

9



**SURVEY OF PARALLEL TRADE**

**A Report for Interpharma  
Prepared by NERA**

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## TABLE OF CONTENTS

<b>INTRODUCTION AND CONCLUSIONS</b>		1
<b>1. THE LOSSES FROM PARALLEL TRADE</b>		5
1.1. What is the estimated current scale of losses from parallel trade for the companies in the sample and how has it changed over time?		5
1.2. What are the shares of overall sales and of particular product sales that are taken by parallel imports?		8
1.3. Do parallel imports have any effect on your pricing decisions in parallel importing countries?		10
1.4. Do parallel imports have any effect on the price decisions of authorities or in fixing the prices at which products are reimbursed?		12
<b>2. THE MECHANICS OF PARALLEL TRADE</b>		14
2.1. What are the average price differences of the most affected products?		14
2.2. Are you aware of instances in which the quality of parallel imports was compromised?		17
2.3. Has your company had cases of counterfeit products reaching pharmacists through the parallel import chain?		18
<b>3. THE FUTURE OF PARALLEL TRADE</b>		20
3.1. Is there an explanation for the apparently limited scale of parallel trade (if that is the case), given the size of the price differentials in the EU?		20
3.2. Are there any reasons to expect the scale of parallel trade between the current members of the EU to increase?		21
<b>4. PRODUCT LAUNCHES</b>		23
4.1. It is possible to document cases where the launch of a product was delayed because of negotiations with national governments, or a product was removed from a reimbursement list because of inability to achieve price agreement due to the threats of parallel trade?		23

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Introduction and Conclusions

## INTRODUCTION AND CONCLUSIONS

### Aim

The survey was commissioned by Interpharma on 24 September 1996. Its aim was to estimate the effect of parallel imports (PIs) of medicines on pharmaceutical companies operating in Europe. The time frame chosen was 1990 to the present. The importing countries to be evaluated were: Denmark, Germany, Ireland, Netherlands and the UK.

The companies whose responses to the survey are incorporated in this report are:

- Akzo-Nobel
- Boehringer Ingelheim
- Ciba
- Glaxo Wellcome
- Hoechst
- Roche
- Merck & Co
- Sandoz
- Sanofi

Between them, they account for 28 per cent of the EU market for prescribed medicines. NERA is grateful for the data and assistance provided, without which this report would not have been possible. All individual company data were provided to NERA on a strictly confidential basis and have not been, nor will be, transmitted to other parties.

### Method

The questions were based on those first suggested by the UK Department of Health in July 1996 and modified following review by Interpharma and a number of manufacturers. A list of respondent companies was supplied to NERA by Interpharma on 24 September 1996. Hoechst Marion Roussel was added to the sample on 14 October 1996.

On 25 September NERA circulated a detailed questionnaire to respondents enabling all data to be presented in tabular or other defined format. This was to ensure a consistent approach by all respondents particularly in relation to the calculation of losses attributed to PIs. The deadline for return of the questionnaires was 24 October. In the intervening period NERA made regular contact with all companies to ensure that the questionnaire on file had been received by e-mail or disk and to deal with some minor points raised by respondents.

Some responses in part or whole were received late, but NERA was able to include these in the analysis. Others were incomplete or did not conform to NERA's format. These are designated 0.5 in the table following. If all 9 companies had supplied full information for all

five countries, 45 company/country responses would have been received. The final total was 29.5.

**Table 1**  
**Questionnaire Responses Received**

Respondent company	Parallel importing country					Totals
	Denmark	Germany	Ireland	Netherlands	UK	
Akzo Nobel	0.5	1	0.5	1	0.5	3.5
Boehringer Ingelheim	1	1	0.5	1		3.5
CIBA		1	0.5	1	1	3.5
Glaxo Wellcome	1	1		1	1	4
Hoechst	0.5	0.5		1	0.5	2.5
Merck & Co	1	1		1	1	4
Roche	0.5	0.5		0.5		1.5
Sandoz		1		1	1	3
Sanofi	1	1		1	1	4
<b>Totals</b>	<b>5.5</b>	<b>8</b>	<b>1.5</b>	<b>8.5</b>	<b>6</b>	<b>29.5</b>

**Notes**

1 = Complete or near complete information supplied

0.5 = Partial information supplied

Given the lack of detailed data for Ireland, the quantitative analysis in this report excludes that market. Several companies reported no parallel imports into Ireland.

Additional data taken from IMS were supplied by Merck to provide total sales figures where not supplied by the companies. This also revealed that the nine participating companies together represent approximately 28 per cent of the ECU 45 billion market for prescription medicines in the EU.

**Conclusions**

**1. Losses due to parallel trade**

The most obvious effect of parallel trade is to reduce the revenues of national operating companies in the importing markets. On the basis of the survey, we estimate the aggregate loss of revenues for the participating companies in Denmark, Germany, the Netherlands and the UK in 1996 to be ECU 323 million. This is equivalent to seven per cent of the total sales revenue of these companies in the markets concerned.

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Introduction and Conclusions

However, this ignores the partly offsetting benefits of higher sales in parallel exporting countries. Taking this into account, the net loss due to parallel trade for the companies is estimated to amount to ECU 113 million. This is an increase of 11 per cent over our estimate for 1995. The data provided to us show losses in 1995 about 2.4 times as large as in 1990, although the limited data provided for 1990 make this result less statistically robust than the others.

Of the ECU 113 million, the largest shares arose in Germany and the Netherlands, with about one-fifth in the UK and five per cent in Denmark. Average penetration rates (market shares of PIs) for the most affected products range from 12 per cent in Germany to 32 per cent in the Netherlands. Figure 1 in Section 1 shows the distribution of penetration rates for individual product presentations.

As far as possible, we have cross-checked the companies' estimates against the underlying data for parallel import volumes and prices. In all we have verified estimates equivalent to a net loss of ECU 101 million in 1996, which relate to 53 products from eight companies.

## *2. Mechanics of parallel trade*

On a sales weighted average, ex-manufacturer prices are approximately one-third lower in the main source countries for parallel trade than in each of the main target countries. However, as Figure 2 in Section 2 shows, there is a wide variation for individual products.

For the eight products on which we received more detailed information on mark-ups at the various stages of the distribution system, ex-manufacturer prices are more than twice as high, on average, in the target country as in the source country. The average mark-up taken by parallel importers on these products is 68 per cent which still allows them to undercut normal route wholesalers by an average of 22 per cent.

Five companies provided us with examples of cases where the quality of the parallel imported product had been compromised in some way. Three companies had experienced cases described as counterfeit products reaching pharmacists through the parallel import chain. The main problems that arose concerned faulty batch numbering or other wrong or missing information.

## *3. Future of parallel trade*

Factors which have led or are expected to lead to increased parallel trade include:

- the ending of the ban on parallel exports from Spain;
- the obligation on pharmacists in Denmark to dispense PIs which are 5 per cent cheaper than normal route products;
- the Federal Court case in Germany requiring wholesalers to stock PIs;

- increased pressure on doctors', hospitals' and pharmacists' budgets;
- internationalisation of wholesalers and parallel importers; and
- the centralised EMEA registration, unification of trade marks and brand names.

However, offsetting influences are likely to result from:

- the ending of the obligation on German pharmacists to dispense cheaper PIs; and
- the price reductions imposed by the Dutch Government from 1 June 1996 (although one respondent felt that lower margins would lead parallel importers to seek to increase volumes).

The remainder of this report sets out the results in the survey in more detail, following the numbering in the original questionnaire (except that the second part of question 1.3 is now section 1.4).

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The Losses from Parallel Trade

## 1. THE LOSSES FROM PARALLEL TRADE

In this chapter we give the results of each question covered by the survey.

### 1.1. What is the estimated current scale of losses from parallel trade for the companies in the sample and how has it changed over time?

There are two main approaches to estimating the scale of losses:

- *value of net losses to the company:* the aggregate loss of profits to the company as a whole due to parallel trade, which can be estimated by:

$$\text{Value of losses} = \text{volume of PIs} \times (\text{target market price} - \text{source country price}).^1$$

- *local revenue losses:* the loss of revenue to the operating company in the parallel importing market, which can be estimated by:

$$\text{Local revenue losses} = \text{volume of PIs} \times \text{target market price}$$

In each case, the prices referred to are ex-factory prices.

In our view, it is the first approach that provides a reasonable estimate of the economic value of losses arising from parallel trade. Looking at just local revenue losses over-estimates the losses from parallel trade by failing to take account of the (partially offsetting) gains to the manufacturing company in exporting markets. Local revenue losses provide an estimate of the effect on the local operating company.<sup>2</sup>

The companies in our survey split approximately half and half between each of the two approaches to estimating the scale of losses. Expecting that this might be the case, we asked each company also to supply underlying data on the volume of parallel trade and on prices to enable us to check which approach each company was using and to generate our own estimates for that company based on each approach. In several cases, we were unable to duplicate the companies' estimates exactly (probably due to the companies using more detailed data than us), although our estimates were in all cases close enough to support the companies' own figures. However, some companies did not supply the underlying data and we were unable to verify their calculations.

Table 2 sets out the estimated values of losses for 1996 (whole year estimate, based on latest available data) and 1995. The value of those estimates which we have been able to verify against underlying data is shown in parentheses below the overall estimate. The ECU 100.9 million that we were able to verify relates to 8 companies and 53 products.<sup>3</sup>

<sup>1</sup> This assumes that costs are the same in both the importing and the source country.

<sup>2</sup> Even for the local operating company, the effect on profits will be partially offset by a reduction in costs.

<sup>3</sup> Each company was asked to give information about its five products most likely to be affected by parallel trade. However, the products chosen varied between countries, giving up to 11 products per company. Other companies supplied data for fewer products (e.g. two companies only provided data for three products each).

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The Losses from Parallel Trade

Table 2 shows a total net loss to the companies involved of ECU 113 million in 1996, an increase of 11 per cent over the 1995 figure. Losses in the UK and Denmark have increased substantially in the past year. Losses in the Netherlands have fallen for several of the companies in our survey

Spain, which has only become a source of parallel exports in the past year, was already quoted as source country for parallel imports equivalent to approximately 15 per cent of all losses in 1996.

Table 2  
Current value of net losses  
(million ECU)

	Denmark	Germany	Netherlands	UK	Total
1996	5.4 (3.4)	43.6 (36.9)	40.1 (37.7)	24.2 (22.9)	113.2 (100.9)
1995	3.1 (1.6)	40.5 (34.2)	42.3 (40.2)	15.7 (15.1)	101.5 (91.1)
Change (’95 to ’96)	+76%	+8%	-5%	+54%	+11%
Companies	Akzo-Nobel Boehringer-Ing. Glaxo-Wellcome Hoechst Merck Roche Sanofi	Akzo-Nobel Boehringer-Ing. Ciba Glaxo-Wellcome Hoechst Merck Roche Sandoz Sanofi	Akzo-Nobel Boehringer-Ing. Ciba Glaxo-Wellcome Hoechst Merck Roche Sandoz Sanofi	Ciba Glaxo-Wellcome Hoechst Merck Sandoz Sanofi	

\* losses as percentage of estimated profits in four target countries.

\*\* losses as percentage of estimated profits in the whole EU.

Note: Figures in brackets are the amounts that NERA has been able to verify from volume and price data supplied by respondents.

Many of the companies in our survey did not provide data for 1990. Table 3 shows the estimated value of losses for those that did, together with comparable figures for 1995 based on the same sub-set of companies. The proportion of the estimate for 1990 that we were able to cross-check using underlying price and volume data was much smaller than for 1995 and 1996.

Based on this sample, the value of losses from parallel trade has increased 2.4 times over the period from 1990 to 1995 (approximately 20 per cent growth a year). However, this result

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The Losses from Parallel Trade

could be influenced by sample selection bias and so cannot be considered statistically robust.

**Table 3**  
Past value of losses  
(million ECU)

	Denmark	Germany	Netherlands	UK	Total
1990	n.a.	0.5	5.1	17.0	22.5
1995*	n.a.	6.0	32.6	15.0	53.6
No. of companies	0	1	5	4	6

\* Only includes companies which provided data for 1990

For some purposes, the estimates of *local revenue losses* may also be of interest. These are shown in Table 4. As with the earlier tables, we have used companies' own estimates where they are based on this approach. NERA estimates have been used where the companies' estimates corresponded to the aggregate value of losses. The proportion of these estimates that we were able to cross-check was broadly similar to the estimates of economic loss in Table 2.

**Table 4**  
Local revenue losses  
(million ECU)

	Denmark	Germany	Netherlands	UK	Total
1996	12.9	63.8	125.8	100.6	323.1
1995	6.4	81.6	121.1	80.7	289.8
1996 loss as % of sales	13%	3%	26%	8%	7%* 3%**
No. of companies	7	9	9	6	9

revenue losses as percentage of sales in four target countries.

\*\* revenue losses as percentage of sales in the whole EU.

The estimates of local revenue losses are about 2.9 times greater than the estimates of economic loss from Table 2. In other words, approximately 65 per cent of the loss to local operating companies from parallel trade is offset by increased sales in the source countries.

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The Losses from Parallel Trade

## 1.2. What are the shares of overall sales and of particular product sales that are taken by parallel imports?

Table 5 shows the share of overall sales taken by parallel imports (the penetration rate) in each country. The figures are averages, weighted by sales value, for all products on which we have this information. However, it does not follow that these PI penetration rates apply to country markets in total. It is likely that respondents have cited their products that are most severely affected.

Table 5  
Average PI penetration rates for sampled products  
(per cent of total sales by volume)

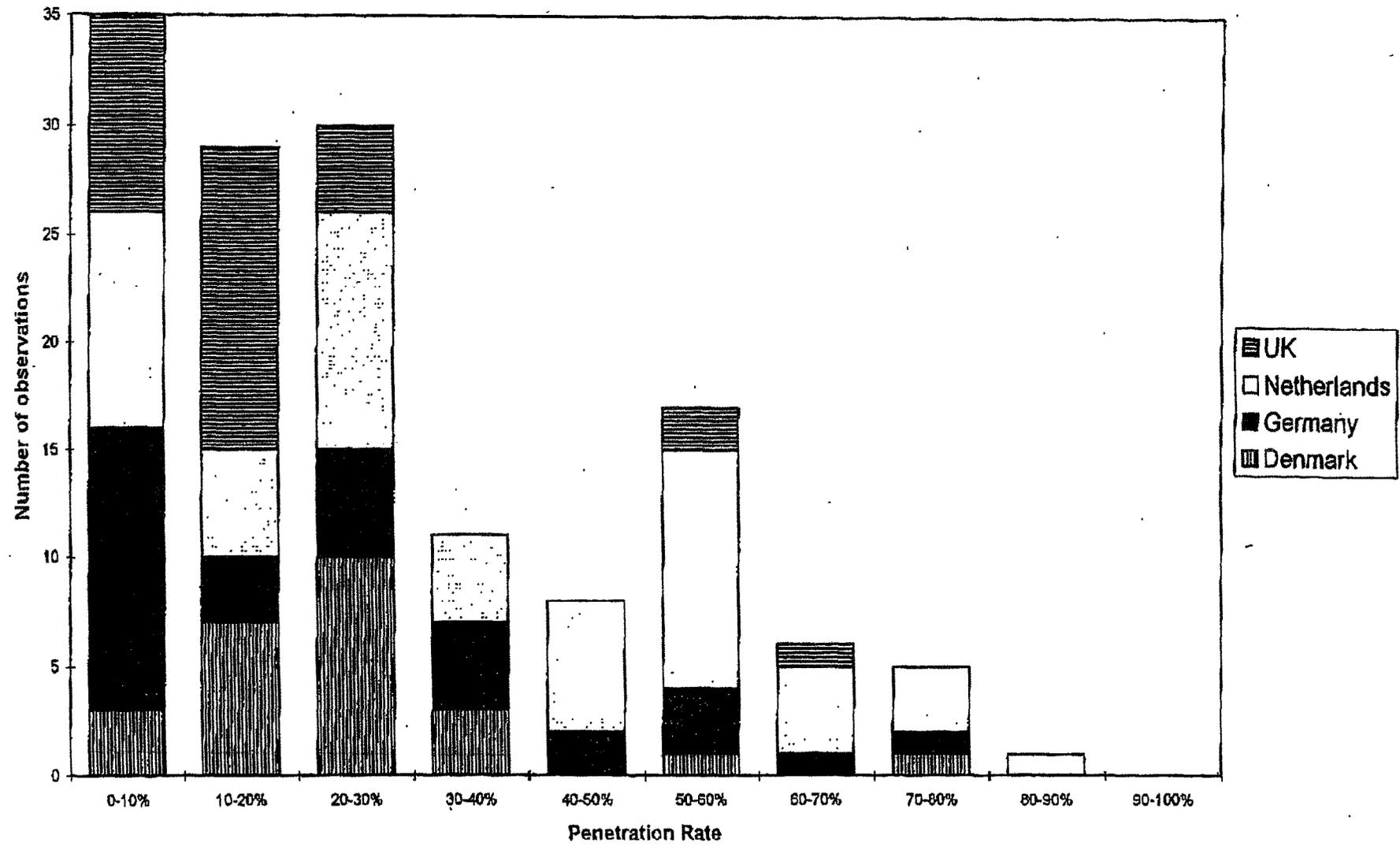
	Denmark	Germany	Netherlands	UK	Weighted average
1996	24	12	32	15	17
1995	9	13	34	7	15
1990*	n.a.	n.a.	11	6	9
No. of companies	3	6	8	5	

\* 1990 data relate to fewer products than 1995 or 1996.

Figure 1 shows the distribution of the shares for individual products. This shows that most parallel imports have market shares of up to 30 per cent. However, there are also a substantial proportion with shares in excess of 50 per cent, particularly in the Netherlands.

The sources of this information varied between companies. IMS was the most commonly quoted source.

Figure 1: Parallel Import Penetration Rates, 1996  
142 observations



n/e/r/a

The Losses from Parallel Trade

### 1.3. Do parallel imports have any effect on your pricing decisions in parallel importing countries?

---

	Number
Yes	5
No	3
No response	1
Countries cited under 'yes'	
Denmark	3
Germany	1
Netherlands	1
General	1

---

#### 1.3.1. Denmark

In Denmark the PI driver that affects respondents' pricing decisions is the combined effect of the following measures:

- the introduction in June 1993 of a reference price system based on the average price of the two cheapest comparable packs of defined products;
- a statement from the authorities to retail pharmacists in 1994 that they were to dispense a parallel import if it was cheaper by more than DKr5 (ECU 0.68); and
- an amendment to Danish pharmacy law, introduced in October 1996, with a schedule which requires pharmacists to dispense the cheapest medicine, whether a PI or generic, if it is five per cent cheaper than the normal route or original product.

The effect has been to force manufacturers to reduce the price of normal route products to within pharmacists' discretionary margin or otherwise lose substantial market share to PIs. The result has been a continuing and large number of price reductions. Examples cited by respondents suggest that from 1993 onwards price cutting began in response to PIs and has become more widespread and frequent as the number of PI products increased on the market. These price cuts, though small individually, have accumulated into a substantial overall price decrease. We were told that there have been 2,400 such price reductions in a year resulting from the presence on the market of 930 PI products. The downward pressure on prices from PIs is facilitated because all pharmacists have prices on computer that are updated by the health authorities every fortnight. Pharmacists therefore know precisely whether they are free to dispense a normal route product or not.

According to one respondent, Danish medicine prices fell by 15 per cent in the past two years, far exceeding the price reduction of 5 per cent for prescription medicines that was negotiated between the industry and the health ministry. We were informed that parallel

imports now account for 7 per cent by value of prescription medicines and that 11 parallel importers have been licensed including Polypharma, one of the largest Dutch parallel traders.

Another respondent cited four of its products whose prices had been reduced by 15 - 50 per cent in order to compete with PIs.

### 1.3.2. Germany

One respondent confirmed that although their company does not lower prices to compete with PIs, they exercise price restraint for products where PIs are offered in the market.

### 1.3.3. Netherlands

In the Netherlands, price competition from PIs compels price reductions in some cases. One company quoted the case history of a product launched in 1992 that had seen its price reduced by 12 per cent in 1993 and 20 per cent in 1994. Even so this had not prevented the market share taken by PIs increasing to 50 per cent.

On the other hand, other respondents said that the new law introduced in June 1996 that reduced Dutch prices for individual products to the average of the price concerned in Belgium, France, Germany and the UK had, by lowering the prices of normal route products, the effect of significantly reducing the penetration of PIs.

### 1.3.4. EU wide

One respondent confirmed that when launching new products it was their intention to keep the band of the selling price level as narrow as possible but this aim was compromised because "authorities in practically all European countries have the final word on prices since they decide on the reimbursement status of a product".

### 1.3.5. Comment

From the survey, it seems that PIs are having a significant and continuing effect of lowering prices in Denmark. In the Netherlands the import penetration of PIs has been checked by the new comparative pricing scheme introduced in June 1996. In Germany, where the penetration of PIs has historically been low, the existence of PIs may deter price increases for some products. Within the EU generally, new products now have their prices set with the threat of parallel trade in mind.

n/e/r/a

The Losses from Parallel Trade

**1.4. Do parallel imports have any effect on the price decisions of authorities or in fixing the prices at which products are reimbursed?**

---

	Number
Yes	5
No	3
No response	1
Countries cited under 'yes'	
Denmark	3
Germany	3
Ireland	1
Netherlands	4
UK	1

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**1.4.1. Denmark**

As noted earlier, the reference price system introduced in June 1993 uses the average of the two cheapest comparable packs of defined products available. Thus, the prices of PIs reduce reference prices and so affect all products in the group.

One respondent stated that under the most recent regulation the pharmacist must inform the patient if he or she proposes to dispense a product other than the cheapest. The doctor or patient can stipulate that the original product be dispensed but in other cases the pharmacist now feels an obligation to dispense the lowest priced product.

**1.4.2. Germany**

Two respondents pointed out that PI prices are included in the calculation of reference prices and so reduce the reference price of the group. Another stated that when the reference prices within a group of medicines are recalculated every two years, the regression model takes account of price and market share of each product in the group.

**1.4.3. Ireland**

Under an agreement between the pharmaceutical manufacturers and the Department of Health reimbursement prices are restricted to the average of prices in Denmark, France, Germany, Netherlands and the UK. Since the price of PIs help to set prices in Denmark, Germany and the Netherlands, there is a knock-on effect on Irish prices.

#### 1.4.4. Netherlands

Respondents referred to the fact that from June 1996 Dutch reference prices are based on an average of the price for the product in question in Belgium, France, Germany and the UK. In the two latter countries, it was stated, PIs hold down national prices and thus affect Dutch reference prices.

#### 1.4.5. UK

One respondent referred to the Department of Health's claw-back scheme that recovers discounts on PIs received by retail pharmacists

#### 1.4.6. Comment

The concept of setting reimbursement prices based on the price of individual medicines in other EU member states is now widespread. In Denmark and Germany no external price comparison occurs, but in the former the price of PIs is now a powerful driver for reducing reimbursement prices. By basing reimbursement prices on the lowest price available, Denmark is *importing* a PI price to the market along with the product itself.

The same is true in Germany, but the impact of PIs on German prices is less than in Denmark. This is because

- the reference pricing system takes account of the prices of all products in the group;
- patented products are excluded from reference pricing; and
- the market share of PIs is low, thus reducing their impact on reference price calculations.

## 2. THE MECHANICS OF PARALLEL TRADE

### 2.1. What are the average price differences of the most affected products?

- a) ex-factory prices in the exporting and importing country
- b) retail prices of the original product and the imported product in the importing country

Table 6 shows the average price differences in 1996 in each country, based on the data provided for each company's top five parallel traded products in each country. The averages are weighted by the value of domestic market sales.

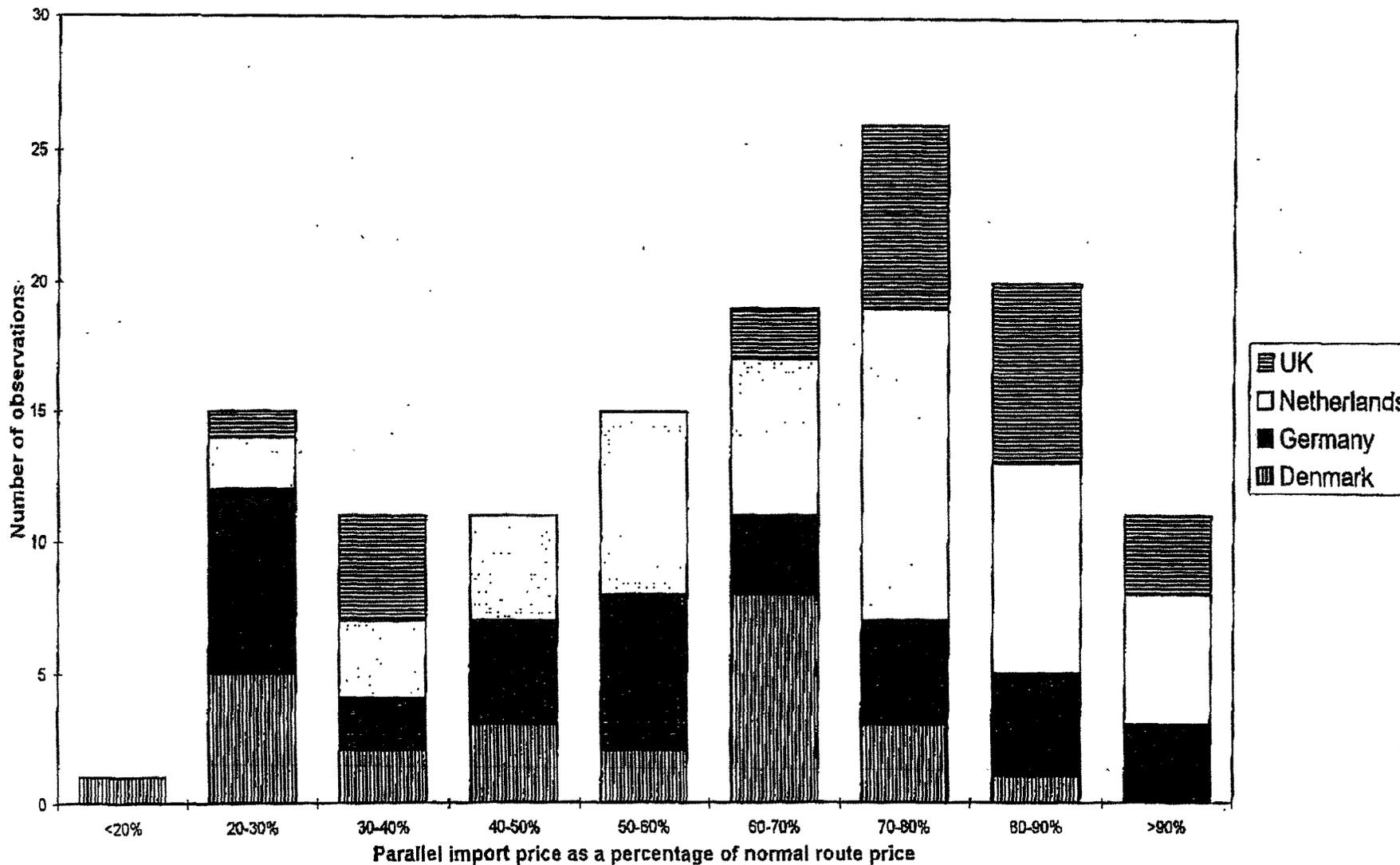
Table 6  
Parallel import prices relative to normal route prices, 1996  
(percentage difference)

	Denmark	Germany	Netherlands	UK	Average
Ex-factory	-38	-34	-33	-33	-34
Retail	-6	-12	-17	n.a.	-13
No. of companies	3	6	7	4	

The average ex-factory price differences for each of the four main target countries are remarkably similar, with parallel import prices being one-third lower than those for normal route products. However, on an individual product basis, there is considerable variation in the price differences, as shown in Figure 2. In half of the 129 product presentations for which we had price data, the ex-factory price of the parallel import was between 60 and 90 per cent of the "normal route" price. As many as 1 in 5 of the products were available to parallel importers at ex-factory prices below 40 per cent of the price in the target country.

Differences in retail prices between parallel import and normal route products are much less marked, indicating that a substantial proportion of the gain from parallel trade accrues to distributors rather than final purchasers. These retail price figures should be treated with caution: in some cases they refer to pharmacy purchase prices.

Figure 2: Parallel Import Prices (ex-factory), 1996  
129 observations



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The Mechanics of Parallel Trade

2.1 (c) Please give one (or more) example(s) of the current mark-ups at each stage of the normal and PI distribution chains for your product(s) using the following table

To be useable, markups at every stage of the normal and parallel routes were needed. Eight such responses were received.

	Number
Denmark	1
Germany	3
Netherlands	3
UK	1

The results for these eight examples are given in the following table. From responses it seems that the volume of PIs sold to hospitals is slight and so hospital sales are not covered by the table. Setting the ex-manufacturer price in the exporting country as 100, on average we found in this sample that:

- the mark-up by the parallel importer was from 113 to 190 or 68 per cent;
- the ratio between the ex-manufacturer price in the exporting and target countries was 2.14; and
- the ratio between the ex-wholesaler price and the ex-parallel importer price in the target country was 1.28. This means that the parallel import undercuts the normal wholesale price by 22 per cent.

Table 7  
Distribution chain mark-ups and price ratios

Parallel import route mark-ups	Average	Highest	Lowest
Price ex-manufacturer, exporting country	100	100	100
Price ex-wholesaler, exporting country	113	114	104
Price ex-parallel importer, target country	190	489	110
Price ex-pharmacist, target country	305	717	148
Selected ratios, normal route over PI route			
Price ratio: (ex-manufacturer, target country)/(ex-manufacturer, exporting country)	2.14	4.67	1.24
Price ratio: (ex-wholesaler, target country)/(ex-parallel importer, target country)	1.28	1.79	1.00

*n/e/r/a*

## The Mechanics of Parallel Trade

## 2.1.1. Comment

The examples provided by respondents indicate the substantial margins that can be made by parallel importers while still significantly undercutting normal wholesale prices. These margins are obtained by transferring medicines between EU Member States. No value is added to the medicine. Indeed, it is arguable that by repackaging, relabelling or reprinting the package inserts in a new language, value is removed from the finished product rather than added to it.

In the present survey we have not attempted to quantify any savings to health funds and patients that may accrue from parallel imports. This would entail a detailed examination of reimbursement schemes, claw-back of discounts received by pharmacists, and exchequer effects in terms of reduced corporation tax on the profits of manufacturers.

Only in Denmark does the patient obtain some *direct* benefit through lower PI prices. By contrast, in Germany and the UK patients pay a flat rate fee that is not related to the price of the medicine.<sup>4</sup> In the Netherlands prescription medicines were free at the point of delivery at the time of the survey. In Ireland we understand that pharmacists do not pass on to patients the discounts they receive from dispensing PIs.

## 2.2. Are you aware of instances in which the quality of parallel imports was compromised?

	Number
Yes	5
No	3
No response	1
Countries cited under 'yes'	
Denmark	2
Germany	3
Netherlands	1
UK	1

The respondents who replied 'yes' all provided concrete examples. Some of these related to minor labelling infringements that the importer rectified. Other examples were more serious, for instance:

<sup>4</sup> In Germany patients can pay an excess as well as the flat rate prescription charge if the manufacturer sets the price above the reference price, but this is rare.

- an indication stated as approved for the PI which was not approved for the direct-route product. As a result the importer recalled the stock, applied for a variation to the licence and then re-labelled and distributed the product;
- content of active ingredient was wrongly stated which the importer then corrected;
- a number of PI products whose repackaging by the parallel importer did not conform to legal requirements as exemplified by
  - 'numerous examples' of faulty batch-numbering such as different batch number on the blister and the box which would become dangerous in the event of recall;
  - adaptation of original batch numbers to those of the importer; and
  - absence of insert leaflets.

**2.2.1. Comment**

Parallel importers have a vested interest in persuading customers that PI products are of the same quality as those of normal-route. Only in one case quoted by respondents was the importer taken to court to rectify its actions. Examples quoted by respondents were not claimed to have compromised the quality of the product itself. However, wrong indications, inaccurate description of the active ingredient, absence of package inserts and faulty batch-numbering could all be considered potentially serious defects. The latter in particular would become so in the event of product recall.

**2.3. Has your company had cases of counterfeit products reaching pharmacists through the parallel import chain?**

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	Number
Yes	3
No	4
Don't know	1
No response	1
Countries cited as 'yes' or 'don't know'	
Denmark	3
Netherlands	1

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One company cited three cases in the Netherlands, all referring to a best selling product. In the first two cases the counterfeit contained the correct active ingredient, and the third case is still under investigation. The counterfeits came to light through sales representatives and wholesalers. In one case, the importer paid compensation to the manufacturer.

n/e/r/aThe Mechanics of Parallel Trade

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One of the Danish cases concerned trade-mark infringement. The respondent reported that certain of their products manufactured in Spain were renamed using the Danish brand-name without authorisation. The other case related to batch-numbering that the manufacturer did not recognise.

The response 'don't know' is based on the suspicion that PIs of a product from Greece to Denmark exceed the amount available in Greece by the manufacturer, suggesting that some of the product entered Greece from another source.

### 2.3.1. Comment

On the basis of the survey, the description and identification of counterfeits seems to be a grey area. For example, faulty batch numbering gives rise to the suspicion but not the certainty the products are counterfeits. If a counterfeit is defined as a product made by a third party and intentionally presented as the original, the incidence of proven counterfeits discovered by respondents in the PI distribution system has been slight to date. However, the 'don't know' response might give cause for concern.

### **3. THE FUTURE OF PARALLEL TRADE**

#### **3.1. Is there an explanation for the apparently limited scale of parallel trade (if that is the case), given the size of the price differentials in the EU?**

Eight of the participating companies commented, generally not agreeing with the premise in the questionnaire. Their comments can be summarised as follows:

- new products are introduced at harmonised prices;
- parallel traders have problems with supply e.g. from Spain, Greece and Italy;
- Ireland is too small to be a commercially interesting market;
- some large volume products have gone off-patent in the UK;
- parallel importers in Germany and UK are generally small concerns with limited financial capacity and marketing power; and
- the degree of acceptance by pharmacists and patients of PIs is lower in some markets, notably if there is no mandate or incentive for the pharmacist to dispense PIs.

##### **3.1.1. Comment**

As shown earlier, some products and companies suffer much more severely from parallel trade than others. The overall level of parallel trade is of less concern to them than the immediate losses of revenue and profit on what may be their most successful products.

##### **3.1.2. Have there been changes to the drivers in each of the main importing markets (Denmark, Germany, Ireland, Netherlands and UK) that in your company's experience have affected parallel imports?**

Eight companies provided comments. The ending of the ban on parallel exports from Spain of patented products was quoted by most respondents as a potent new driver. Other comments are summarised as follows:

- in Denmark reference pricing coupled with the obligation on pharmacists to dispense PIs when they are more than 5 per cent cheaper than normal route products has proved a powerful driver;
- in Germany during the '90s there was a legal obligation on pharmacists to dispense PIs if they were DM5 or 10 per cent cheaper. This has recently been rescinded. On the other hand, the decision of the Federal Court that wholesalers should stock PIs was mentioned as working in the opposite direction. The Gesundheitsstrukturgesetz (structural health law) which aimed to contain expenditure on medicines led to a boom in PIs;

- in Ireland there has been increased discounting and bonuses for normal-route products and this has reduced the attraction of PIs;
- in the Netherlands the price reductions imposed by the government from 1 June 1996 under the new system of cross-border price comparison were cited by some respondents as having lowered the penetration of PIs. One respondent felt that pharmacists would compensate for lost revenue by trying to increase the volume of PIs dispensed; and
- centralised EMEA registration, the unification of trade marks and brand names were mentioned as likely to stimulate parallel trade.

### 3.1.3. Comment

From the survey it seems that government intervention in the market is seen as a potent driver for parallel trade. For example, in Denmark the obligation of pharmacists to dispense the cheapest product (generic or PI) under the 'five percent' rule is seen as both stimulating the volume and value of PIs and also driving down the price of normal route products.

### 3.2. Are there any reasons to expect the scale of parallel trade between the current members of the EU to increase?

	Number
Yes	6
No	1
No response	1
Yes and no	1

Four companies expressed the view that lifting the ban on Spanish exports will continue to stimulate parallel trade. Other reasons given included the following:

- about 11 importers have now been established in Denmark, some with links to other countries, notably Polyfarma. The original and leading Danish importer, Paranova, has set up branches in Norway, Sweden, Germany and Finland;
- pressure on doctors' medicine budgets in Germany will influence them to prescribe PIs;
- centralised registration of new medicines will assist PIs;
- international mergers and acquisitions of wholesalers also will assist PIs;
- in the Netherlands there will be increased pressure on hospitals and pharmacists to substitute PIs; and

**n/e/r/a****The Future of Parallel Trade**

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- the trend towards unification of trade-marks, brand names and pan-European trading will stimulate parallel trade.

**3.2.1. Comment**

The evidence of parallel trade flows presented in Section 1 tends to confirm respondents' perceptions that, taking the EU as a whole, PIs are likely to increase in volume, value and penetration. Spanish parallel exports have achieved significant penetration in 1996. Traders have evidently judged that Clause 47 of the treaty of accession has expired and that even though the ECJ has found in favour of Merck and Co, parallel products from Iberia traded between October 1995 and the court's decision would have been legal. Since Spanish prices remain well below those of most other EU member states, the prospects for increased parallel trade are limited only by the availability of supply. The latter point is now under consideration in Bayer's appeal against the EC in the case of Adalat.

**n/e/r/a**

Product Launches

**4. PRODUCT LAUNCHES**

**4.1. It is possible to document cases where the launch of a product was delayed because of negotiations with national governments, or a product was removed from a reimbursement list because of inability to achieve price agreement due to the threats of parallel trade?**

Two companies replied 'yes' and gave specific cases:

- Company A. One product was withheld from Spain in 1992. A second product was introduced in Spain in 1996 after a three year delay;
- Company B. One product's introduction was delayed in Italy for 18 months, another for two years, and a third has been withheld for 12 months to date pending price negotiations.