablets in place of stronger dosages). Assuming that pharmacists do not tell patients to break tablets in half, the weakest dosage of 37.5mg is under no competition. The relative price movements of Efexor dosages that are and are not subject to competition provided a useful study case for the presence of a competition effect. Figures 2.4 and 2.5 overleaf show time plots of Efexor 75mg 98 tablets and Efexor 37.5mg 28 tablets.

Figure 2.4: Venlafaxin (Efexor) 75mg (98)

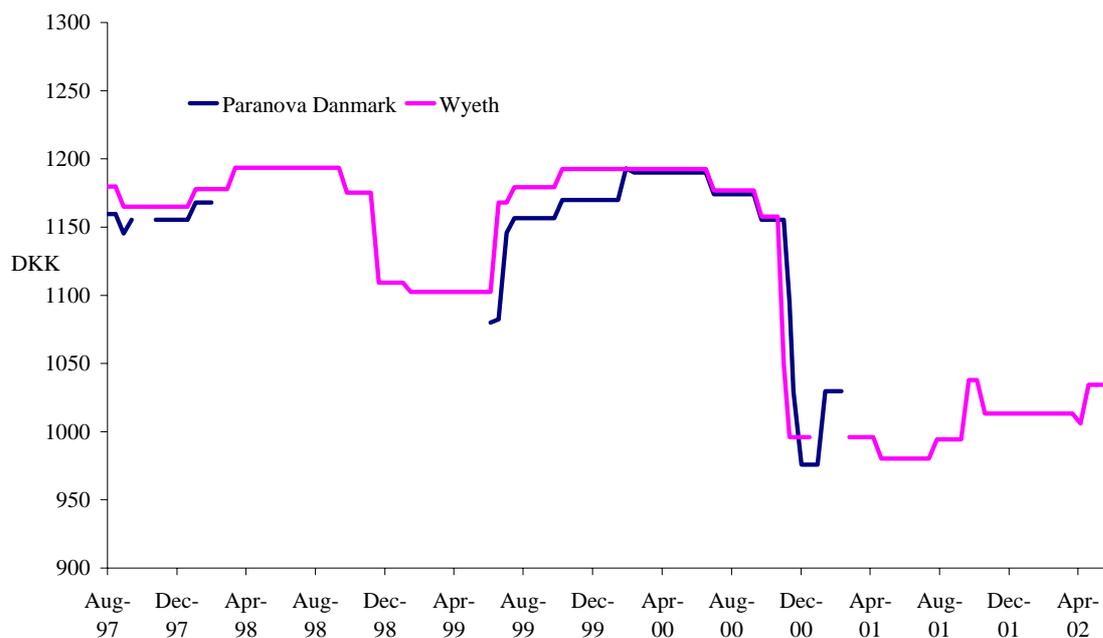
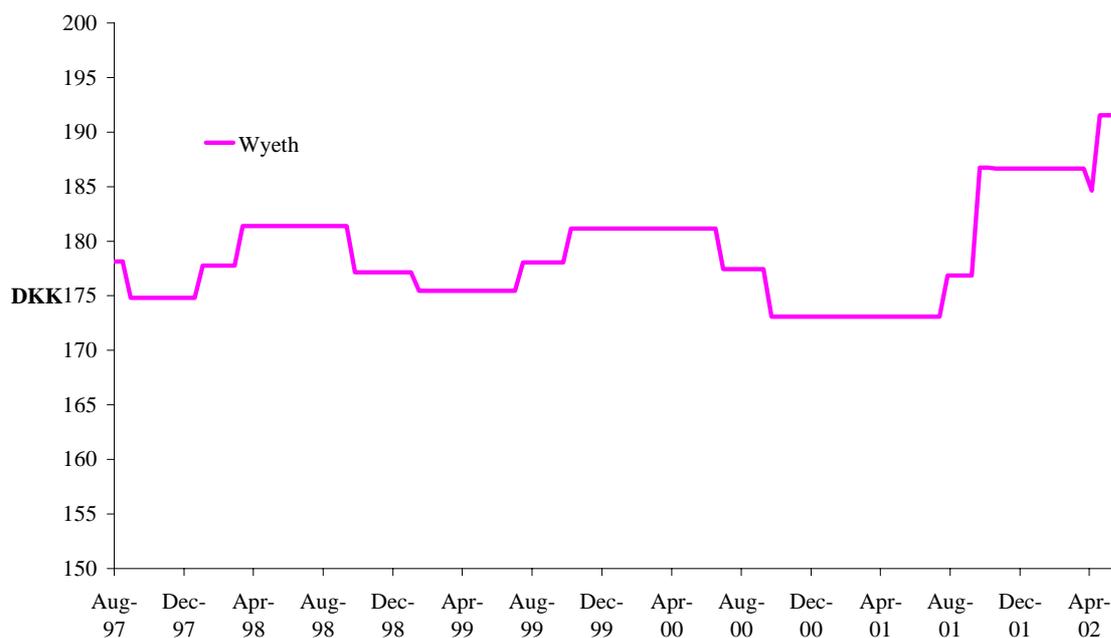


Figure 2.5: Venlafaxin (Efexor) 37.5mg (28)



Assuming that factors affecting the price of a particular chemical entity do so regardless of its strength, the above graphs provide strong evidence of the existence of a competitive effect for Efexor 75mg. It would appear that Wyeth entered into a price war for Efexor 75mg at the end of 2000 to compete Paranova out of the market. However, fear of competition re-entering and probably reluctance from the medicines agency to allow Wyeth to raise the price

back to pre December 2000 levels have kept down the price of the 75mg dosage. This activity is in stark contrast to the relatively stable price of the competition free 37.5mg dose.

2.6.7 Conclusions of the Time Plot Analysis

Whilst there appears to be a competitive effect for a few individual product lines, on the whole there is limited evidence for its existence in the time plots analysed. As stated previously, the results must be treated with caution, as they are a small sample of the total market. Of the products sampled, the market between domestic and parallel suppliers appears to be characterised as one of Stackeberg duopoly, with the proprietary manufacturer setting the price and the parallel distributors following.

If the market is of a Stackeberg type, which it must be borne in mind is an inference from a very small sample, and then, given the fundamental positions of the market and its players, this is not a surprising outcome. However, such a situation can only exist where one player is able to out supply the other, and given the free movement of goods throughout the EU legally justified in the Treaty of Rome, this should not be the case. There is therefore evidence here that in Denmark parallel-distributors have limitations on their supply that may well be due to supply limiting activities that could be challenged in the European Court.

Given this situation, it is questionable whether it is in either party's interests to enter into direct competition on price. If the parallel distributor decides to start a price war with a manufacturer, they will ultimately be the loser as they are unlikely to meet the supply or sustain the losses of the manufacturer. Equally, if the manufacturer tries to price the parallel distributor out of the market, success may mean having to maintain their price at a new lower level. Whilst manufacturers may have been willing to do this in the past, given the use of European average pricing which is now common across most of Northern Europe³, cutting the price of a product in Denmark will have repercussions in other, larger and more important markets.

In some cases, such as Efexor 75mg and its manufacturer Wyeth, individual companies may from time to time feel it is profit maximising behaviour to drive a parallel distributor out of the market. The reasons for doing so are grounded in game theory and are beyond the scope of this report⁴. Intuitively, it seems that some companies are undergoing a learning process in how to respond to parallel distributors or may be trying to threaten parallel-distribution against entering markets for their other products.

The time plots therefore provide some limited evidence that there is competitive price-cutting by some firms on particular products to try to drive out parallel-sourced products.

³ In fact, the Danish price enters the calculation for pharmaceutical prices in eight of the seventeen EEA countries.

⁴ Anecdotal evidence from PFL indicates that each manufacturer has an individual strategy for products that are faced with parallel-distributed competition.

However, it would appear that whilst this may have been more common in the past, the influence of the Danish price on other more important markets has meant that manufacturers are now seeking alternative ways to restrict the activities of parallel-distributors.

2.7 AVERAGE PRICE MOVEMENT 1997-2002

Table 2.6 below shows average price reductions between the product groups described in Section 4.

Table 2.6 Average price change between 1997-2002 of pharmaceuticals in Denmark with differing competitive positions

	No Competition	Generic Competition	Parallel-distribution Competition	Generic and Parallel Competition
No. Of Chemical Entities	42	21	27	24
Av Price Change 1997-2002	2.4%	2.2%	-13.3%	-6.8%
St. Dev.	24.4%	31.3%	19.2%	51.6%
Upper 95% CI	10.7%	17.5%	-5.0%	16.8%
Lower 95% CI	-5.8%	-13.1%	-21.6%	-30.4%

There is evidence at the 5% significance level that there is a significant difference in the price change over the past five years between those drugs that have only parallel-distributed competitors and all other groups. The evidence points to a lowering of prices of around 13% over the period for drugs with parallel-distributed competition. To confirm the result, a second sample was taken of some 50 chemical entities that only had parallel-distributed competition (the sample contained some pharmaceuticals in the original sample). This revealed an average price change over the period of -12.4% (95% C.I.: -5.1%, -19.7%).

Over the period 1997 to 2001, the Danish Medicine Agencies' AIP index fell from 95.0 to 86.0: the index was 10.5% higher in 1997 than in 2001. Although the time period is slightly different from the sample considered above, when coupled with the information in Table 5.2 there is evidence that none of the groups had price changes significantly different to the average with the exception of the no-competition group.

2.7.1 Discussion

The results set out above would appear to provide evidence that parallel-distribution has forced the prices down of their competitors when compared to pharmaceuticals that have no competition between 1997-2002. However, the price reduction is not significantly different from that experienced by the market as a whole over roughly the same period. This may be because the products that are supplied by the parallel distributor make up a large volume of

the drugs bill in Denmark and so have a large impact on any weighted average index. Without volume information it is impossible to say whether or not this is the case.

Price changes of drugs will be subject to systematic factors that affect the whole market, and non-systematic or idiosyncratic factors that affect specific drugs. Parallel-distributed competition is an idiosyncratic shock to particular pharmaceuticals that has a cumulative effect over time. A substantial time period is therefore required to fully analyse its effect. However, over a longer period, other idiosyncratic factors will also accumulate causing wide variations in price fluctuation between different pharmaceuticals. This is evidenced by the large confidence intervals seen in the analysis and makes drawing any firm conclusions difficult without having more information, such as volume data identifying supply fluctuations.

As mentioned in Section 1, there is a European price corridor in place for pharmaceuticals that are under patent. This should therefore affect the price of both the drugs with parallel imported competition only and of those with no competition. However, the evidence suggests that pharmaceuticals with no competition rose slightly in price whilst those with parallel imported competition fell in price. This would appear to provide evidence of the existence of a competition effect. However, it may be the case that the pharmaceuticals with no competition are priced below the European average and so their price has not been forced down by the government. It transitively follows that the lack of any parallel distributing competitor in this group may be due to a lack of price differentials between Denmark and supplying countries that form the basis of the European average.

The price reduction in the parallel distributor competitor group may have little to do with competition but rather be due to the relative price of those particular products in comparison to the European average. That is, there may be no incentive for parallel-distribution. Without European wide data it is impossible to say, but it is fair to conclude that there is evidence that prices of goods in Denmark with parallel-distributed competition have fallen in comparison to those products with no such competition.

2.8 CONCLUSIONS

Denmark has one of the highest penetrations of parallel-distributed pharmaceuticals in Europe, at around 10% of the total drugs bill. Growth was facilitated by obligations on pharmacists to substitute domestically for parallel sourced goods. Over the past 5 years, growth has been proportional to the growth in the drugs bill.

Data and calculations made available from DLI and PFL suggest a saving in 2001 from the use of parallel-sourced products of some 120 million DKK (€15.7 million). This was split roughly 60/40 between the Government and patients respectively. Insufficient data for 2002

was available to calculate a figure for this year, but it is not unreasonable to assume that the savings were at least as great in that 2002 as in 2001.

The time plots indicate limited price competition between 1997-2002 between parallel and domestically sourced products. This is likely to be due to the use of Denmark in reference pricing schemes across Europe. The evidence points to Stackleberg duopoly, which in itself may indicate supply limiting behaviour by manufacturers that could potentially be challenged in the European Court.

Average price changes for on-patent drugs between 1997 and 2002 were 2.2% for those without any competition and around -13.0% for those with parallel sourced competition. There was evidence at the 5% level that these two estimates were statistically different.

Section 3: Sweden

3.1 PRICING AND REIMBURSEMENT MECHANISM

Reimbursement of pharmaceuticals in Sweden is similar to that in Denmark, with patients having to meet part of the cost of their pharmaceutical bill up to an annual limit. In 2002 this limit was SEK 1800, with patients meeting the full cost of the first SEK 900. The Pharmaceutical Benefits Scheme (PBS) is in place to meet the cost of reimbursing patients pharmaceutical bills. Although this subsidy was originally paid from central Government, responsibility passed in part to County Councils in 2002 with full County Council responsibility aimed for in the year 2005.

The initial pricing of a product designed to be on the reimbursement list is heavily regulated in Sweden. Until late 2002, the pharmacy purchase price (AIP) of a prescription product was authorised by the National Social Insurance Board (RFV). In making its pricing decision, the RFV considered the cost effectiveness of the product, the impact on the drugs bill and the price in other European countries, although no European average was considered. Particular weight was placed on the price in the products' country of origin, with the Swedish price not allowed to be any higher than this. A discrete regressive pharmacy margin and dispensing fee are added to the AIP to give the AUP, the pharmacy retail price.

At the end of 2002, pricing responsibility passed to a new body, the Pharmaceutical Benefits Board (LFN). Although the written "areas of responsibility" of the LFN make it clear that the body will place greater emphasis on economic analysis of new products, the body will decide on the prices of products in a similar way as its predecessor. The big changes are perhaps on the members of the committee of the LFN, on whom the pricing decision ultimately falls and the fact that all prescription products will no longer receive a fixed AIP. The new Committee contains members from the County Councils, who can for the first time have input on the prices of products for which ultimately they will have to pay. It is therefore expected that the County Council members will exert more pressure on industry to lower the costs of products and be stricter on those products becoming eligible for reimbursement.

3.2 PARALLEL-DISTRIBUTION

Under both the old and new pricing bodies, pharmaceuticals that have been sourced in parallel have been and are given a fixed AIP. It had been the RFVs' aim to make the parallel-sourced AIP at least 10% lower than the domestically sourced AIP, but this was deemed to be effectively an exploitation of a monopoly position by the European Commission and so this target was officially dropped. The LFN now offer reimbursement to all parallel- distributed

products provided they have the same price or lower than the domestically sourced alternative.

All pharmacies in Sweden are part of a State owned monopoly (the “Apoteket”), and all products are distributed by one of two wholesalers, regardless of whence the product is sourced. This means that individual pharmacists have no direct financial incentive to substitute pharmaceuticals for more inexpensive alternatives. To counteract this, the Apoteket instructed pharmacists to dispense a parallel sourced alternative where this was both cheaper and available, and from October 2002, substitution with the lowest-priced parallel-distributed alternative became law provided the doctor does not block the substitute on medical grounds and the patient does not decline to accept it. If the patient does refuse the substitute they will be required to pay the price between the cheaper alternative option and the more expensive alternative

Despite the absence of any strong incentives to use parallel-sourced products prior to October 2002, growth in parallel-distribution was strong between 1997 and 2002. This is illustrated in Table 3.1 below.

Table 3.1: Growth in the market for parallel-distributed products in Sweden 1997-2001 valued at AIP

Year	Value SEK million	% Total Market	Annual Growth %
1997	269	1.9	N/A
1998	1007	6.1	274.3
1999	1396	7.6	38.6
2000	1749	8.6	25.3
2001	2011	9.3	15.0
2002	2309	10.1	14.8

Source: Apoteket

Even though prior to October 2002 there was no clear incentive or legal obligation for pharmacists to dispense parallel sourced alternatives, there is no disincentive for them not to. The rapid growth in parallel-distribution can probably therefore be explained by the strength of the Apoteket in modifying the behaviour of pharmacists.

3.3 POTENTIAL BENEFICIARIES

As stated above, pharmacists are given no financial incentive to dispense parallel-distributed products. Sweden therefore stands alone as being the only country considered in depth in this study where pharmacists can in no way benefit directly from the savings available through parallel substitution.

Due to the presence of a co-payment in Sweden, an element of the savings from parallel-distribution passes straight to the patient. The remaining savings pass straight to the Government in the form of lower level of subsidy through the PBS.

Table 3.2 below shows the split of the Swedish prescribed pharmaceutical bill between that met by the County Councils through the PBS and that paid for by patient co-payment.

Table 3.2: Split of Swedish prescribed drug bill between the Government and patient co-payment 2000-2002 at AUP

	2000 SEK million	2001 SEK million	2002 SEK million
PBS	15,689 (76.5%)	16,782 (77.5%)	18,277 (78.3%)
Co-payment	4,824 (23.5%)	4,884 (22.5%)	5,067 (21.7%)
Total	20,513	21,666	23,344

Source: Apoteket

3.4 METHODS AND DATA

The Apoteket provided data on the value of the Swedish pharmaceutical market, growth rates and levels of reimbursement. They also provided general information on the size and growth of the parallel-distribution market and background information on the future, current and past workings of the Swedish reimbursement and pricing system.

Individual price and sales data was that published by PharmX and made available via FPL (Foreningen for Parallellimportorer), and is similar to the data made available for Denmark. FPL had calculated a previous estimate for total savings in 2001. Full data for 2002 was unavailable, so the FPL 2001 calculations were checked and then rolled forward by the growth rate in the parallel-distribution market in Sweden to give an estimated saving in 2002.

In addition to their calculations, FPL provided PharmX price data for all products, both domestically and parallel sourced, for the period January 1996 to November 2002. This data was used to try and identify any competition effect. This was done by firstly exploiting data mining techniques, examining time plots of domestically and parallel sourced products as done for Denmark, with similar limitations.

Statistical identification of a competition effect was then attempted, in the same manner as for Denmark, by separating products into those with parallel-distribution competition and those without and examining price changes from January 1996 or from the introduction of a product onto the market until November 2002. No products that had generic competition were subject to the analysis.

3.5 DIRECT SAVINGS

FPL estimated direct savings for Sweden to be in the region of SEK 369.6 million (€40.7 million) for 2001. Table 3.3 below shows the savings for the top ten products in Sweden.

Table 3.3: The ten largest saving parallel-sourced products in Sweden in 2001 by AUP

Active Ingredient	Product Name(s)	Saving SEK million	% of Total Saving	% of Market
Budesonid	Pulmicort	68.3	18.5	93.3
Felodipin	Plendil	39.6	10.7	80.6
Metoprolol	Seloken Zok	34.1	9.2	52.3
Ciclosporin	Sandimmun	32.2	8.7	91.8
Paroxetin	Seroxat	18.8	5.1	72.3
Omeprazol	Losec	16.0	4.3	20.0
Terbutalin	Bricanyl	13.0	3.5	62.9
Sertralin	Zoloft	11.3	3.1	29.5
Insulin	Insulatard	8.8	2.4	34.2
Ranitidin	Zantac	6.7	1.8	24.4

Source: FPL

As the above table suggests, ten products account for almost 70% of the savings from parallel-distribution are accounted. To confirm FPL's total savings calculations, the savings offered by these ten products were checked and found to be accurate. It is therefore reasonable to assume that the total figure is also accurate. The savings represent a weighted average AUP differential of some 18% between parallel and domestically sourced products.

In contrast to other markets but in common with Denmark, the savings offered by parallel-distribution are highly concentrated. Also in common with Denmark, the savings are greatest on asthma remedies, with parallel substitution of Pulmicort alone producing savings of SEK 68.3 million (€7.5 million) at AUP.

Rolling on the direct savings in 2001 by the growth in parallel-distribution over 2002, it is estimated that the savings from parallel-substitution over 2002 amounted to some SEK 424.3 million (€46.7 million) at AUP.

Combining this with the information in Table 3.2, an approximation of the destination of the savings is given in Table 3.4 overleaf.

Table 3.4: Distribution of savings from parallel-distribution in Sweden for 2001-2002 at AUP

	2001	2002
PBS	SEK 286.1 million (€1.5 million)	SEK 332.3 million (€36.6 million)
Co-payment	SEK 83.5 million (€0.2 million)	SEK 92.0 million (€0.1 million)
Total	SEK 369.6 million (€10.7 million)	SEK 424.3 million (€46.7 million)

3.6 COMPETITION EFFECT

3.6.1 Time Plots

Time plots were drawn for a random sample of the top ten products by savings offered in 2001. As the Swedish market is so concentrated, it is plausible that if domestic suppliers will seek to compete on any product it could well be on these products. There is the danger however that by looking at only these products that the analysis could be subject to survival bias. If a domestic supplier has competitively cut their price and driven out a parallel-distributor for a particular product then this will not be picked up in the analysis. Indeed, it could be argued that as the savings are so high for the products considered it may well be that these are products for which domestic suppliers do not bother to compete. Never the less, it should be remembered that data mining such as looking at time plots can only paint a limited picture and provides only part of the story.

Again, as for Denmark, it is acknowledged that whilst price competition exists between parallel distributors, it is the competition between domestic and parallel suppliers that is of interest. By far the two largest distributors are Paranova and Orifarm. Whilst other distributors are present in the market, the prices of these two companies are therefore the only ones considered.

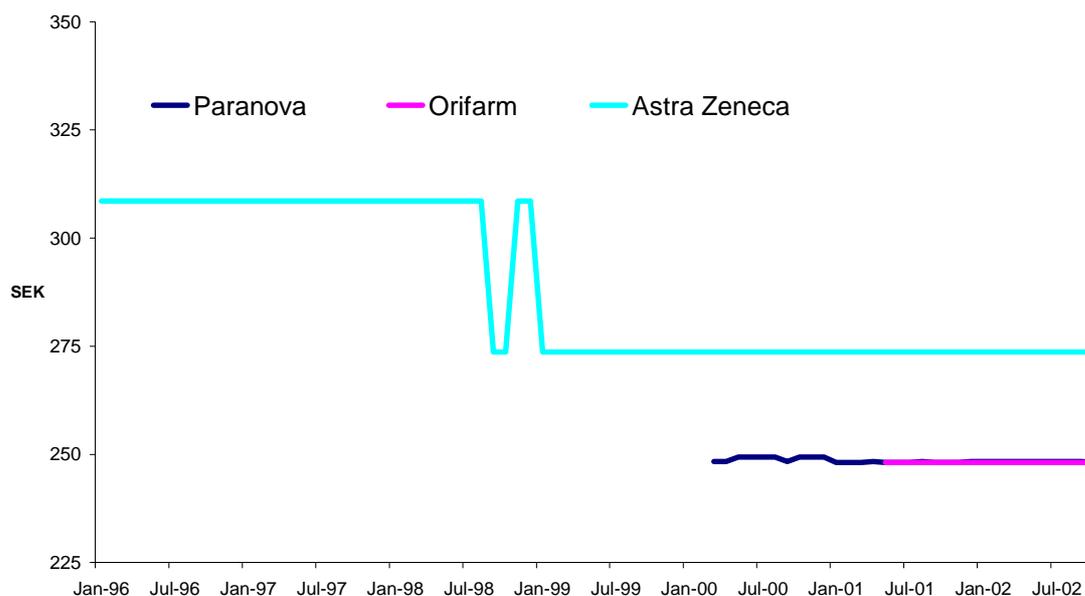
3.6.1.1 Pulmicort)

AstraZeneca is the proprietary manufacturer of Pulmicort, the active ingredient of which is Budesonide.

Budesonide was off patent and was subject to parallel-distributed competition for the whole time period.

As in Denmark, a variety of strengths and pack sizes are available from both AstraZeneca and the parallel-distributors, the price path of all of which are all broadly similar over the sample period. An example is given in Figure 3.1 overleaf.

Figure 3.1: Spiricort 100microgram 200 Dose



The savings delivered by any product are a factor of both the price differential and the volume of sales. There are products with a greater price differential than the 10% offered for Pulmicort, but as shown in Table 3.3, parallel-distribution supplied almost 94% of the market for this product in Sweden in 2001. With such large market share, it is noteworthy that there appears to be no movement by AstraZeneca to compete with parallel distributors. The only price cuts by the manufacturer occurred eighteen months before the parallel-distributors entered the market, although this does correspond with time when parallel-distribution for a higher strength of the product began

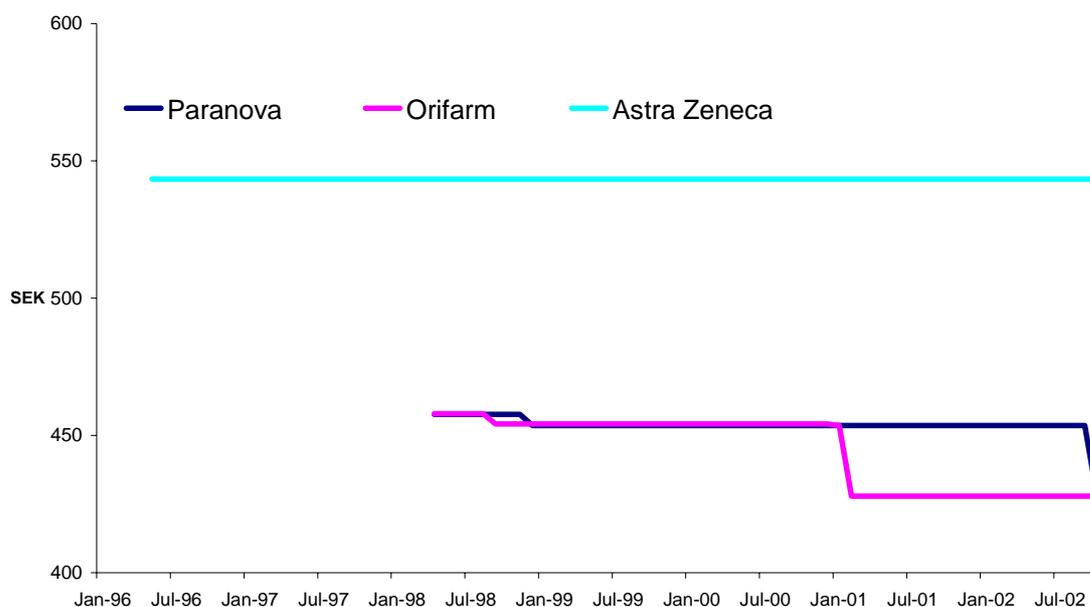
3.6.1.2 Losec

AstraZeneca is the proprietary manufacturer of Losec, the active ingredient of which is Omeprazole.

Losec was subject to parallel-distributed competition from early 1998. At this time, Astra Zeneca released an alternative version of Losec, Losec MUPS. This was only available in Sweden.

A variety of strengths and pack sizes are available from both AstraZeneca and the parallel-distributors, the price path of all of which are all broadly similar over the sample period. An example is given in Figure 3.2 overleaf.

Figure 3.2: Losec 20mg 28stk



As is illustrated above, the price of Losec MUPS from Astra Zeneca was stationary over the almost six years considered. This was true for all pack sizes, strengths and forms of Losec, save for two that had single price reductions over the period. Neither of these products had a parallel-distribution competitor.

The lack of price movement is in spite of parallel-distributors offering a saving of between eighteen and twenty-one percent over the domestic supplier and claiming twenty percent of the market in 2001. It may however be the case that parallel-distribution has stopped the domestically sourced price rising, which will be touched on further in the statistical analysis. Parallel-distribution of Losec offers a greater potential saving to the PBS and patients than Pulmicort yet it does not achieve anything close to Pulmicorts' penetration. Whilst this may be evidence of the savings offered by parallel-distribution being limited by the ability to supply a particular product, it is more likely a result of the reformulating of Losec in the MUPS form that is unavailable to parallel-distributors.

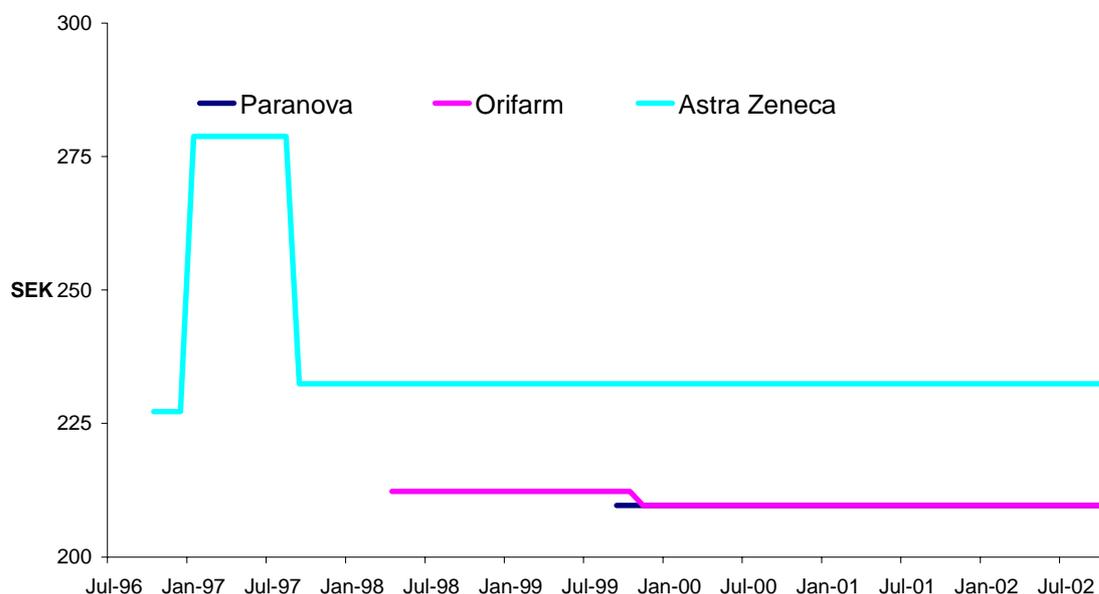
3.6.1.3 Plendil

AstraZeneca is the proprietary manufacturer of Plendil, the active ingredient of which is Felodipine.

Plendil was subject to parallel-distributed competition from early 1998, with parallel-distribution taking over 80% of the market in 2001.

A variety of strengths and pack sizes are available from both AstraZeneca and the parallel-distributors, the price paths of all of which are all broadly similar over the sample period. An example is given in Figure 3.3 below.

Figure 3.3: Plendil 10mg 28stk



The time plot for Plendil seems to tell a similar story as that for the previous two pharmaceuticals considered, also Astra Zeneca products. The price differential offered by parallel-distributors for Plendil is in the region of 9% when compared to the manufacturers price. The fact that they supply over 80% of the market implies the product is relatively easy to source.

3.6.1.4 Sandimmun

Novartis is the proprietary manufacturer of Sandimmun, the active ingredient of which is Cyclosporin.

Sandimmun is available as an oral suspension or as an infusion. The oral suspension was subject to parallel-distributed competition from early 2001, and from a zero base accounted for over ninety percent of the market by September of that year. The infusion faces no parallel-distribution.

A variety of strengths and pack sizes for both Sandimmun preparations are available. Although the price paths for strengths and pack sizes within each preparation are similar, the paths are very different between the preparations. This is exemplified in Figures 3.4 and 3.5 and overleaf.

Figure 3.4: Sandimmun neoral 50mg 50stk

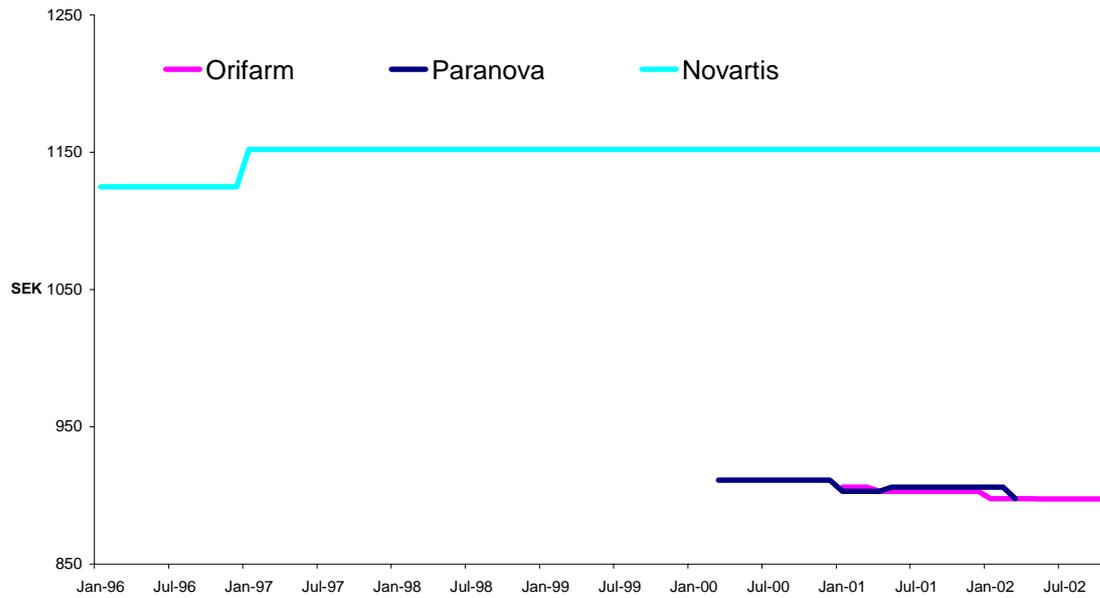
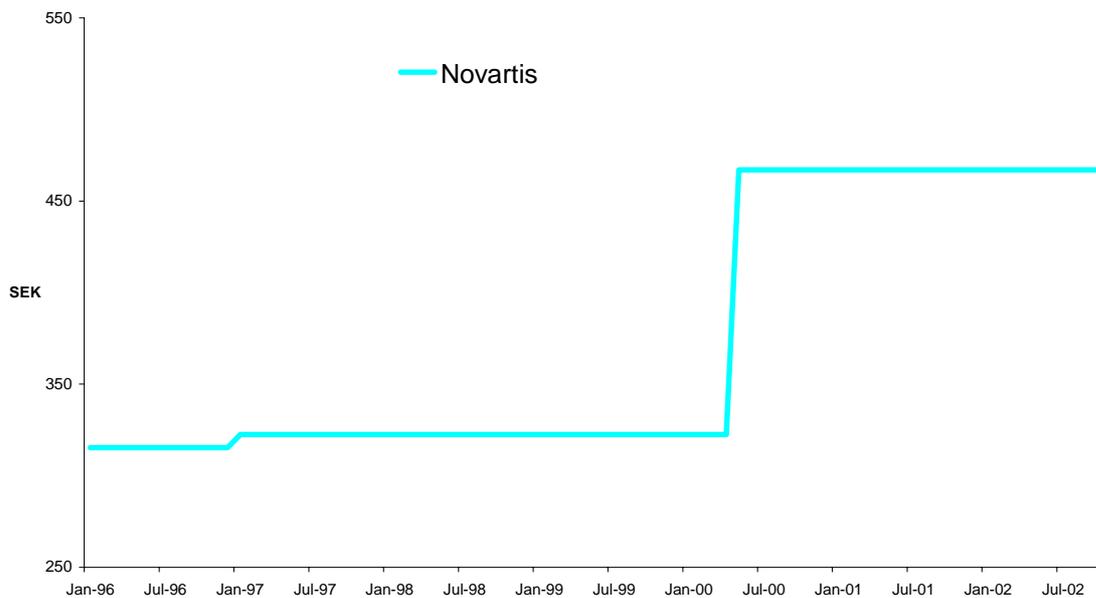


Figure 3.5: Sandimmun infusion 50mg/ml 10x1ml



The difference between the two time plots is stark. Whilst both the infusion and oral suspension experienced a price rise of just over 2% in early 1997, the infusion, with no parallel competitors, experienced a 44.9% price increase in 2000 whilst none of the oral suspension preparations experienced any significant price increases post 1997.

This price increase is unlikely to be just down to raw material cost increases affecting the infusion only, and so seems to provide evidence of competitive forces from parallel-distributors suppressing price increases for the oral suspension. Whilst this may well be the case, consideration must be given to the way price increases are approved in Sweden and the market penetration of parallel-distribution for the oral suspension.

A case for price increases had to be made to the RFV, which in theory would only be approved if the manufacturer had financial grounds for the increase. It is questionable that Novartis could have made a successful case for a large price increase for the infusion whilst the oral suspension price remained unchanged. As the market penetration of parallel-distribution of the suspension was already over 90%, it seems illogical that Novartis would be unwilling to raise the price of this product also as they have little of the market left to lose. Further information is therefore required to provide a conclusive answer as to why the price of the suspension was not increased.

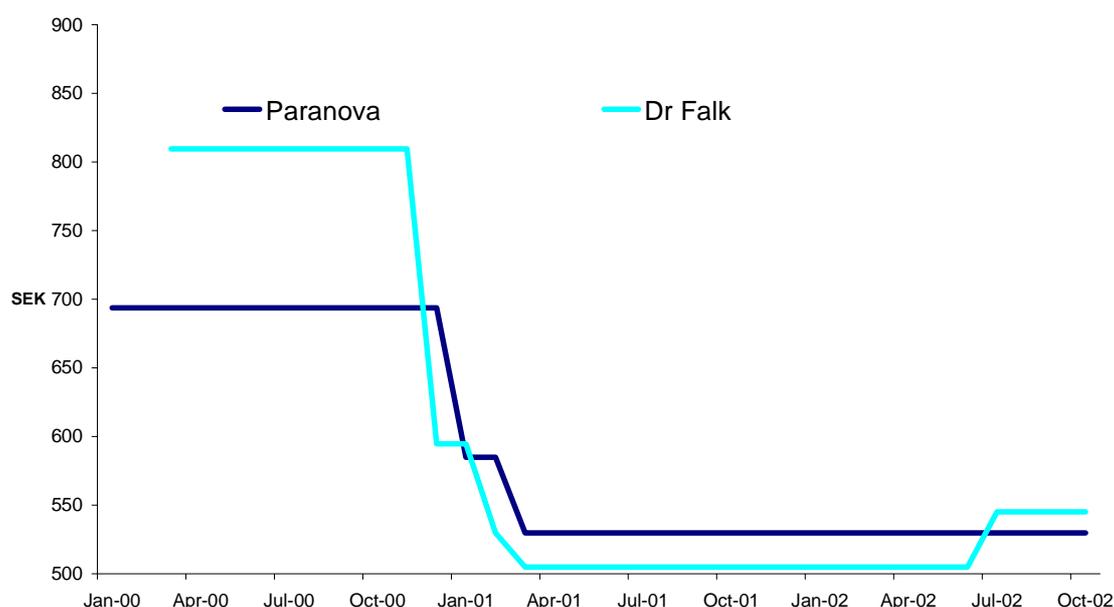
3.6.1.5 Ursofalk

Dr.Falk Pharma is the proprietary manufacturer of Ursofalk, the active ingredient of which is ursodeoxycholic acid. Ursofalk is a treatment for cirrhosis of the liver.

Ursofalk was subject to parallel-distributed competition from Paranova from early 2000, and by the end of that year Paranova supplied almost half the market.

Ursofalk is available in only one strength, 250mg, and only in packs of 100. The time plot for this product is given in Figure 3.6 below.

Figure 3.6: Ursofalk 250mg 100stk



Within twelve months of Paranova entering the market, Dr. Falk had cut its price below that of Paranova. By September 2001, Paranova had been driven out of the market. Other factors could have been important in Dr. Falk's pricing decision, but given the almost 40% price cuts between October 2000 and April 2001, to a level that just undercut Paranova, this would appear to be strong evidence of parallel-distribution producing competitive activity from a domestic manufacturer.

3.6.1.6 Clarityn

Schering-Plough is the proprietary manufacturer of Clarityn, the active ingredient of which is Loratidine.

Clarityn was subject to parallel-distributed competition from early 1998, with parallel-distribution taking almost two thirds by of the market by mid 1999.

Clarityn is available in syrup form or as a tablet. Tablets are available in slightly different forms and pack sizes but all have the same strength, 10mg. Parallel-distributors supply the tablet form of Clarityn but not the syrup. Price movements of one of the tablet pack sizes and of the syrup are given in Figures 3.7 and 3.8 below.

Figure 3.7: Clarityn 10mg 100stk

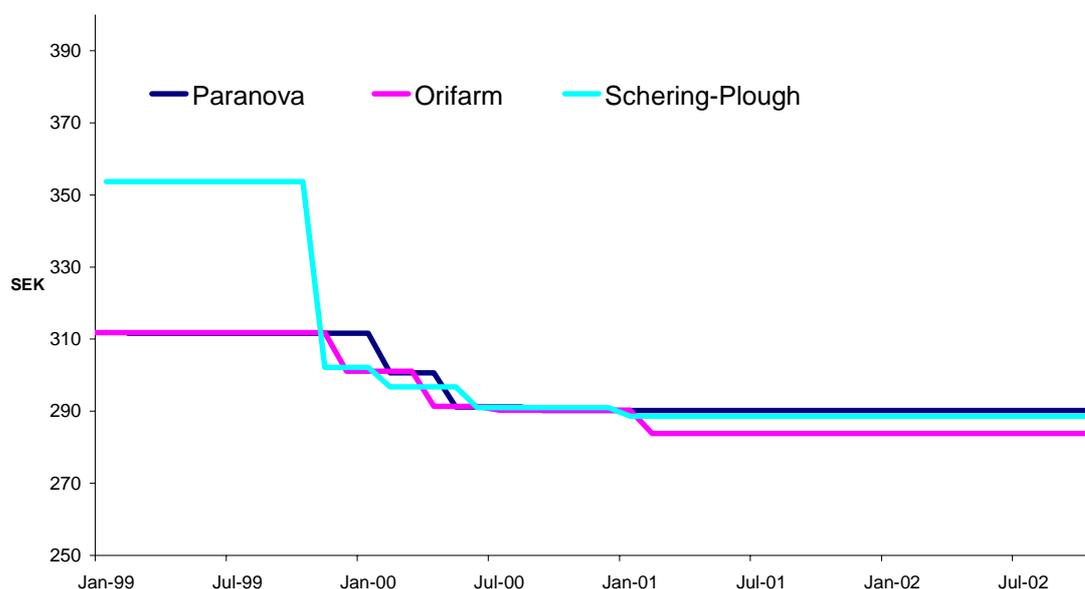
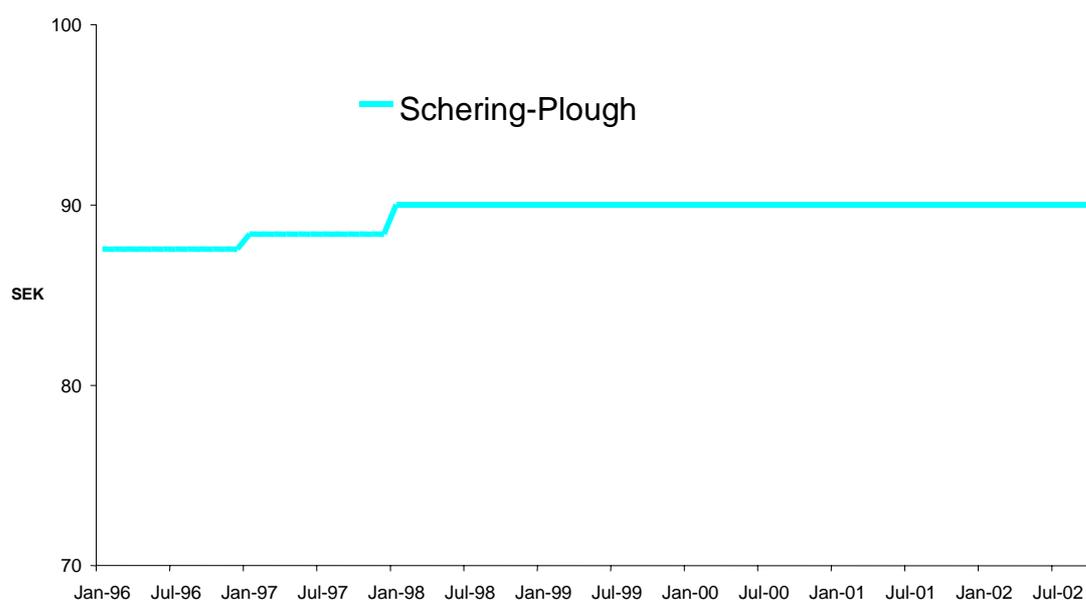


Figure 3.8: Clarityn syrup 1mg/ml 120ml



In common with Dr. Falk with Ursolfalk, Schering-Plough cut the price of Clarityn tablets by around 20% to undercut the parallel-distributors, who by the latter half of 2001 had been driven out of the market. That the price cuts were largely due to the presence of parallel-distribution is evidenced by the lack of similar cuts to the syrup-based product, which was subject to no parallel competition.

3.6.1.7 Time plot discussion

Many of the conclusions drawn from the time plots will inevitably be similar to those in Denmark. Parallel-distributors seem to essentially be forced to be price followers, indicating a limitation in supply. However, there are several noticeable exceptions where certain companies for certain products do appear to have competed on price. The wisdom behind this may be questionable, due to the difficulty in raising prices once they have been lowered and the impact this may have on other European markets. However, it can only be beneficial for the Swedish reimbursing and patients with co-payments.

3.6.2 Average Price Movement 1996-2002

The statistical analysis of the samples of products with and without competition from parallel-distribution is summarised in Table 3.5 overleaf.

Table 3.5: Results of the statistical analysis of the competition effect in Sweden

	No Parallel Competition	Parallel Competition
Sample Size	28	27
Average Price Change	7.4%	-0.8%
Standard Deviation	14.3%	3.7%
95% C.I.	1.2%, 13.6%	-2.4%, 1.6%

It can be seen from the table above that there is statistically significant evidence at the 5% level that the average change in price of products with parallel-distribution competition has been lower than that for products with no competition. Of equal interest is the variance of the price changes, as measured by the standard deviation. Products with no parallel competition have a statistically significantly higher variance than those without. This provides evidence that products subjected to parallel competition are more likely to have stable prices, indicating either a reluctance to compete or competition making manufacturers wary of raising their prices.

The results confirm the similar findings of Ganslandt and Maskus (2001) who find that for the period 1995-1998 products subject to parallel distributed competition increased less than for those without such competition.

3.6.3 Discussion

Evidence from the time plots and the statistical analysis suggests that for at least some manufacturers competition from parallel traders exerts a downward pressure on prices. This is either evidenced in price-cutting or in the reluctance to raise prices.

The fact that the Swedish and Danish parallel-distribution markets are so concentrated compared to other European countries is perhaps evidence in itself that competitive price-cutting by some manufacturers to drive out competition is a feature of the Nordic markets.

3.7 CONCLUSIONS

Uniquely of the five countries considered in depth in this report, the growth in parallel-distribution in Sweden seems to be independent of any direct incentives to pharmacists, although from October 2002 the pharmacists had a legal obligation similar to that existing in Denmark. This is probably a reflection of the fact that Sweden is also the only country of the five where pharmacists are all part of a State monopoly. By exerting pressure from the centre, the Apoteket seems to be able to at some extent modify pharmacists' dispensing behaviour.

Due to the rapid growth in parallel-sourced substitution and the price differential between domestically sourced and parallel sourced products, parallel-distribution produced an estimated direct saving to the Swedish PBS and the patient of some SEK 424.3 million (€6.7 million) over 2002. Approximately 78% of this saving passes to the Government through smaller payments through the PBS, and 22% to the patient with lower levels of co-payment.

There is statistical evidence that price changes for products with competition from parallel-sourced products are lower than those without competition. This in some cases appears to be due to price-cutting behaviour but also in a reluctance to raise prices where competition exists.

Section 4: Netherlands

4.1 PRICING AND REIMBURSEMENT MECHANISM

Until 1996, the Netherlands allowed pharmaceutical manufacturers the freedom to set the prices of their products at whatever level they felt was suitable. However, under the Drug Reimbursement System (GVS), the Dutch Government set the maximum price at which they would reimburse a product. This was a reference price system for both on and off-patent products with products grouped largely by therapeutic action and intended patient group. The maximum reimbursement price of any product in the group is fixed at the price of the product immediately below the average in a group as at actual prices in October 1998.

A manufacturer is still free to set their price higher than this level, but the patient would then have to pay a co-payment between the GVS price and the actual price. Due to the resistance of Dutch patients to make co-payments, the GVS effectively set the maximum price of a product.

In 1996, to curb spiralling growth in the drugs bill, the maximum pharmacy purchase price that could be charged for a product was fixed at the average price in four Northern European countries: France, the UK, Germany and Belgium. This price is referred to as the WGP (“Drug Prices Act”) price. The WGP price can exceed the GVS, and in some cases the GVS exceeds the WGP. However, the WGP price sets the clear maximum price that could ever be charged in a pharmacy for a particular product, even if the patient co-payment was 100%.

Information provided by the SFK, the Dutch pharmacy market research company, shows that moving to this WGP price system did have an effect on the growth rate in the cost per prescription. This fell from 1996-1998 to just 3.0% p.a. compared to 9.2% p.a. between 1992-1994. However, prescription prices rose by 6.0% p.a. between 1999-2001. Whilst this is partly a reflection of a move to new, often more expensive drugs, it probably also reflects the fact that whilst there was an initial curbing in the growth rate of the price of pharmaceuticals from the adoption of the WGP, prices are now growing in line with European pharmaceutical price inflation.

Reimbursement of prescriptions is transacted through the private and public insurance or “sick” funds. A premium is deducted from individuals’ wages each month and depending on their income level, this passes to the public or a private insurer. Even if an individual pays into the public sick fund, their money is still passed to a private insurer to cover the individual.

4.2 PARALLEL-DISTRIBUTION

The Dutch market is the most mature market for parallel-distributed pharmaceuticals in Europe. The first importing activity was undertaken into Holland from the UK almost 30 years ago, with the ground breaking de Peijper case (1975).

Distribution of externally sourced products into Holland is not as heavily regulated as in some European countries, and in many ways is amongst the most unregulated. Nevertheless, the activities of the Dutch Government to regulate drug prices in general inevitably impacts on the activities of parallel distributors.

Pharmacists at the beginning of the 1990s were concerned at the level of the dispensing fee being insufficient for their business to remain viable. An embargo was in place prohibiting wholesalers and distributors discounting products by more than 4% of the reimbursement price. Rather than raise the level of the dispensing fee, the Dutch Government removed the discount embargo. Effectively this based the viability of pharmacies on the ability of the pharmacist to seek out the cheapest source for a product.

This in many ways was an unofficial sea-change in the way the activities of pharmacists were viewed by Government. Pharmacists had been employed to provide an information, advice and dispensing service to patients, with reimbursement of their services via the dispensing fee. With the lifting of the embargo on discounts, their activities were now to include making themselves financially viable and achieving savings in the drugs bill.

Reimbursement to pharmacists for dispensing individual molecules is fixed, with different reimbursement levels for parallel distributed or generically manufactured products. The reimbursement level for a parallel-distributed product depends on the number of parallel-suppliers. If there is only one parallel-distributor, then the reimbursement level is the distributors' price. If more than one distributor supplies a product, then the reimbursement level is set at list price of the lowest priced source country. The actual price paid for the product is in most cases discounted below this level.

On average, products that are distributed in parallel have a reimbursement level 3% lower than domestically sourced goods, with pharmacists keeping one-third of this difference and the sick funds keeping two-thirds.

Whilst the effect of the introduction of the WGP was to reduce the drugs bill, it also impacted on the potential activities of parallel distributors. After peaking in the mid 90's, the penetration of parallel trade in the Netherlands fell until 2001, when it picked up again.

The reasons for this become apparent when it is considered how parallel distributors are able to supply a given market. A sufficient price differential must exist between the price of a

product in Holland and the price elsewhere in the European Union to make importation of the product profitable. The products where such a differential exists must, by definition, be those whose price will have been lowered by the imposition of the WGP. As such it is not surprising that parallel-distribution declined after this was introduced. Products that were imported from Southern Europe may not have been affected so severely; it has been suggested that there were actually some price rises as firms raised the price to the average, resulting in opportunities to distribute products where the margin had been too small.

4.3 THE CLAWBACK

Although there is a declared average price difference of approximately 3% between parallel-distributed and domestically sourced pharmaceuticals, as stated above the actual discounts offered to pharmacists exceed this level.

To reflect this, and also in recognition that pharmacies also gain discounts from generic substitution and from domestic wholesalers, a deductible or clawback was placed on all reimbursed products. The clawback was calculated on the basis of a study undertaken by PriceWaterhouseCoopers (PWC) who found an average discount offered to pharmacists of approximately 8.9%. The Ministry of Public Health, Welfare and Sports (VWS), who regulate pharmaceutical reimbursement, used this study to impose a clawback at a flat rate of 6.82%. This is in contrast to the clawback in the UK, where the deductible is on a sliding scale.

The clawback provides an incentive for the use of parallel trade quite contrary to that before its introduction. Whilst the pharmacist still has the incentive to use parallel-sourced products to supplement their income, they would now be punished financially if cheaper alternatives were not dispensed.

4.4 POTENTIAL BENEFICIARIES

Although in theory patient co-payments do exist, they are rare⁵. As such, patients do not benefit directly from the savings offered through parallel-distribution.

As stated previously, pharmacists keep one-third of the declared price saving and the sick funds two-thirds. As such, both these parties benefit directly from parallel-distribution. The sole direct beneficiary from the clawback is the sick fund.

⁵ The third generation contraception pill is one exception, as the Ministry of WVS refused to meet the full cost of a pharmaceutical that both has cheaper alternatives and can be viewed as a lifestyle drug.

4.5 METHODS AND DATA

Data and information for the Netherlands was provided from four sources:

- The SFK provided details on the size and growth of the pharmaceutical market in general and specifically for the market for parallel-sourced products. They also provided details of the clawback and average price differential between parallel and domestic sourced products;
- Details of the top selling parallel sourced products were taken from IMS published data;
- The Ministry of VWS supplied background information on the market;
- Pharos and Stephar, two parallel-distributors operating in the Netherlands, provided general information on the Dutch reimbursement system and of the workings of parallel-distribution within that system.

Interviews with representatives from the above took place on site in the Netherlands.

The generality of the data meant that the direct savings from parallel trade were calculated by applying the average price difference between parallel-distributed and domestically sourced goods. Estimates of the savings from parallel-distribution recouped through the clawback were provided directly through the SFK. Statistical detection of a competition effect was not viable with the data we obtained..

4.5.1 Market Overview

The top ten pharmaceutical products by prescription and by reimbursement value in 2001 are given in Tables 4.1 and 4.2 below. Also given is the proportion of these products sourced through parallel-distribution.

Table 4.1: Top 10 products in the Netherlands by prescription volume

Substance Name	Brand Name	Prescriptions	Parallel-Distribution Penetration
Oxazepam	Seresta ®	2,812,000	N/A
Paracetamol	Various	2,607,000	N/A
Diclofenac	Voltaren ®	2,387,000	N/A
Temazepam	Normison ®	2,385,000	N/A
Omeprazol	Losec ®	2,031,000	4.7%
ASA	Aspirin ®	1,891,000	N/A
Oestrogen+Ievonorgestrel	Various	1,830,000	N/A
Ibuprofen	Various	1,798,000	N/A
Metoprolol	Lopresor ®, Selokeen ®	1,772,000	N/A
Paroxetine	Seroxat ®	1,707,000	N/A

Source: SFK

Table 4.2: Top 10 products in the Netherlands by expenditure

Substance Name	Brand Name	Expenditure (€million)	Parallel-Distribution Penetration
Omeprazol	Losec ®	225	4.7%
Simvastatine	Zocor ®	108	58.5%
Atorvastatine	Lipitor ®	88	20.2%
Paroxetine	Seroxat ®	73	22.4%
Enalapril	Renitec ®	46	N/A
Salmeterol	Seritide ®	42	26.3%
Pravastatine	Selektine ®	40	N/A
Amlodipine	Norvasc ®	39	46.5%
Human Insulin	Various	37	N/A
Flutiscan	Flixotide ®	36	N/A

Source: SFK

It can be seen from the above tables that although parallel-distribution has little impact on the highest prescription volume products, amongst half of the most expensive products it makes up a significant proportion of supply.

The size of the Dutch pharmaceutical market split between domestic, parallel and generic supply as well as the growth rate of each segment between 1997-2001 is given in Table 4.3 below.

Table 4.3: Size and growth of the Netherlands' Reimbursed Drugs Bill and parallel-distribution and generic substitution within the Bill 2000-2002

	Parallel-Distribution			Generic			Total Reimbursed Drugs Bill		
	€million	% of Total	Growth*	€million	% of Total	Growth*	€million	% of Total	Growth*
2000	364.7	16.4	-12.4%	335.7	15.1	6.2%	2,221.3	100.0	2.1%
2001	424.2	17.3	16.3%	375.3	15.3	11.8%	2,455.6	100.0	10.5%
2002	456.2	17.3	7.5%	495.0	17.3	31.8%	2,631.3	100.0	7.2%

Source: IMS, SFK

NB: Years refer to periods start of November to end of October for size of market and calendar years for growth.

After a sizeable reduction in the value of parallel trade in 2000, the market has recovered over 2001 and 2002 to have a market value of almost half a billion Euros in 2002.

Table 4.4 overleaf shows the top ten parallel sourced pharmaceuticals by sales volume over 2002.

* Annual growth compared to previous year

* % Of total market

Table 4.4: Top 10 parallel-distributed pharmaceuticals in the Netherlands by expenditure 2002

Substance Name	Total Market €million	Parallel-Sourced	
		€million	%
Simvastatin	120.5	56.9	47.2
Atorvastatin	102.2	20.4	20.0
Amlodopine	42.1	18.5	43.9
Terbinafine	24.1	15.9	66.0
Budesonide	46.6	14.2	30.5
Pantoprazole	12.2	12.2	100.0
Ciclosporin	15.4	11.3	73.4
Somatropin	34.6	10.4	30.1
Itraconazole	18.5	10.2	55.1
Goserelin	17.9	9.6	53.6
Total	434.1	179.6	41.4

Source: IMS

Although accounting for some 17% of the total reimbursed pharmaceutical market in 2002, the above table shows that for the top selling products anywhere up to 100% penetration is achieved. Interviews with parallel-distributors revealed that this was as much a function of the supply they have available for a particular product rather than the price differential and discounts they could offer to pharmacists.

4.6 DIRECT SAVINGS

Table 4.5 below shows the direct savings from parallel-distribution calculated by multiplying the average price differential and the value of the market.

Table 4.5: Direct savings from declared price difference in the Netherlands 2000-2002

Year	Ave Price Diff. %	Value €million	
		Parallel Market	Saving
2000	4.0	364.742	14.6
2001	4.0	424.174	17.0
2002	3.0	456.238	13.7

Source: IMS, SFK

In terms of individual products, the ten products offering the largest savings, assuming a 3% declared price differential, are given in Table 4.6 overleaf.

Table 4.6: Top 10 parallel-distributed products by saving from declared price difference

Product Name	Parallel Sales €million	Saving €million
Simvastatin	56.9	1.7
Atorvastatin	20.4	0.6
Amlodopine	18.5	0.6
Terbinafine	15.9	0.5
Budesonide	14.2	0.4
Pantoprazole	12.2	0.4
Ciclosporin	11.3	0.3
Somatropin	10.4	0.3
Itraconazole	10.2	0.3
Goserelin	9.6	0.3
Top Ten Total	179.6	5.4

Parallel-distribution of Simvastatin provides a saving in the Netherlands of some €1.7 million with the top ten products providing around 40% of the total savings available. This compares to Denmark and Sweden where almost 70% of the savings are derived from ten products.

On top of the direct savings reported above is the portion of the clawback that is attributable to parallel-distribution. According to the SFK, this amounted to some €16.5 million in 2001. Given the desired growth rate in the clawback over the periods 2000-2001 and 2001-2002 of 10.1% and 10.3% respectively, this gives estimated savings from parallel-distribution that were recouped through the clawback of €15.0 million and €17.9 million for 2000 and 2002 respectively.

4.7 DIVISION OF SAVINGS

As stated above, the disclosed savings from substituting from one source of a product to another are shared one-third to the pharmacist and two-thirds to the Sick Funds. The savings from the clawback pass directly to the sick fund. Any further savings over and above those recouped in the clawback pass directly to the pharmacist. Unfortunately data was not made available to estimate what the level of this additional saving may be. Whilst the savings accruing to the sick fund can be seen as an accurate estimate, the savings accruing to the pharmacist are therefore at the lower end of what they may be in reality.⁶ Table 4.7 overleaf shows the estimated split of the savings that were quantifiable.

⁶ The same is true for the savings calculated for individual products given in table 4.6. The actual savings from these products, both from the clawback and the additional pharmact savings, will be higher than quoted.

Table 4.7: Split of the quantifiable savings in the Netherlands 2000-2002

Year	Saving €million	Pharmacist €million	Sick Fund €million
2000	29.6	4.9	24.7
2001	33.5	5.7	27.8
2002	31.6	4.6	27.0

The benefits to Dutch individuals of these savings are not altogether clear.

Basic labour economics indicates that pharmacists have to achieve an income that is in line with the effort and intellectual demands required both to enter and remain in the industry. If this income level is not met, then the number of people wishing to supply their labour as pharmacists will contract. This will lead to a shortage in the number of pharmacists, which is the situation in Holland. Whilst it is simplistic to put this shortage simply down to the income level of pharmacists, it is indisputable that if income levels were to fall further then this would have a negative impact on the number of pharmacists. Pharmacy income derived from savings from parallel-distribution substitution can only be beneficial in this respect.

For the savings that pass to the sick funds, benefits to patients could be seen either in a reduction in premiums or in an improvement in the quality of service offered. No evidence was provided that pointed to either of these events occurring. It must be noted that this does not mean that such outcomes are not happening. Whilst premiums may not be being reduced in the face of a growing drugs bill, they may be rising slower than if the savings from parallel-distribution were not available. Improvements to service as a direct result from savings from parallel-distribution would need a sizeable volume of data and, as was the case for the competition effect, would be worthy of a study on its own.

4.8 COMPETITION EFFECT

As stated in the data section of this chapter, data was not accessible to accurately identify and quantify a competition effect in the Netherlands.

Interviews with the VWS and SFK made it clear that they do not believe that parallel-distribution causes any significant competition effect, in terms of actually reducing the price of products. They believe this to be due to the lack of penetration in product markets. This argument, whilst true for perhaps the majority of products, is certainly not true for a significant minority of products, as highlighted in the earlier sections.

Whilst interviews with parallel-distributors produced no empirical evidence of a competition effect, it was felt that products with parallel-distributed competition were less likely to be priced at the maximum allowable either under the GVS or the WGP. In a similar vein, as in

all countries, whilst parallel-distribution may not necessarily result in falling prices, the presence of the competitor may stall the incumbent from giving price increases. These are areas that may prove of interest for further research if data can be made available.

4.9 THE FUTURE

The ministry of VWS plan to move the purchasing of pharmaceuticals away from the pharmacists and up to the Sick Funds. The plan is to introduce this by around 2007. The impact this will have on parallel distributors is unknown, and it is not in the remit of this report to hypothesise. According to the VWS, this is being done to improve purchasing power and so the Sick Funds can recoup all the savings that are available through generic manufacture or parallel-distribution.

A plan to introduce a differentiated clawback with different levels for generic and parallel-distributed products had been proposed to begin in 2003, as was the removal of the price setting regulations for parallel-sourced products. Whilst it is believed that the latter of these proposals could still go ahead, according to the SFK at the time of writing, the differential clawback appears to have been shelved in its proposed form.

The removal of the minimum price regulations governing the price of a parallel-distributed product will increase the transparency of the Dutch market. It is a move that appeared to be welcomed in interviews with parallel-distributors, as it will allow competitive forces to work more efficiently. This move could prove to be of benefit to the Dutch reimbursers, as savings available will both grow and be easier to identify.

Simvastatin will be off patent in 2003 allowing generic competitors to move into the market. When Omeprazol (Losec) came off patent, it resulted in a slump in demand in the parallel-distributed product. As Losec provides three times the level of savings compared to the next highest saving parallel-sourced product, the losing of patent protection will impact on the total savings available from parallel-distribution in Holland, although will lead to potentially greater savings from low price generic simvastatin

The market for parallel-sourced products is not as highly concentrated in the Netherlands as elsewhere, which may well be a reflection of the maturity of the market. The impact on parallel-distributors following the loss of Simvastatin will not be as large as would have been the case in a more product-concentrated market.

4.10 CONCLUSIONS

The savings from parallel-distribution in the Netherlands in 2002 amounted to some €31.6 million. Of this, €4.6 million were savings to pharmacists and €27.0 million savings to sick funds. Given that pharmacists are likely to receive savings from parallel-distribution that are neither declared in the price nor deducted in the clawback, this estimate is liable to be lower than in reality.

No empirical evidence of a competition effect could be found, although future research could prove this to exist if data was accessible. The competition effect could be of the form of products not being priced at the maximum allowable rather than a reduction in price.

For the most mature market for parallel-distribution in Europe, the situation for parallel distributors in the Netherlands is by no means stationary. New policies and changes in pricing regulations will present challenges and opportunities for parallel-distributors and for recouping the savings they are able to generate.

Section 5: Germany

5.1 PRICING AND REIMBURSEMENT MECHANISM

Germany operates perhaps the lowest regulatory pricing system for new, patented pharmaceuticals in Europe. Once a product has been considered to be medically suitable for treatment, it is automatically available for reimbursement. This is on proviso that the product is not viewed as “uneconomic”. This has meant that drugs for trivial illnesses such as the common cold are not reimbursed, but also that products such as Viagra and nicotine replacement therapies must also be paid for entirely by the patient.

For many pharmaceuticals that are off patent, a reference pricing system is in operation. Pharmaceuticals subject to reference pricing, approximately 60% of the market, are classified into groups that are formed in similar ways to that under the GVS in Holland. The Federal Committee of Physicians and Sick funds (“BuAusAKK”) decide into which reference group a product should be placed and the Federal Association of Sick funds determines the price of products in a particular group.

The statutory health insurance (GKV), discussed in detail below, will only reimburse an off-patent pharmaceutical product up to the reference price. If the cost to the patient is greater than this, then the patient must meet the difference through a co-payment. As in the Netherlands, most products are priced below the reference price and so are fully reimbursed with no additional payment.

In a system similar to the UK, German patients pay a fixed prescription charge that is independent of the actual price of the product but variable with pack size.

Statutory health insurance (GKV) covers approximately 90% of the German population. Health insurance premiums are deducted automatically from salaries and are proportional to income until a maximum premium is reached. The premium is split evenly between the employee and employer. An employee’s membership of a Sick Fund automatically includes coverage for children and non-working spouses. The exact premium varies slightly from region to region and to which Sick Fund an individual belongs; each Fund is able to set their own premium subject to Government approval.

The retail price of a product is calculated after Government-fixed wholesaler and pharmacist profit margins have been applied to a product. The percentage margins are on a regressive sliding scale, reducing as the price of a product increases. On dispensing a reimbursed product, pharmacists receive the full retail price from a Sick Fund, less a fixed deduction of 6-10%.

5.2 PARALLEL-DISTRIBUTION

Pharmaceuticals that have been sourced in parallel are priced at a lower level than those that have been domestically sourced. As stated above, pharmacists' profit margins are strictly regulated. Although this regulation is through a regressive margin system, this is a discrete rather than continuous system with margins falling into price bands. This means that for products that are relatively closely priced, such as those that can be both domestically and parallel-sourced, a pharmacist will have a greater absolute margin through dispensing the more expensive product. There is therefore a disincentive for pharmacists to dispense parallel-distributed products, even if doing so produces savings for the Sick Funds. The Sick-Funds have consequently moved to develop quotas for the distribution of parallel traded products by pharmacies.

Prior to 2002, if a parallel-sourced product was both available to the pharmacist and 10% or 1DM cheaper than the proprietary product, then the pharmacist was legally obliged to dispense it.

In 2002, an obligation was placed on pharmacists to dispense a certain quota of parallel-distributed products as a cost control measure. In April 2002 this was set at 5.5%, and was raised in January 2003 to 7.0%. If pharmacies fail to dispense this proportion then the pharmacist is subject to financial penalties

Both these measures have seen the penetration of parallel-distribution as a proportion of the total reimbursed market rise from just 2.2% in 1999 to 6.6% for the first half of 2002.

5.3 POTENTIAL BENEFICIARIES

The incentives for pharmacists to dispense parallel-distributed products in Germany are certainly more punitive than rewarding. As such, in Germany the major beneficiary from parallel-distribution are the Sick Funds through the lower level of reimbursement of parallel-sourced products. As is discussed further below, patients may benefit indirectly from the savings from parallel-distribution. Pharmacists may also benefit if they are offered discounts that are not transparent in the price. The information and data made available however only allows the assumption that all direct savings pass to the Sick-Funds.

5.4 METHODS AND DATA

IMS data for 2002 on all parallel-distributed products, together with their domestically sourced equivalents, were provided to YHEC.

Given the high quality of the data, direct savings could be estimated by calculating the savings generated from the supply of each individual product and then summing across all products. Individual product groups could also be examined.

Kohlpharma also made time series data of price movements of several products available on products where it had been felt that parallel-distribution had induced competitive behaviour from a domestic supplier.

5.5 DIRECT SAVINGS

The IMS data allowed calculation of the top ten parallel-sourced products in Germany by sales, average price difference and by total saving. These are given in tables 5.1, 5.2 and 5.3 below. The calculations represent all pack sizes and strengths for a particular product.

Table 5.4 presents summary statistics of the market.

Table 5.1: Top ten German parallel-distributed products in Germany in 2002 by savings

Product Name	Manufacturer	€Million Parallel Savings	Average Price Difference	Penetration	
Risperdal	Janssen-Cilag	9.6	-10.1%	66.2%	
Microgynon	Schering	5.9	-30.6%	56.0%	
Zyprexa	Lilly	5.2	-6.2%	64.2%	
Clexane	Aventis	4.9	-10.4%	52.9%	
Stilnox	Sanofi-Synthelabo	4.3	-26.2%	35.4%	
Lamisil	Glaxo	4.3	-10.3%	72.3%	
Combivir	Glaxo	3.6	-9.2%	58.3%	
Salofalk	Dr.Falk Pharma	3.4	-9.6%	50.2%	
Ciprobay	Bayer	3.1	-24.6%	38.2%	
Fraxiparina	Sanofi-Synthelabo	3.1	-10.1%	36.1%	

Source: IMS

Table 5.2: Top ten German parallel-distributed products in Germany in 2002 by sales

Product Name	Manufacturer	Parallel Sales 2002 €million	Average Price Difference 2002	Penetration2002
Zyprexa	Lilly	114.6	-6.2%	64.2%
Risperdal	Janssen-Cilag	86.3	-10.1%	66.2%
Clexane	Aventis	43.9	-10.4%	52.9%
Zocor	MSD	39.9	-4.5%	16.5%
Lamisil	Novartis	36.7	-10.3%	72.3%
Prograf	Fujisawa	33.1	-4.9%	46.1%
Combivir	Glaxo	32.8	-9.2%	58.3%
Lamictal	Glaxo	32.4	-10.2%	44.5%
Iscover	Sanofi-Synthelabo	32.2	-2.9%	20.4%
Glucobay	Bayer	31.5	-3.7%	48.2%

Source: IMS

Table 5.3: Top ten German parallel-distributed products In Germany in 2002 by average price difference

Product Name	Manufacturer	Price Difference	Penetration
Valium	Roche	-48.0%	1.7%
Renagel	Genzyme	-44.4%	1.6%
Neogynon	Schering	-39.0%	24.7%
Decoderm	Boots	-38.2%	3.9%
Sequilar 21	Schering	-37.4%	53.3%
Neo Stediril	Wyeth	-37.1%	68.0%
Trigynon 21	Schering	-33.0%	2.6%
Diprogenta	Schering	-32.4%	5.1%
Baycip	Bayer	-32.4%	1.7%
Perikursal 21	Wyeth	-31.9%	60.6%

Source: IMS

Table 5.4: Summary statistics of penetration and price differences of parallel-distributed products in Germany in 2002

	Average (raw) (Standard Deviation)	Average (weighted by sales) (Standard Deviation)
Price Difference	-9.5% (6.8%)	-8.2% (0.003%)
Penetration	25.7% (23.1%)	37.3% (0.007%)

The tables above appear to show that whilst some products sourced in parallel have large price differentials when compared to their domestically sourced counterparts, it is not the case that these products have the largest sales volumes or offer the absolute largest savings to German Sick Funds. What needs to be examined however is the penetration. Regression

analysis of market penetration on price differential indicates that for every 1% increase in the price difference, penetration increases by approximately 3.2% (95% CI. 0.7%, 5.5%).

The data indicates that the total value of the parallel-distribution market within Germany for 2002 was approximately €2000 million. The top ten parallel products by sales volume accounted for approximately 25% of the parallel market, showing the German market to be far less concentrated than the Danish, Swedish or even the mature Dutch market.

Using the data provided by IMS, the total savings from the use of parallel-distributed products amounted to €194 million during 2002. On average, domestically sourced products are 9.4% more expensive than a parallel sourced substitute.

Table 5.1 shows that over 2002, five products alone saved the German Sick Funds some €30 million. Two classes of products that produce high levels of saving that are hinted at in the tables are human insulin and the contraceptive pill. Savings from the contraceptive pill alone amounted to over €10 million. This is a product group that is not always fully reimbursed. As such, some of this saving will pass directly to the patient. As table 5.3 indicates, savings from individual brands can be over 30%. Insulin savings such as that achieved through the humalog preparations amounted to over €6 million.

5.6 COMPETITION EFFECT

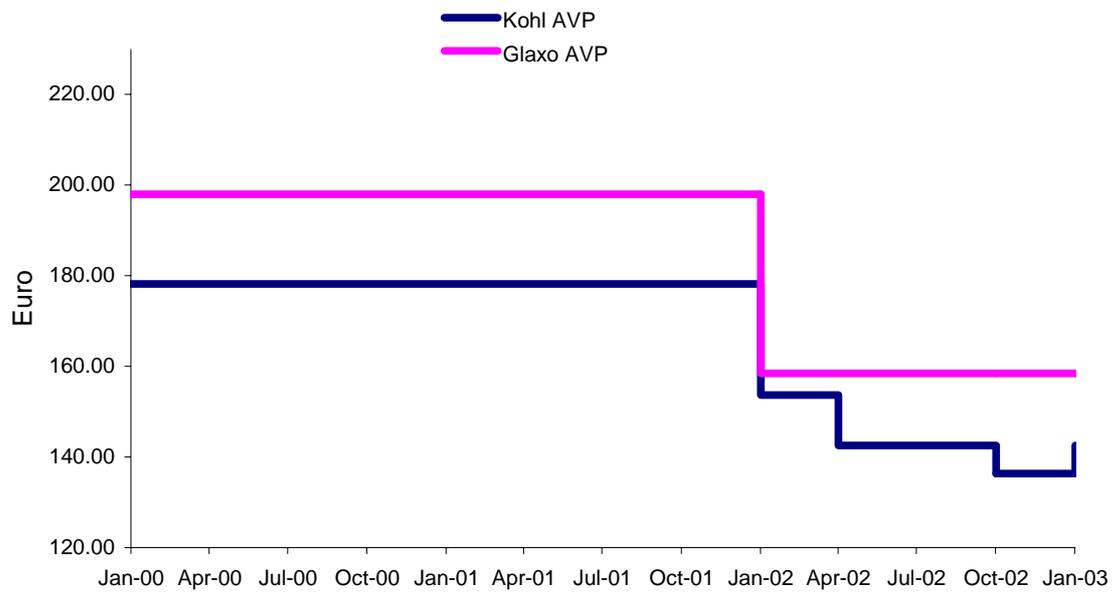
In 2002, Germany applied the “aut-idem” system to dispensing of doctors’ prescriptions. Pharmacists are allowed to replace a product with an identical product. Doctors can specify a product more tightly but only when the specified product is within the lowest third in price. While this may produce more competition where generic alternatives are available, it may also stimulate competition in price between parallel traded and locally sourced medicines still under patent.

To provide evidence of a competition effect in Germany, a number of products were identified, where a competition effect was thought to have occurred. YHEC was provided with IMS data on the prices of these products. Since there were products where German suppliers identified a price effect, they may not be typical of the market as a whole.

5.6.1 Seroxat

The proprietary manufacturer of Seroxat is GlaxoSmithKline. The time plot below shows the price of Seroxat 100 FTA from January 2000 to January 2003, over which time it was subject to parallel-distributed competition.

Figure 5.1: Seroxat 100 FTA

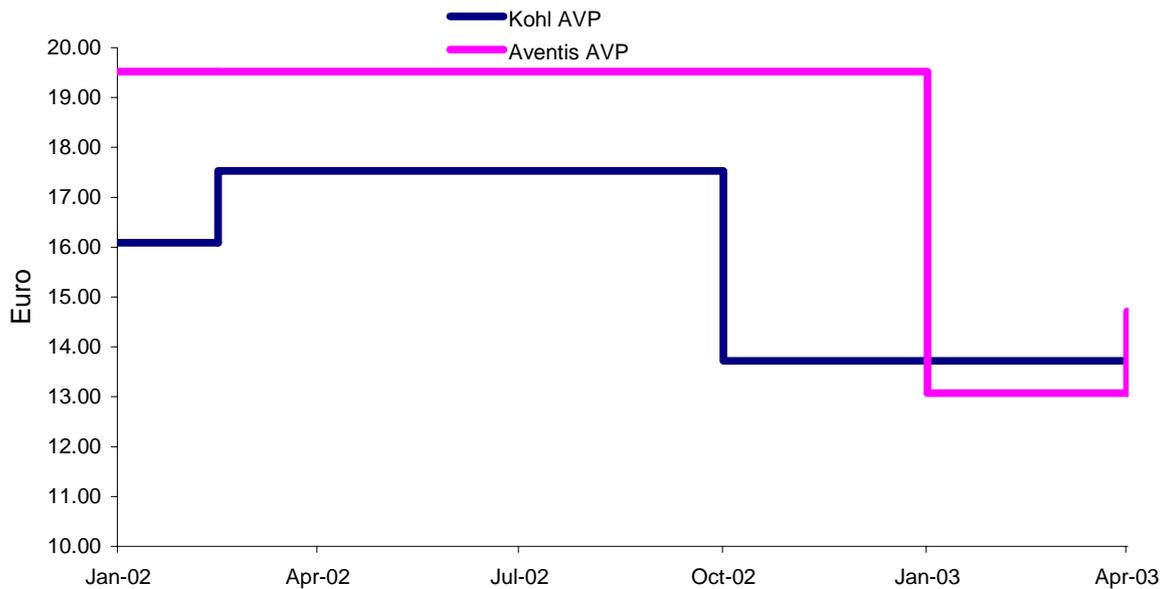


The above chart appears to show a downward movement in price by Glaxo simultaneously with Kohlpharma. Without additional information it is impossible to say whether or not this erosion of price would have occurred without parallel competition, but it also cannot be discounted.

5.6.2 Stilnox

The proprietary manufacturer of Stilnox is Sanofi-Synthelabo. The time plot below shows the price of Seroxat 20 FTA from January 2002 to April 2003, over which time it was subject to parallel-distributed competition.

Figure 5.2: Stilnox 20 FTA

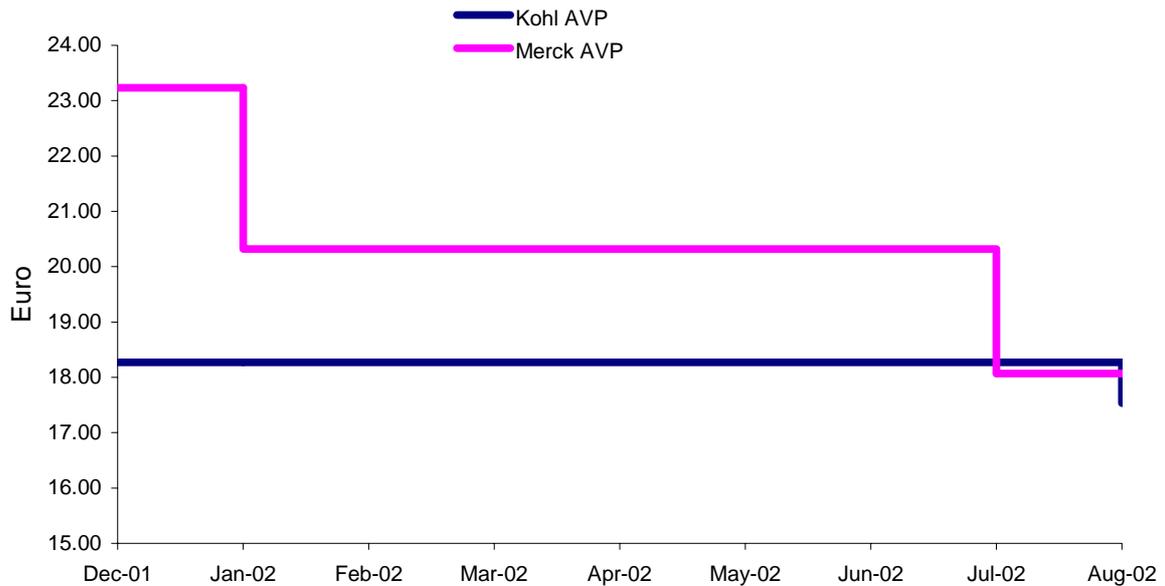


The above chart appears to show that in response to a price cut by Kohlpharma, Sanofi-Synthelabo responded by decreasing their price to a level below that of the parallel-distributor, although soon afterwards the price was raised back above that of Kohlpharma. The original price cut was to a level just below that of Kohlpharma, which is more likely to be competitive activity rather than coincidence. The behaviour of Sanofi-Synthelabo is also interesting, as they appear to decide to aggressively compete and then withdraw, although at a significantly lower price than before the initial price cut.

5.6.3 Glucophage

The proprietary manufacturer of Glucophage is Merck. The time plot below shows the price of Glucophage 850mg 120 FTA from December 2001 to August 2002, over which time it was subject to parallel-distributed competition.

Figure 5.3: Glucophage 850mg 120 FTA

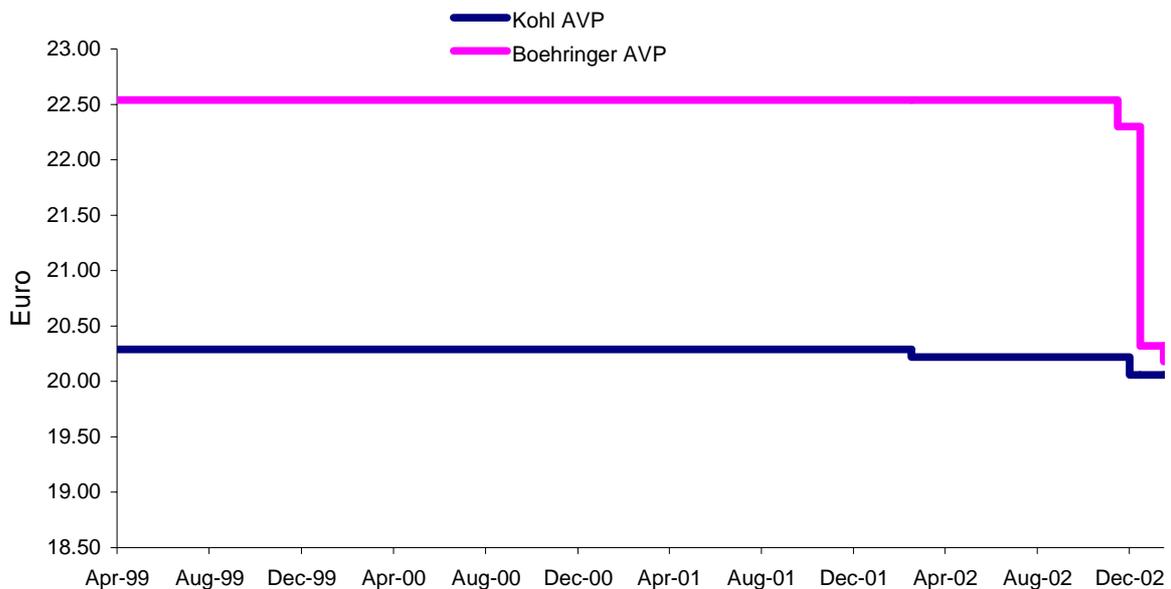


In December 2001, Merck reduced their price to a level closer to the parallel distributor before pricing at a level just below Kohlpharma in June 2002. As with Sanofi-Synthelabo, it is unlikely to be coincidence that the price was just below that of the parallel-distributor.

5.6.4 Catapresan

The proprietary manufacturer of Catapresan is Boehringer Ingelheim. The time plot below shows the price of Catapresan 100/150 Tab from April 1999 to January 2003, over which time it was subject to parallel-distributed competition.

Figure 5.4: Catapresan 100/150 Tab

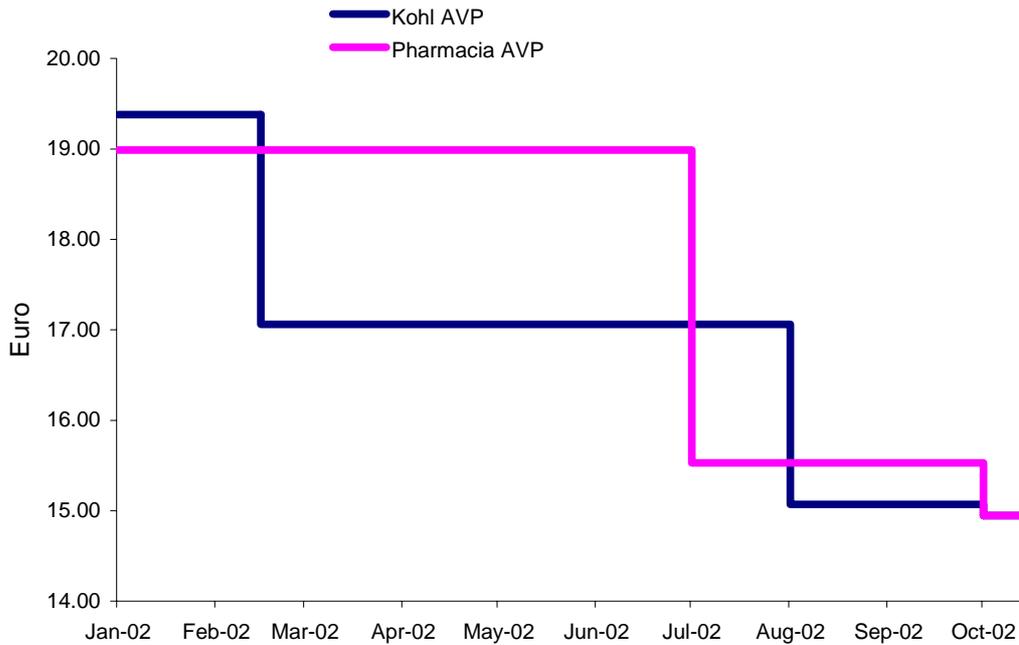


The above chart shows stable prices for two years until February 2002, when there was a slight price decrease by both the domestic and parallel supplier. At the end of 2002m Boehringer reduced their price by almost 10% to a level that would have been equivalent to Kohlpharma, had Kohlpharma in turn not lowered their price. At the start of 2003, Boehringer reduced their price again to a level closer to that of the parallel distributor. This behaviour is consistent with Boehringer aggressively competing on price with the parallel distributor.

5.6.5 Sobelin

The proprietary manufacturer of Sobelin is Pharmacia. The time plot below shows the price of Sobelin 300mg 12 caps from January 2002 to October 2002, over which time it was subject to parallel-distributed competition.

Figure 5.5: Sobelin 300mg 12 Caps

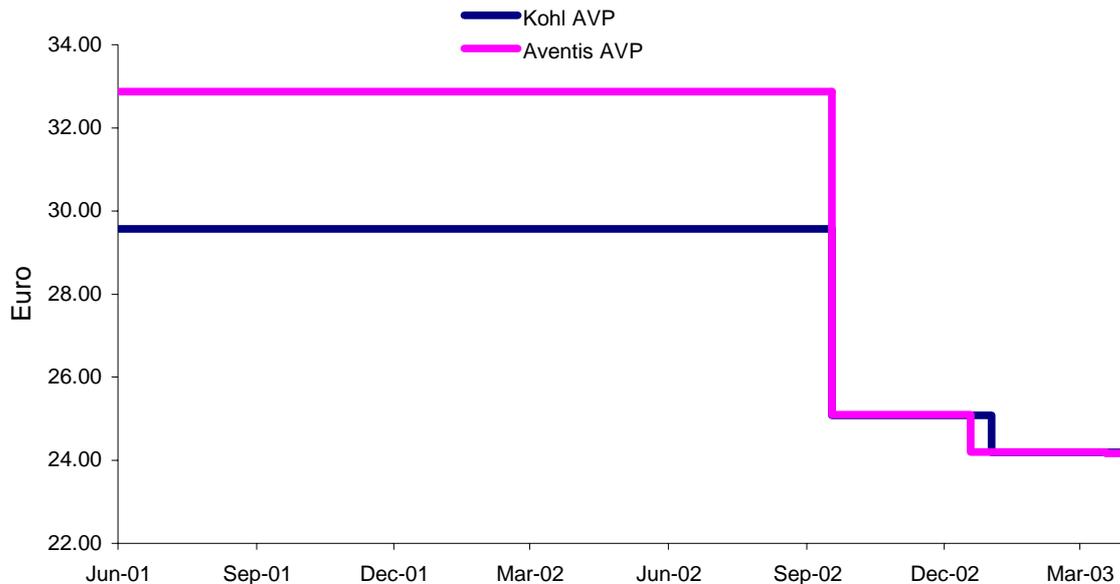


During 2002, there was a spiralling downwards in the price of Sobelin 300mg 12 caps resulting in the price at the end of the year being around 25% lower than at the start for both the domestic and parallel suppliers. The time plot appears to show aggressive competitive behaviour from both suppliers, with a pattern of cyclical undercutting.

5.6.6 Tarivid

The proprietary manufacturer of Tarivid is Aventis. The time plot below shows the price of Tarivid 200/10 FTA from June 2001 to April 2003, over which time it was subject to parallel-distributed competition.

Figure 5.6: Tarivid 200/10 FTA



After over a year of stable prices from both domestic and parallel suppliers, both Aventis and Kohlpharma reduced their price significantly towards the end of 2002, with Aventis pricing at a level fractionally above Kohlpharma. At the start of 2003, Aventis twice reduced their prices to a level just below that of Kohlpharma a level closer to the parallel distributor before pricing at a level just below Kohlpharma in June 2002. As with Stilnox and Glucophage, this behaviour is consistent with that of the domestic suppliers acting in a competitive manner towards the parallel distributor.

5.7 CONCLUSION

The German market for parallel-distributed products has grown rapidly in recent years, and experienced exponential growth over 2002 as new measures were introduced to encourage pharmacists to substitute domestically for parallel sourced products. The rapid growth and average 10% price differential compared to domestically sourced products has seen parallel-distribution produce an estimated saving of some €194 million over 2002. Savings on female

contraceptive and insulin products are particularly great at over €10 million and €6 million respectively, although the savings are accrued on a wide range of products.

The majority of the savings pass to the German Sick Funds though for oral contraceptives and other non-reimbursed products, the consumer is a beneficiary. The benefits to patients from these savings are entirely dependent on the behaviour of the individual Funds.

Time plot analysis, whilst never going to be conclusive evidence of a market wide competition effect, certainly show that for some products domestic suppliers do aggressively compete. This is particularly shown in the cases of Glucophage, Stilnox, Tarivid and Sobelin where the domestic supplier of the products is shown to reduce their price significantly to just undercut the price of the parallel distributor. This price level is unlikely to have been chosen by chance and would seem to be clear evidence of competitive intent.

The evidence for a competition effect here is from a small sample. However, it is noteworthy that the competitive activity mostly occurs towards the end of 2002, perhaps in response to the growth in parallel-distribution stimulated by the obligation now placed on pharmacists. It is plausible therefore that the introduction of this obligation has produced considerable savings not just directly but also indirectly in the form of price reductions by domestic suppliers.

Section 6: UK

6.1 PRICING, DISTRIBUTION AND PATIENT REIMBURSEMENT MECHANISM

Pricing of pharmaceuticals in the UK is left entirely in the hands of the manufacturer. However, pharmaceutical profits are capped under the Pharmaceutical Price Regulation Scheme (PPRS) and the Government may intervene on an ad hoc basis if it believes that the PPRS is not sufficiently controlling the drugs bill. As a further control on the drugs bill, price rises for existing products must be agreed with Government.

Full reimbursement of products is given to all products on launch unless they are subsequently blacklisted or have to be prescribed only under certain circumstances. A fixed patient prescription fee independent of the price of the product is payable, but this is a means tested payment and only occurs in around 15% of all prescriptions. Although collected by the pharmacist, this fee passes straight to Government and is no way part of the pharmacists' remuneration.

Reimbursement prices for generic pharmaceuticals are published regularly in the Drug Tariff with reimbursement prices for branded products being published in the Chemist and Druggist Price List.

Discounting is commonplace and so-called "brand equalisation" deals are also available, as is substitution by parallel-distributed products; pharmacists therefore usually pay a price for pharmaceuticals well below that published in the Tariff or Chemist and Druggist Price List.

Pharmaceuticals are distributed through either community or hospital pharmacies. Community pharmacists purchase pharmaceuticals from wholesalers and parallel distributors usually on an "as and when" required basis. Community pharmacists can either be independent or part of a "Chain" (e.g. Boots, Moss). Independent community pharmacy purchasing is fragmented and so they are less able to exercise collective purchasing power, although buying groups do exist to help in this area (OXERA, 2001).

Hospital pharmacists are usually supplied directly via a manufacturer, although distribution is usually passed to a wholesaler. Contracts are issued for supplying pharmaceutical products and purchasing is largely centralised, and so therefore hospital pharmacies have been seen to use their collective purchasing power (OXERA, 2001).

6.2 PHARMACIST REIMBURSEMENT AND THE “CLAWBACK”

Pharmacists in the UK receive income from selling non-prescription pharmaceuticals and from a dispensing fee. By shopping around and purchasing pharmaceuticals at a lower price than the reimbursement price a third source of income can be derived.

As stated in the previous section, the costs of providing a prescription medicine are reimbursed to the pharmacist at the NHS list price. This is the price in the Chemist and Druggist Price List for branded pharmaceuticals and the Tariff price for generic prescriptions.

As also stated previously, the price actually paid by a pharmacist for a drug is rarely the NHS list price. Pharmacists can obtain discounts below the list price from wholesalers on most products that are dispensed (brands and generics). Unlike the situation in the other countries in this report, where pharmacies are reimbursed the list price of the exact product they dispense (domestic or parallel-distributed versions), UK pharmacies initially receive the full list price of the domestic brand (i.e. the product's NHS price), and are then subject to a reimbursement adjustment procedure designed to withhold any amount in excess of the net acquisition price. This is done through the Discount Recovery Scheme (or 'clawback') by offsetting reimbursement made to each pharmacy the following year. To simplify administration, recovery is based on total purchases and savings realised by the average pharmacy as quantified by periodic discount inquiries from a representative sample of premises.

Pharmacies that obtain higher cost savings than the average gain in the short term, though their actions result in raising the amount clawed back from everyone in subsequent years. Pharmacies that fail to hit their savings target are financially penalised. The clawback is seen as the main driver for use of parallel trade in the UK. It also acts as an important price deflationary measure benefiting the NHS.

Following a discount inquiry, separate calculations are made on the savings achieved on purchases of domestic brands, generics and – since 1988 – parallel-traded products. In the case of parallel trade, the saving is the difference between the NHS list price and the average of five prices for the same product being offered by five different parallel trade suppliers.

The savings are weighted according to the value of each product type in the pharmacy's returns and combined to give a clawback scale. This currently varies from 6.5% to 13.1%, depending on the number of NHS prescriptions the pharmacy dispenses each month, with 10.2% the average.

6.3 POTENTIAL BENEFICIARIES

As the patient receives prescribed medication free or pays a fixed fee, in the UK all the savings from parallel trade either pass directly to the Government through the clawback or to the pharmacist, if they are able to achieve a level of discount savings greater than that recouped by the clawback.

6.4 METHODS AND DATA

Data on the UK market was hard to access, with problems arising due to commercial sensitivities. Whilst the prices of parallel-distributors were readily available, time series data in a usable form on domestic suppliers prices were not. In any case, the published prices in the Chemist and Druggist Price List are at best a reference due to the prevalence of brand equalisation deals and discounting.

As stated above, the hospital pharmacies purchase pharmaceuticals via contract. There was unwillingness from the purchasing agency to provide us with information due to a particularly acute principal-agent problem. They are encouraged by the Department of Health to seek out cheaper alternatives for pharmaceuticals, so would be put under pressure from this side if they were not seen to be issuing enough contracts to parallel distributors. However, they are also under pressure from the pharmaceutical industry to avoid issuing contracts to parallel distributors. As such, the purchasing agency will not release details on the level of usage of parallel-distributed products within hospitals, or on savings that result from usage. Discussions with the NHS purchasing agency show they acknowledge savings exist, but without data they cannot be quantified.

The sliding scale of clawback deductions is published monthly in the Drugs Tariff, with as mentioned previously the average clawback being in the region of 10.2% for 2001-2002. The calculations for the clawback are not published, but data was available from the Pharmaceutical Services Negotiating Committee (PSNC) on the average price saving between parallel-distributed products and domestically supplied products used in the calculation of the clawback for the year 1999-2000.

General data was made available from IMS on the overall size and growth of the parallel-distribution market, and on market penetration.

An interview was undertaken with Doncaster Pharmaceuticals, a parallel-distributor operating in the UK. Another UK parallel-distributor, provided details of individual products they supply and the declared price difference for their company.

As no specific price data was provided for the whole market, direct savings could only be estimated from the total market data available. This also meant that no competition effect could be empirically identified in the UK.

6.5 SIZE AND GROWTH OF THE PARALLEL-DISTRIBUTION MARKET

Tables 6.1 and 6.2 below detail the size and growth of the UK parallel-distribution market when compared to the UK domestically sourced branded ethical market for the years 1998-2002.

Table 6.1: Domestically and parallel sourced branded pharmaceuticals 1998-2002

	1998		1999		2000		2001		2002	
	£m	%								
Domestically Sourced	4,420	90.5	4,665	88.1	4,754	86.4	5,232	82.9	5,454	80.2
Parallel Sourced	462	9.5	633	11.9	749	13.6	1,076	17.1	1,346	19.8
Total	4,882	100.0	5,298	100.0	5,503	100.0	6,308	100.0	6,800	100.0

Source: IMS

Table 6.2: Growth in domestically and parallel sourced branded pharmaceuticals 1998-2002

	1998-1999	1999-2000	2000-2001	2001-2002	1998-2002
Domestically Sourced	5.5%	1.9%	10.1%	4.3%	5.4% pa
Parallel Sourced	37.0%	18.3%	43.7%	25.1%	30.6% pa
Total	8.5%	3.9%	14.6%	7.8%	8.6% pa

Source: IMS

The growth in parallel-distributed products between 1998 and 2002 has far outstripped that of domestically sourced branded products, with annualised growth rates over the period of 30.6% p.a. and 5.4% p.a. respectively.

Although parallel-distributed products accounted for 19.8% of the retail market in branded products in 2002, they held nearly 40% of the market of the five top selling drugs in that year (IMS).

6.6 DIRECT SAVINGS

Figures from the PSNC acknowledge that calculations for the clawback in 1999-2000 assumed savings available from parallel trade to be on average 17.43%.

Price and volume data for 2002 provided by a distributor point to an average “book price” discount on the top ten selling products of 10.8% compared to the NHS list price. However, a weighted average of the actual discounts given to pharmacists based on actual sales on the

top 10 products was 16.9% (range 1.6% to 24.3%). The product with the largest discount is the Serevent inhaler (25 micrograms, 120 dose) with a discount of 24.3% when compared to the NHS list price .

If this data is to be taken as representative of parallel-distributors in the UK, and the clawback calculations have not changed significantly since 1999-2000, then it would be a reasonable assumption that the weighted average price differential between parallel and domestically sourced products will be approximately 17%.

Our source is one of the larger parallel-distributors in a market that is concentrated. Just four companies account for fifty-five percent of the market for parallel-distributed pharmaceuticals. Larger companies will have larger purchasing power than their smaller competitors; it is not implausible that they are able to gain larger discounts from their suppliers and so offer greater discounts to the pharmacist. The 17% average price difference that will be used in calculations may well be a slightly high estimate of actual discounts available.

Conversely, smaller companies may concentrate on shorter lines and offer bigger discounts to gain market share for particular products. It may well be that the average discount available from the whole parallel-distribution market is higher than 17%. Indeed, the rapid growth that has continued since 1999-2000 provides evidence that discounts may well have been larger in 2002 than 2 years ago.

If the figure of 17% is applied to the value of parallel-distributed pharmaceuticals in the UK for 2002, it points to savings, compared to if the products had been purchased at the Drug Tariff price, of £228 million (£342 million). If it is assumed that on average the Government reclaims 10.2% of the 17% discount through the clawback, then £134 million of this will pass to the Government and £94 million will be income for pharmacists.

It is likely that the Government actually takes a larger share of this figure as hospital purchasing has been ignored. Any savings that accrue to hospital pharmacists will be passed directly to the NHS.

Given that there are approximately 11,000 pharmacies in the UK, and that approximately 50% are independent, this implies an average income of some £8,600 for each independent pharmacy in the UK from dispensing parallel trade. The importance of independent pharmacies is discussed later in this chapter.

This figure is only approximate and will undoubtedly vary greatly between pharmacies, being largely dependent on the financial drive of the head pharmacist but also on turnover and individual clawback. With lower levels of clawback for smaller pharmacies, there is greater incentive for them to use parallel-distributed products. For larger pharmacies, as the

clawback deductible rises there is a financial disincentive if they do not use parallel-distributed products. Given this “carrot and stick” approach taken by the Government, it is unsurprising that the growth rate of parallel-distributed products has been so high.

6.7 COMPETITION EFFECT

Identification and quantification of a competition effect would be difficult in the UK even if extensive data were made available, as the prices actually paid by pharmacists are not transparent as mentioned previously. This is further evidenced by the difference between the book price and actual price in data available to us.

No previous studies could be found that explicitly examined the effect of price competition from parallel-distributors on domestic suppliers. However, as part of a joint study by the Department of Health and the Association of the British Pharmaceutical Industry into competition in branded medicines (2002), hospital pharmacists were asked as to their opinion of the effect of parallel-distribution. All respondents concluded that “...*(the) use of parallel imports had resulted in some affected manufacturers reducing their prices.*”

This is evidence that a competition effect is present in the UK, although it does refer specifically to the hospital sector. Specifically, the quote says that *some* manufacturers have altered their prices in the face of competition. This confirms the findings in Denmark that manufacturers behave in different ways when responding to parallel-distribution, a fact reinforced by an interview with a British parallel-distributor.

6.8 BENEFITS TO THE INDEPENDENT PHARMACIST

There have been moves over recent years that have opened up competition in the pharmacy market. In 2001 Resale Price Maintenance (RPM) was ruled illegal by the Restrictive Practices Court. RPM allowed manufacturers to fix the price of over the counter medicines. This in turn allowed smaller community pharmacists to compete with supermarkets and chain pharmacies on service rather than price. The full effect of the removal of RPM is perhaps yet to be seen, but as its aim is to increase price competition it can only perceivably have a negative impact on most small, independent community pharmacies.

The Office of Fair Trading (OFT) reported in January 2003 that the rules regarding new NHS dispensing community pharmacies entering a particular locality should be relaxed. If this should happen, chain pharmacies and high street supermarkets could enter localities where they had previously been prohibited. Again, this will have a negative impact on the viability of independent community pharmacies.

A report by the Kings Fund (Lewis & Jenkins, 2002) on how best to develop community pharmacy pointed out some strengths of independent pharmacy in comparison to chain or supermarket pharmacies. They find that independent pharmacies are more likely to:

- Offer a greater variation of service provision from nicotine replacement therapy to giving advice to nursing homes;
- Be planning future developments such as health screening;
- Offer a private consulting area;
- Offer extended services to ensure more equal access.

The ability of independent pharmacists to supplement their income through the dispensing of parallel-distributed products could therefore prove to be a lifeline, allowing some pharmacies to stay open that would have otherwise become unviable.

It is not suggested that the use of parallel-distributed goods will be the saviour of all independent pharmacies. Rather, at the margin, it may be that parallel-distributed products provide part of the income that ensures some independent pharmacists remain viable rather than closing. If independent pharmacists are viewed as a societal good, as can be inferred from the finding of the Kings' Fund report, then it is therefore beneficial for parallel distributors to be present in the market.

6.9 CONCLUSION

It is disappointing that a detailed statistical analysis of pharmaceutical prices in the UK could not be conducted, as normative evidence points to the existence of a competition effect in the UK. As the UK is one of the largest markets for parallel-distribution it would have proved beneficial for the findings of this report as a whole if we had been empirically able to show the presence of a competition effect. However, it must be stated that the normative evidence for a competition effect is, however, strong and, in the case of the ABPI report, apparently unbiased.

Direct savings from the use of parallel-distribution in the UK are estimated to be in the region of £228 million (€342 million). This is based on 17% savings from parallel-sourced products used in the calculation of the clawback in 1999-2000 and from data provided by, a UK parallel distributor, which also pointed to savings of around 17%. This Figure may be an under or over approximation, depending on how representative the data is of the market as a whole. The rapid growth in the market over the past two years points to there being the possibility that discounts available have risen over the past two years.

Under the assumption that the Government deducts 10.2% of the reimbursement price of a product via the clawback, then much of the saving passes directly to the State. However, a significant proportion passes directly to the pharmacy, and in the case for the independent

pharmacy this income could prove to be a lifeline as competition further opens up the market to chain and supermarket pharmacies.

Section 7: Conclusions

7.1 DIRECT SAVINGS

7.1.1 Results

Compared to the agreed reimbursement price in each country, the savings accrued in the five countries considered in this report over 2002 are given in table 1.1 below. As discussed for each country, these savings result from either direct differences in the cost of the drug reimbursed or that which is deducted from pharmacists' reimbursement through a clawback.

Table 7.1: Direct Savings in the UK, Germany, Netherlands, Sweden and Denmark from the use of Parallel Sourced Goods in 2002

Country	Saving €million
UK	342
Germany	194
Netherlands	32
Sweden	47
Denmark	16*
Total	635

*2001 figure

These savings either pass to the reimbursor, the patient if co-payment is involved or to the pharmacist. As has been discussed at length in this report, savings that pass to the pharmacist have been used to subsidise their activities and in the UK may prove to be a lifeline to independent pharmacists.

7.2 COMPETITION EFFECT

7.2.1 Conclusions of the Time Plot Analysis

Evidence from the time plots in the Scandinavian countries suggests that different companies behave differently when faced with parallel-distribution competition. Astra Zeneca in Sweden seems content to lose massive market share to parallel distributors for some of its products whilst other companies engage in real price competition to drive out parallel distributors

In theory, a manufacturer will always be able to out-compete a parallel supplier, as they will always be able to increase supply and reduce price to the point where parallel-distribution is

not viable. However when deciding to compete on price the manufacturer must take into account some or all of the following factors and issues:

- The influence of the European average on the price level of a product in some countries. This means lowering the price in one country could have a negative influence on the price in other, larger markets;
- Lowering the price of a product may create another source of supply to other countries that are experiencing parallel competition, exacerbating any losses from parallel competition in those countries;
- If the actual price difference between that from selling to the supplying countries' wholesalers and price gained in the domestic market is not large, then the loss in profits may be such that it is not a strategic priority to engage in a price war. There may also be the case that for off-patent products, parallel-distribution provides a channel through which manufacturers can compete with generics on price, without lowering the price of the domestically sourced product;
- If the parallel sourced product is only available in limited strengths that are not divisible, and if lowering the price of a particular strength would mean a manufacturer has to lower the price of all strengths, then it may not be revenue-maximising to compete against those products for which a parallel alternative exists.

Having considered all the above, the strategy of the manufacturer may be that to compete on price is not in the interests of the firm. However, this does not mean that there is nothing they can do to try and stem parallel-distribution. In the Netherlands for example, the SFK reported an instance of the GVS price calculated for an unnamed product being much lower than in the rest of Europe. To maintain this price would affect both the European average price of the product and create a source of parallel supply to other markets. As such, the manufacturer priced the product well above the GVS but self-subsidised it such that Dutch patients would have to make no co-payment.⁷ This tactic is in a similar vein to that mentioned in the analysis in the UK, where the domestic manufacturer supplied a parallel distributor with a form of a brand equalisation deal.

Given all of the above, there was still evidence in the time plots of the Nordic countries that aggressive price competition was undertaken for some firms for some products, particularly in Sweden.

7.2.2 Conclusions of the Statistical Analysis

Statistical analysis of Sweden and Denmark provides robust evidence that the prices of products that are subjected to parallel-distribution competition behave differently over time to those that experience no such competition. The different behaviour may be in the form of

⁷ Although not discussed in the report, this can be seen as an unquantified direct saving to the Dutch reimbursers.

price reductions or price freezes, but the analysis seems to suggest that the competition is more in the form of a reluctance to raise prices if a parallel competitor exists. Further econometric analysis of pan European data sets and total Scandinavian pharmaceutical sales would be needed to accurately quantify the effect and the savings that this has generated.

Time series data on domestically sourced prices was not accessible. Identification the competition effect in the other countries considered was therefore not possible. However, there was evidence of its existence in the UK from the ABPI report into branded medicine. Anecdotal evidence of products in the Netherlands with parallel-distribution competition suggests they are more likely to be priced below the maximum under the GVS or WGP than products without competition. Insufficient data was available to confirm or disprove this proposition.

Statistical evidence from Sweden and Denmark points to passive price competition, in the form of reluctance to raise prices of products with parallel-distributed competitors. As this affects the total market for a particular drug, these savings could potentially be much larger than the direct savings calculated, which are a function of the parallel-sourced proportion of the market only.

7.3 CONCLUSION

The exploitation of available savings in Europe was in time past limited by the lack of companies engaging in parallel-distribution, anti-competitive behaviour by manufacturers and the anti-parallel-distribution attitudes of member states. Rulings by the European Court, the maturing of the parallel-distribution industry and the desire for Governments to curb spiralling drug bills has ensured many of these barriers no longer exist.

It is now the case that the level of savings achieved in Europe from the parallel-distribution of pharmaceuticals both directly and indirectly have played a considerable role in tempering the spiralling drugs bill in many EU countries.

Statistical evidence has been presented in this report of the existence of a competition effect generated by parallel-distribution, a fact that has often been disputed. This competition effect could potentially have indirectly have produced greater savings to the health systems of the countries considered than the calculated direct savings.

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