The economic impact of parallel import of pharmaceuticals

June 2006

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Preface

Parallel import is an important policy issue in many countries and is surrounded by controversy, in part because of the many contradictory stakeholder interests. Research undertaken independently of these interests is therefore in demand from all quarters.

In 2003 the York Health Economics Consortium at the University of York published a study commissioned by The European Association of Euro-Pharmaceutical Companies (EAEPC) of the benefits to payers and patients from parallel trade. A report commissioned by Johnson & Johnson Ltd was published the following year by the London School of Economics as a stakeholder analysis of pharmaceutical parallel trade. These two studies reached different conclusions as to the impact of parallel imports.

Against this background of conflicting conclusions, the EAEPC commissioned during the summer of 2005 the Centre for Applied Health Services Research and Technology Assessment (CAST) at the University of Southern Denmark to undertake a critical review of the theoretical arguments and empirical evidence concerning parallel imports. The results of this study are presented in this report.

The main analysis and drafting of the report was undertaken by Ulrika Enemark, who is an associate professor of Health Economics at Aarhus University. Kjeld Møller Pedersen, who is professor of Health Economics at the University of Southern Denmark, developed the project description and had the initial contacts with EAEPC. He has also contributed to the analysis and drafting of the report. Jan Sørensen, who is director of CAST at the University of Southern Denmark, made the formal agreement between EAEPC and the University of Southern Denmark and has provided input and comments during the early stages of the analysis and on the draft report.

The preliminary analyses and the draft report have been discussed in three meetings with staff from EAEPC, in particular Hans Bøgh Sørensen, Jesper Teil Johansen and Heinz Kobelt.

The report has been finalised by Charlotte Bruun Pedersen and linguistically edited by medical writer Claire Gudex, both from CAST.

The analyses and conclusions reached are, however, the responsibility of the authors.

Odense, June 14th 2006

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Executive Summary

Parallel trade in pharmaceuticals is an important policy issue in Europe and is surrounded by controversy, in part due to contradictory stakeholder interests but also due to the limited attention given to the issue in the theoretical and empirical literature.

This study seeks to bring some clarity to the debate by reviewing the existing literature, in particular the 2003 LSE report and the 2002 York report. These two studies, and especially the former, have dominated the debate on parallel trade in recent years. They draw opposing conclusions about the benefits of parallel trade in pharmaceuticals. While the LSE report concludes that benefits to patients and health care systems are negligible, the York report claims that parallel trade generates significant savings, over €600 million in 5 countries in 2001.

This study analyses the differences between the two studies and concludes that the methodology applied for estimating direct savings on drug expenditures by the York study is the most appropriate.
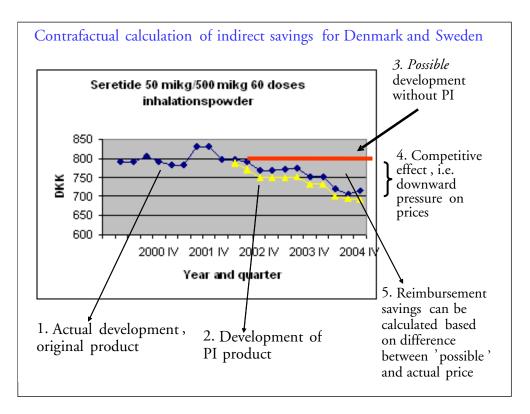
Using a methodology similar to that of the York report, the present study finds that parallel distribution generates considerable savings. It is estimated that direct savings to patients and health insurers in four countries – Denmark, Germany, Sweden and the United Kingdom – amounted to €441.5 million in 2004. It should be noted that the German estimate for direct savings is exceptionally low due to temporary changes in the regulatory measures in 2004.

Estimated direct and indirect savings in 2004 (€ Million)

	Direct	Indirect
Denmark	14.2	8.3
Sweden	45.3	16.4
Germany	145.0	n.a.
UK	237.0	n.a.
Total	441.5	24.7

This study also quantifies indirect savings for two countries – Denmark and Sweden. Indirect savings are generated through the downward pressure exerted on the price of the original, directly imported product. It finds that indirect savings for 2004 in Denmark and Sweden amount to €8.3 million and €16.4 million, respectively. According to these estimates indirect savings add another 58% to direct savings in Denmark, and another 36% in the case of Sweden.

The calculation of direct savings is relatively straightforward as they result directly from the difference in medicine prices between the more expensive local product and the cheaper parallel-imported product. The measurement of indirect savings is more difficult as it requires assumptions about how prices would have developed in the absence of parallel imports and about the causal link between parallel imports and changes in the price of the direct import.

The graph below, taken from the study, shows the study's approach to quantify the indirect savings. The evolution of the original product's price before the entry of competition from parallel imports is examined to predict the hypothetical evolution of the price in the absence of competition. This fictive or 'possible' price is then compared to the actual price with competition from a parallel import to calculate the savings from the price differential.

Contrafactual calculation of indirect savings for Denmark and Sweden

Seretide 50 mikg/500 mikg 60 doses inhalationspowder

3. Possible development without PI

4. Competitive effect, i.e. downward pressure on prices

1. Actual development, original product

2. Development of PI product

5. Reimbursement savings can be calculated based on difference between 'possible' and actual price

The main findings in relation to direct and indirect savings in the four countries are as follows:

- For the United Kingdom, the largest market for parallel imports in Europe, savings are estimated to be €237 million for 2004. This amount would be larger if the savings made by the pharmacies were included. Estimates are not possible for indirect savings as price competition is primarily on the discounts given to wholesalers and pharmacies, for which no data are available. Under the UK regulatory regime the consumers will benefit on the assumption that the savings in the NHS drug budget will translate into improvements in quantity and quality of health services.
- The estimated direct savings due to parallel imports in Germany in 2004 amount to €145 million. The 2004 estimate is, however, exceptionally low given that 2004 was characterised by a temporary increase in mandatory rebates resulting in withdrawal of a number of parallel-imported products. Due to modest co-payment on drugs, consumer savings are indirect through savings accruing to the sickness funds, thus contributing to lower premiums (or lower growth in premiums) for the same benefit package. Additional direct patient

benefits also materialise from the reductions in self-payment for non-reimbursed products.

- For Sweden direct savings are estimated at €45.3 million in 2004, and indirect savings at €16.4 million. Under the Swedish regulatory system the savings will have directly benefited patients through reduced payment under the co-payment limits, and indirectly when savings on the county and state budgets translate into more and better services.

- For Denmark, direct savings amount to €14.2 million and indirect savings to €8.3 million in 2004. Under the Danish regulatory regime the estimated savings will have benefited consumers directly through lower co-payment, as well as indirectly through savings to the National Health Insurance.

The four countries are the most significant markets for parallel imports of pharmaceutical products in Europe. As the table below indicates, the savings represent a substantial share of the parallel import (PI) turnover in the four import markets.

Savings from parallel trade as a share of PI turnover, 2004 (%)

Denmark*	11.7
Sweden*	20.4
Germany	10.5
UK	10.0

* = Includes indirect savings

The level of savings and differences between countries depend to a large extent on the national regulatory frameworks, which provide different incentive levels for using the cheaper imported product instead of the local product from the manufacturer. In Germany, for example, the government requires that a given percentage of the pharmacies' turnover comes from parallel-imported products. In the UK, on the other hand, a clawback system provides incentives for pharmacies to dispense PI medicines to improve their margins although part of their increased profitability due to PI will benefit the UK health care system through the clawback.

The study highlights these regulatory differences between national markets and their effect on the level and distribution of savings. By doing so, the study illustrates the complexity of the pharmaceutical market per se in which a number of actors are involved in the decision as to which medicines are consumed and in what quantities – namely doctors, pharmacies and patients. In many instances, however, the economic consumer of the medicines are the national health insurers, who in most cases end up paying most or all of the medicine bill.

Although the present study employs a methodology similar to that of the York study, it finds that compared to the 2001 estimates produced by York University, savings have decreased, most notably in Germany and UK. Regulatory changes, such as the strict price control in Sweden and the change in PI quotas and increases in mandatory rebates to sickness funds in Germany in 2004, may have contributed to this decline. An alternative explanation could be that prices have converged in Europe or that supplies have been increasingly restricted by manufacturers, meaning that parallel importers can deliver less stock, and hence generate fewer savings.

To counter the competitive pressure from PI, manufacturers have developed defensive strategies, often so-called non-price strategies, such as controlled supply of raw materials (licences), restrictive distribution agreements, product differentiation (various pack sizes and brand names), multiple small batches and supply restrictions, i.e. limiting sales to win market share. As parallel trade has characteristics of a spot market and therefore tends to be limited by supply more than demand, it is especially susceptible to supply restrictions. Overall then, to the extent that supply restrictions and other non-price strategies by manufacturers work – and there are indications that this is the case – savings from PI are being artificially limited.

Finally, the study also seeks to develop an analytical tool to address the question of how the overall price margin between directly imported and parallel-imported products is split among the various stakeholders in the parallel distribution chain. It is the first attempt by researchers to assess the added-value of parallel trade.

1. Background

Parallel trade in pharmaceuticals has existed in Europe since the 1970s, but has increased significantly with the maturing of the single European market. The share of parallel imports in Denmark, Germany, Sweden and the UK in 2003 varied between 7 and 17% (1), while it was less significant in the early 1990s.

Parallel trade in pharmaceuticals is an important policy issue in many countries and is surrounded by controversy, in part due to the many contradictory stakeholder interests, but also because the theoretical literature shows conflicting results and the empirical literature is still scant, albeit growing.

Two recent studies conducted by independent research organisations have produced contradictory results concerning the net benefits of parallel trade in drugs (2;3). The York Health Consortium at the University of York conducted a study in 2003 sponsored by the European Association of Euro-Pharmaceutical Companies, while the study carried out by LSE Health and Social Care at the London School of Economics in 2004 was sponsored by Johnson & Johnson. The two different sponsors clearly reflect different stakeholder interests. The York study concluded that parallel trading gives significant direct savings with signs of indirect competitive effects, while the LSE study found only very modest savings and no signs of competitive effects. The York study pointed to benefits to patients directly as well as indirectly through savings to the national health system, while the LSE study found that direct benefits to patients are limited and that the main beneficiaries of parallel trade are the parallel traders.

The York report concluded that direct and indirect savings from the parallel trade of pharmaceuticals have helped contain the mounting public health care expenditure in many European countries. It further concluded that due to the nature of the national health systems, users of health services would benefit from such savings. The conclusion in the LSE report was that the lack of sizeable direct benefits to health insurance organisations, the limited price competition in individual markets, the existence of reported product shortages in some member states, and the size of absolute and relative profits accruing to parallel traders may force policy-makers to re-evaluate the rationale behind parallel trade.

This study is a new attempt to provide empirical evidence of direct and indirect benefits of parallel trade in pharmaceuticals. The overall study objectives were to

- Assess the empirical evidence and methodology of past studies analysing the benefits of parallel trade, with a particular focus on the two studies mentioned above
- Estimate the savings in 2004 from parallel importing in four countries (Denmark, Sweden, Germany and UK). These countries are characterised by being mature parallel import countries with a considerable market share in parallel imports.
- Develop a template for a value chain for parallel trade in drugs and illustrate this for a number of products.

2. Theoretical arguments and empirical evidence

2.1. Introduction

Manufacturers' prices for pharmaceuticals vary between countries. Such price variations are, among other things, the results of 1) different national regulatory environments, in particular price regulation, 2) a degree of monopolistic power on the supply side, 3) price discrimination, and 4) price-setting response to exchange rate variations.

Parallel imports (PI) may be defined as goods produced genuinely under intellectual property right (IPR) protection, placed into circulation in one market, and then imported into a second market without the authorisation of the IPR owner. They are identical products, except that they may be repackaged and may not carry the original manufacturer's warranty.

The basic underlying driver of parallel trade is the variation in the manufacturers' prices of pharmaceutical products across markets. Importing occurs from countries with a low drug price relative to the price of the same product in the importing country and where the price difference is sufficient to cover the costs of transport, registration, relabelling/repackaging, creating and inserting leaflets according to national requirements etc.

PI is essentially an arbitrage business, i.e. the practice of taking advantage of a state of price imbalance between two or more (national) markets, regardless of the source of the price imbalance. One important consequence of parallel imports may be to arbitrage away the international price discrimination that is widely observed for pharmaceutical products, i.e. leading to price convergence.

The extent to which price differences lead to PI depends on how lucrative the process is, which in turn depends on factors such as price, availability of sufficient supplies in the source country, market size in the destination country and the size of the price difference and other demand-stimulating factors, for example substitution at the pharmacy level. These price differences are in turn affected by the price formation and regulation in the market, the degree of product differentiation between markets (which would affect transaction costs) and the market acceptance and incentives for purchasers, prescribers and distributors to use PI pharmaceuticals.

Parallel trade in pharmaceuticals has existed in Europe since the beginning of the 1970s in Germany, Netherlands and United Kingdom. Parallel trade was introduced later in the Scandinavian countries. According to IMS, approximately 5% of prescription drugs in Europe are re-imported.

The establishment of a single European market challenged the price discrimination that was widely practised up until then by the pharmaceutical industry, as the EU pursues 'regional exhaustion' – goods once purchased may be freely resold within the EU. The European Court of Justice has declared that free circulation of goods take precedence over intellectual property rights (IPR). The European Court of Justice has established

the circumstances under which repackaging is permissible through a number of decisions[1].

Parallel importing puts pharmaceutical manufacturers under competitive pressure with regard to both price and quantity. For a given market size, the entry of parallel-imported brand drugs implies – all other things being equal – a smaller profit for the manufacturers. Consequently, manufacturers have developed defensive strategies, often so-called non-price strategies (4), such as controlled supply of raw materials (licences), restrictive distribution agreements, frequent variations in marketing authorisation numbers, product differentiation (various pack sizes and brand names), multiple small batches and supply restrictions, i.e. limitation of drug sales in order to win a greater market share (5;6). The various cases that have been brought before the European Court are concerned with alternative strategies to protect IPRs, such as dual pricing, supply restrictions, packaging and trade mark infringements (7). As parallel trade has characteristics of a spot market and therefore tends to be limited by supply more than demand, parallel trade is especially susceptible to supply restrictions. Overall then, to the extent that the non-price strategies work – and there are indications that this is the case – at least part of the manufacturers' profit is unaffected by PI.

Various opinions about the advantages and disadvantages of PI in pharmaceuticals have been voiced over the years. The purpose of this chapter is to briefly review the theoretical issues and to discuss the available empirical evidence.

2.2. Key actors

For non-prescription drugs, the market is very similar to other markets. The consumers are the decision-makers and purchasers and price sensitivity is likely to be relatively large.

For prescription drugs several agents are involved in the purchasing process: the prescribing doctor, the dispensing pharmacist and the consumer. Whether the original manufacturer's drug or a directly imported drug or the repackaged parallel import of the same drug is purchased depends on the local regulations and incentives:

a) Prescribing doctors
In most countries, doctors are not involved in drug dispensing and do not have any financial gains from prescribing a higher number of drugs. This separation of interests is very deliberate in many countries; there is generally much higher drug consumption in countries where there is no such separation (and not necessarily a healthier population). In order to maintain their good professional reputations, doctors are typically interested in prescribing effective drugs. Where they are responsible for drug budgets or have to operate within the limitations of a drug budget, there are incentives to prescribe the cheapest drug available in the market or to allow the pharmacy to substitute the cheapest alternative with the same active ingredients.

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[1] According to Kyle (4), these include Hoffman-La Roche vs. Centrafarm (C-102/77); Bristol-Myers Squibb vs. Paranova (C-427/93); Boehringer Ingelheim vs. Paranova (C-429/93); Bayer vs. Paranova (C-436/93); Pharmacia & Upjohn vs. Paranova (C-379/97); Boehringer Ingelheim vs. Dowelhurst (C-143/00); Merck, Sharp and Dohme vs. Paranova (C-443/99); and Aventis Pharma vs. Kohlpharma (C-433/00).

b) Pharmacists
Profit margins for pharmacies are regulated in many countries. Where a percentage profit margin is allowed, the pharmacy will have a financial disincentive to dispense cheaper parallel imports. Where the pharmacy is reimbursed the pharmacy purchase price plus a fixed prescription fee, there is no disincentive, but no incentive either. As the choice of drug dispensed does not make any financial difference to the pharmacy, the drug that requires the least effort is most likely to be dispensed, e.g. a drug that does not require detailed explanation to the consumer that the product is the same but just looks a bit different and is just as good as the usual product. In order to stimulate the dispensing of parallel imports, a legal obligation to dispense the cheapest of products would have to be combined with an obligation to keep all products in stock.

c) Patients
In the case of no co-payment the consumer does not have any financial incentive to choose either the originator or the parallel-imported product. In the case of co-payment, the design of the co-payment system determines the incentives. In a system where a third party payer reimburses drugs up to a certain limit beyond which the consumer will have to pay, the consumer will be encouraged to choose the cheapest equivalent product presented. Similarly, a percentage co-payment provides an incentive for the consumer to choose the cheapest of interchangeable products. Where the co-payment by patients is a fixed fee per drug or prescription and is unrelated to the price of the drug, there is neither incentive nor disincentive to choose a parallel-imported product over the originator product. Co-paying consumers are assumed to choose a parallel-imported product only if there is a price advantage compared to the original.

d) The financing third party
In all countries prescription medicine is to a considerable extent paid by a third party, rather than the consumers themselves. This third party, whether it is 'krankenkassen' in Germany or the Danish and Swedish tax-funded county health services, not only has financial interests in the prices of medicines, but also in some cases considerable influence on the regulation of the market for medicines, reimbursement systems, etc.

e) The regulatory authorities
Knowledge of the regulatory processes in the market for medicines is of crucial importance in understanding the various forces that impede or support parallel trade. National Medicines Agencies are often the key players in determining the rules surrounding parallel imports, reimbursement decisions and regulation of pharmacies. In other cases one has to look directly to national government (Department and/or Ministry of Health) for legislation on the market for medicines.

It is clear that in countries with, for instance, reimbursement tied to reference pricing, parallel imports and generics have more impact than in countries without such systems. Considerable caution should be shown when generalising across countries and the regulatory environment for parallel trade should always be taken into consideration.

2.3.   Consequences of parallel trade

The expected effects of parallel trade in drugs depend to a large extent on a subtle combination of theories about parallel imports and available empirical evidence. In addition one should always look at the extent to which the regulatory environment is reflected in the theories and empirical analyses. The intention of this chapter is to review and analyse the consequences of parallel trade in drugs on prices in (European) importing countries and on overall welfare effects.

Parallel importing of pharmaceuticals is controversial because its net welfare effects are generally ambiguous. There is both theoretical and empirical tension between two major public policy objectives: innovation and development of new drugs on the one hand, and short-run cost-containment strategies for the health care system and broad access to existing medicines, on the other. The research-based pharmaceutical industry relies heavily on patents, the value of which depends in part on the scope for price differentiation. The existence of barriers to arbitrage/parallel trade is critical, however, to the exploitation of this scope.

The point of departure for part of the theoretical literature is third degree price discrimination, e.g. Danzon (8). Price discrimination is said to exist when sales of identical goods or services are transacted at different prices from the same provider. In third degree price discrimination, the price varies by location (e.g. country) or by customer segment. Price discrimination requires market power, for instance the monopoly provided by patents. However, price discrimination assumes that no trade takes place between market segments. And this is where parallel trade enters the picture, in a sense undermining price discrimination. Two recent examples of models that incorporate PI are those by Ganslandt & Maskus and Jelovac & Bordoy (9;10). These models are good attempts to come to grips with the complexities of parallel trade. One should be careful, however, not to draw too wide-ranging conclusions from these models due to their theoretical and hence assumption-based nature.

2.3.1.   Drug prices in the importing country

Before market entry of parallel imports
The decision to enter a market as a parallel importer will depend on the potential profit that can be made, which in turn depends on establishment costs (such as registration, special equipment, reprogramming of production), production costs (transport, repackaging etc.), price of the original product, availability of supplies, the size of the market and price sensitivity in the market.

In response to this threat of entry, the original manufacturer dominating the market may decide to use limit pricing i.e. to reduce the price, not to the marginal cost, but to a limit at which it is no longer profitable to enter the market. The original manufacturer charges the corresponding limit price and earns more than normal, but less than monopoly profits. In the limit pricing model the manufacturer can also prevent entry by committing to a limit quantity such that residual demand is too low for the potential entrant to break even.

The decision to use limit pricing is likely to depend on the price sensitivity of the market as well as the general contestability of the market. The potential loss of profits to the original manufacturer increases with increasing price sensitivity of the market, but decreases with decreasing availability of supplies (which to some extent is controlled by the original manufacturer). The limit pricing strategy may, however, also be used to signal an additional entry barrier to potential future entrants.

Where limit pricing strategies are practised one would expect to see the prices of some of the originator products being reduced in the period prior to entry of PI into the market or at the threat of market entry.

After market entry of parallel imports
Once the parallel importer has entered the market the original manufacturer, who is still dominating the market, may choose various strategies:

a) Adapt to the price sensitivity in the market
The manufacturer takes the PI price formation into account when setting its own prices, while the competitors take the price from the original manufacturer as given (i.e. a Stackelberg game). The quantity of originals sold then depends on the size of the price sensitive and insensitive market segments. Demand for PI depends on the original price, own price and the number of competitors. In some cases it can be profit maximising to increase price in order to increase profits from the loyal (price-insensitive) customers.

b) Enter into price competition
The manufacturer may choose to enter into price competition to drive the entrant out of the market or to minimise the entrant's market share. However, if the market potential for parallel products is considered small either because the price-sensitive market segment is considered small or the available supplies to the entrant is limited, the gains from reducing the losses in sales and consequent profits may not outweigh the losses in profits from the large price-insensitive segment of the market. Loss in manufacturers' revenues depends on the size of the cross-price elasticity between the PI and the original product. Through product differentiation between markets, elasticity can be kept low. The signal effect from entering into competition may, however, be important in the longer term.

c) Non-price strategies
Increasingly it seems that non-price strategies are used to counteract PI. Non-price strategies are typically adjustments in product offerings such as slight changes in brand name or dosage form, see Kyle (4).

Once a parallel product is in the market some price convergence would be expected (9). Lower price variability may emerge to counteract the parallel import. Where competition is limited due to limited supplies, the parallel importer may become the price follower. Price convergence depends on consumers valuing the original and the PI drug equally, otherwise some level of price difference that reflects the differences in consumer preferences and willingness/ability to pay will always persist.

Factors affecting price sensitivity
The price sensitivity of the market also depends on the regulation and the incentives of decision-makers to select among products. National governments use a series of measures, contracts and incentives to influence the supply of and demand for drugs. The regulation may be conducive to parallel trade or not, and may determine how any savings arising from parallel trade are split between stakeholders. For example mandatory substitution to the cheapest alternative is a strong tool for stimulating PI. Regulation can take different forms: direct control of product price, indirect control through reference pricing and competition from generics and PI (applied in Denmark, Netherlands, Sweden and Germany) and profit control as in the UK & Ireland. In reference pricing reimbursement ceilings are set by payers that fully cover drugs up to a reference price. This system provides a strong incentive to lower the price, but not below the reference price.

A generic scheme and application of a reference price system generally stimulates PI. Similarly, a system with capped budgets stimulates cost containment and therefore the use of PI (at least to the extent that cost savings are realised). The clawback system applied in the UK (and the Netherlands) provides an incentive for cost minimisation and therefore stimulates PI to the extent that these products are less expensive. The clawback system further aims at guaranteeing savings – the NHS recovers the average savings it estimates pharmacies have realised from their total purchases of PI and generics.

Many governments have defined profit margins for drug wholesalers and retailers. Some countries, e.g. the Netherlands, encourage PI actively through financial incentives to pharmacists. Regressive margins, especially for pharmacists, have been introduced in a number of countries to reduce the disincentive to dispense cheaper medicine (decreasing the percentage profit margin with increasing price) (11).

2.3.2.   Between-country effects

For many years the pharmaceutical industry has been practising price discrimination across market segments characterised by country. The ability to price discriminate depends on the ability to preserve market segments as distinct markets through the use of patents, restriction on arbitrage and prevention of leakage. Parallel trade undermines the ability to form segments by country. Parallel trade functions as an arbitrage device and offers a mechanism for levelling out price differences between countries that are not reflecting not only differences in preferences, but also differences that are caused by regulation.

Price convergence between countries in the European Union may occur as a result of PI, but the reference price system that is in operation in several countries especially since the early 1990s would also stimulate price convergence.

In an attempt to continue market segmentation along country lines, some manufacturers have responded by applying a dual pricing strategy in end-destination countries, i.e. selling drugs in Spain to the domestic market at a lower price than the drugs sold for re-export. Such practice has, however, been ruled illegal by the European Commission.

In order to curb re-export the supply of drugs may be restricted under certain conditions referred to in the Adalat case. It has been claimed that over the past 2-3 years supply quota systems have resulted in a reduction of the surplus stocks that were once traded and have consequently resulted in occasional stock-outs, i.e. product shortages in export countries (12).

Greece has experienced considerable growth in parallel exports of medicine (from €50 million in 1996 to €300 million in 2000, or from 2.9% of total sales in 1996 to 11.7% in 2000). This is claimed to have resulted in pharmacies reporting problems that include shortages of products for the Greek market (13). Others (14) claim that there is no evidence of such supply bottlenecks and argue that parallel trade has rather prevented such shortages.

Both dual pricing and supply restrictions in the exporting markets would tend to severely limit the ability of PI to produce price competition in importing markets and thus price convergence.

Countries with high general drug prices and parallel importing will in the short and medium terms see a savings benefit through two effects. First, there will be direct savings in drug expenditure as the same quantity of drugs is consumed, but some (parallel imports) are now sold at a lower price. It is assumed that the overall demand does not change when prices decrease. Secondly, if price competition results in a downward pressure on the price of the originator products then there will be savings on the remaining quantity consumed as the originator price will be lower than it otherwise would have been without parallel imports in the market.

Price convergence may result in higher wholesale prices in exporting countries. Depending on the regulatory framework and cost-consciousness of the national authorities, this may in turn result in higher national drug expenditures or lower price margins in the distribution chain.

2.3.3.   Welfare effects

Total welfare is defined here as the sum of consumers' surpluses net of the public expenses, and the profits of both the drug manufacturer and the parallel importer(s).

To the extent that price competition materialises it will have a direct positive welfare effect as reduced prices result in lower total drug expenditure. Savings may occur through two mechanisms. The availability of cheaper PI of the same brand products as currently in the market will translate into direct savings as part of the current volume of consumption is shifted to PIs. The magnitude of such savings depends on the volume of consumption shifted and the difference between the PI and originator prices.

Furthermore, to the extent that the manufacturer responds to potential or actual competition from PI by changes in pricing strategy, additional savings may occur. The increased competitiveness of the market may result in a decrease in originator price or a reduction in any planned growth in price. In that case savings will not only be limited to the consumption of PI, but will also occur in relation to consumption of products at the originator price. The magnitude of such indirect savings depends on the total volume of

products in the market as well as the degree to which manufacturers respond to increased competitiveness. Depending on the financial arrangements such savings may directly benefit the user (e.g. when co-payment is related to price) or indirectly benefit the user through a reduction in third party drug expenditure, thus allowing resources to be used for other purposes.

While there are direct benefits to importing countries of parallel trade in terms of direct savings and perhaps indirect savings, it has also been argued that parallel importing could on balance have negative welfare effects in the long term due to a negative impact on research and development (as a result of declining profitability of research and development). This argument rests on a number of critical assumptions, however, e.g. that (marginally) declining profits in the pharmaceutical industry translate into reductions in research and development rather than in other areas within the respective companies.

The pharmaceutical industry is characterised by an unusual cost structure with extremely high upfront investments, a very high product failure rate and high product liability. In comparison the variable costs of production is relatively low. The payback time required is thus relatively long and is one reason for the patent protection of such highly research- and development-intensive goods.

When there are considerable joint production costs, e.g. research and development costs, compared to short-term variable costs, Ramsey pricing (8), in which price discrimination is used to generate higher profits in market segments with higher willingness and ability to pay and lower profits in market segments with low ability to pay, can be an efficient pricing strategy for paying for research and development. It depends, however, on an effective segmentation of distinct markets with limited leakage and arbitrage. With parallel trade it is difficult for the pharmaceutical industry to uphold such market segmentation. Gyldmark et al. (15) has pointed out that the conclusion that price differences increase welfare depends on an assumption that price discrimination is based on a segmentation of markets according to true individual demand elasticity. But do individual demand elasticity follow national borders?

It has been argued that reduced revenues to manufacturers and transfer of profits to parallel importers who do not invest in research and development may result in lower investment in research and development. Thus, despite sufficient willingness to pay (through higher prices) among some consumers, the development of new medicines will suffer in the long run, e.g. Danzon (8). As such parallel trade, while targeting static efficiency (to keep costs low), is in conflict with the objective of promoting dynamic efficiency because of the disincentives for research and development as opposed to a situation without parallel trade but with Ramsey pricing. This argument, however, depends on an assumption that reduced profits necessarily translate into reductions in research and development. As research and development is the core value driver, such a response strategy by the manufacturer would not necessarily be profit-maximising in the long term.

While increased price competition is likely to reduce investments in research and development this prediction is not sufficient to determine the net effect on social welfare (16). The net effect will depend on the shape of the innovation production function

over the research and development cost levels before and after increased price competition. Assuming diminishing returns to scale, there will be cost levels at which the marginal productivity is low and at which the effect of reduced research and development costs on innovation will only be moderate. Obviously, there will also be cost levels at which this effect is substantial. The starting point, i.e. the current level of research and development costs and the shape of the production curve, will determine how the gains in static efficiency (through the reduction of prices towards marginal costs) and the loss in dynamic efficiency (long-term reduction in innovation) balance out. Indeed, it is possible that at low marginal innovation productivity, increased price competition will be welfare-improving, as long as the price competition does not shift profit margins below the margins associated with minimum total social costs.

The welfare effects from parallel trade will depend on the drug regulations, efforts of originators to exert vertical price control, the level of demand dispersion across markets and the need for manufacturers to achieve payback on their global research and development costs. Jelovac & Bordoy (10) show that for equal levels of income between countries, PI decreases total welfare when the only difference between the two markets is in terms of the level of patient co-payment, i.e. where price differences are due to regulation only. However, when the countries differ in the utility patients obtain from consumption then PI increases total welfare as resources are allocated from those with low needs (exporters) to those with high needs. This conclusion is, however, only relevant when comparing countries with similar income.

There could be a risk of high launch prices for new products as the development of parallel trade has reduced the period during which high profits can be gained. Manufacturers may use higher launch prices to gain profits in high-price markets before parallel importers can mobilise and may also launch in fewer countries in order to reduce the scope for parallel trade (8). As low prices in one market may spill over to other markets due to parallel trade and/or reference pricing, manufacturers may prefer longer launch delays in some countries. Since price-sensitive market segments will have a greater reduction in demand relative to a hypothetical demand curve this would imply that low-income consumer countries with significant co-payment will have slower access to innovation drugs. This is argued to be welfare-decreasing. This argument is based, however, on an assumption that the point of departure was optimal.

2.3.4. Summary

The theoretical literature recognises the short-term benefits of parallel trade to importing countries in terms of lower drug expenditures, provided that lower costs are transferred to the consumers of pharmaceuticals. There are likely to be direct effects through lower drug expenditures due to parallel imports entering the market at prices lower than the originator price. The level of such savings is an empirical question. Important factors in the level and distribution of any savings and resulting welfare effects are the regulatory conditions of the market and the payment mechanisms in place. To the extent that parallel trade puts competitive pressure on the originator price, thus producing price decreases or a deceleration of price increases, there will be indirect savings in drug expenditures. From a theoretical point of view, however, the response to parallel importing in the market may not necessarily be to enter into competition. To what extent that happens is an empirical issue.

In the longer term it has been argued that research and development could suffer from reduced profits in the pharmaceutical sector, but it has also been shown that this is not necessarily the case under all circumstances.

2.4. Empirical evidence

2.4.1. Direct savings

The amount of direct savings from parallel imports in importing countries has been estimated for several countries in two larger studies, in the following referred to as the York Study (3), and the LSE study (2;17). In addition, a few smaller studies have attempted to estimate savings in a one-country context, see Table II.1.

The results vary considerably, especially between the two larger studies. However, the studies also differ in methodology and intent. The York study was aimed at estimating the financial benefits related to parallel trade of medicine in terms of savings to national health insurance systems. The LSE study had a wider aim, as it also intended to compare prices across countries with a view to analysing price convergence and assessing possible profits to parallel traders.

The York report focused on the financial benefits available through savings from products included under some form of public health insurance. The main conclusion was that the total direct savings from the parallel trade of pharmaceutical products in 2002 were estimated in the UK as €342m, in Germany as €194m, in Sweden as €47m, in the Netherlands as €32m and in Denmark as €16m (2001), totalling €635m.

The York study focused for each country on the top-selling products plus a random sample of 150 products (for the price effect estimations). Savings estimates for three countries (Denmark, Germany and Sweden) were based on detailed calculations for all parallel-imported products. Savings were estimated by multiplication at individual product level of the quantity sold and the price differential between the selected parallel import price and the originator price using the actual fortnightly price differential and quantity sold. For the UK and the Netherlands the estimates were based on average price differences between parallel and originator products and total pharmaceutical data. The direct savings of €342m estimated for the UK include the clawback collected by the NHS (€134m) as well as an estimated saving from discounts that accrue to pharmacists.

The LSE study covered the period 1997-2002 and was based on the selection of six product categories that covered 21% of the brand market. Amongst other objectives the study aimed at studying price convergence between countries. The between-country comparison of prices required that information for the same products were collected in all countries. This method is less suitable, however, for estimating savings and requires careful interpretation of the results. The study used the same products in all selected countries, but some products were not subject to parallel import in all countries and not during the entire period. The savings were estimated for 2002 for 19 products only. The estimated savings for Denmark were based on 14 products, as there were no parallel imports in the Danish market in 2002 for 5 of the 19 products. Furthermore, the

market penetration of parallel imports of the selected products was relatively low, with two-thirds of the products having less than 20% PI market shares.

Direct savings were estimated using the intra-country price spread in pharmacy purchase price (originator price – parallel import price) and the quantity sold, assuming inelastic demand and using a hypothetical average price for parallel imports (which does not give an accurate picture of the savings to the end-users and end-payers). The savings realised should also include the pharmacy profit margins and VAT. It is thus not surprising that the LSE study resulted in a low estimate of €45 million for the direct savings in the 6 countries. If the selected brand drugs, covering 21% of the market, were representative for the rest of the market in terms of the extent and price of parallel importing, then for the total market a rough estimate for the direct savings in pharmacy purchase price terms would be five times the €45 million, or €225 million. This is still considerably lower than the York study estimate, however. The difference appears to be mainly due to the results for Germany, Sweden and the UK.

In the case of Germany the selected products only accounted for 13% of the national brand prescription drug market and none of the products were on the 2002 top ten list of German parallel distribution products in terms of savings. This would suggest a serious underestimation of the savings in the German market. If the selected drugs were representative of the rest of the market in terms of the extent and price of parallel importing, then a rough estimate for the direct savings would have a magnitude of €130 million.

For Sweden, only three of the drugs included in the LSE study were on the top ten list of parallel drugs in terms of savings for 2001 and although the list changes from year to year the variations are not of such magnitude. In 2001, those three drugs accounted for 12.5% of total savings (corresponding to 46 million SEK or approximately €5 million), when using the most accurate calculation method.

For the UK the presented estimate disregards the clawback collected by the NHS to recoup the savings from discounts given by wholesalers and manufacturers to the retail sector. The authors report the total clawback related to parallel trade to amount to €144 million and estimate that one-third of this amount is associated with the selected products.

The methodology applied in the York study in regard to estimating savings is the more accurate and comprehensive of the two. Similar estimation principles have been attempted in a Finnish study (18), but at that time Finland had only had parallel importing for a relatively short time.

Persson et al. (19) attempted to assess the economic consequences for health care expenditure of the introduction of parallel trade in Sweden. The study estimated the direct and indirect savings for seven products, five of which represented drugs with major PI market shares and accounting for 46% of the sales in the market, and two of which had relatively low sales.

The savings were estimated based on the following assumptions:

- Prices without parallel importing would have remained constant over time;
- All price reductions occurring at the introduction of parallel trade and in the time after are assumed to be an effect of increased competition;
- Percentage price reductions for a specific package size can be generalised to all package sizes
- There is a -0.2 price elasticity, i.e. a price reduction of 10% will increase the quantity consumed by 2%.

Direct savings were calculated using the difference between the pre-PI originator price and the PI price multiplied by the quantity of parallel imports sold and adjusted for increased consumption due to the price elasticity. Indirect savings were calculated using the difference between the pre-PI and the post-PI originator price multiplied by the quantity of originator products sold and adjusted for increased consumption due to the price elasticity. This approach underestimates the savings when the originator price is following an upward trend and overestimates the savings when the originator price is following a downward trend.

Using this approach the authors estimated direct savings of around 110 mill SEK (2000) and indirect savings of about the same magnitude, in total 218 million SEK. These savings were primarily due to the five high-selling products. The estimated savings for the two low-selling products were very small and were estimated to be outweighed by the increasing pharmacy costs of handling more drugs.

Taking into account the differences in methodologies and adjusting for the fact that the LSE study due to its other objectives was based on a sample of varying representativeness in the countries studied, it appears that the study results are much less different than might be perceived just by looking at the total estimates presented. The estimates from the York study are probably the most appropriate.

Table II.1. Summary results of selected studies.					
	Year (data)	Country	Direct savings	Indirect savings/price effect	Comment
York study (3)	2002	UK Germany Sweden Netherlands Denmark Total	342 194 47 32 16 **635** million €	Limited price effect. Decreasing price for on-patent drugs with competition. Increasing price for on-patent drugs without competition.	Top-selling products + random sample of 150 products.
LSE study (2)	2002 (1997-2002)	UK Germany Sweden Netherlands Denmark Norway Total	6.9 17.7 3.8 12.8 3.0 0.6 **44.8** million €	No price effects.	6 product categories, 19 products covering 21% of brand market.
Persson et al. (19)	1998-2000	Sweden	110 million SEK (13 million €)	108 million SEK (13 million €)	6 selected products with 2-3 sub-categories. Additional pharmacy costs estimated to be 2% -133% of realised savings.
Riksförsäkrings-verket (20)	1999	Sweden	40-50 million SEK (5 million €) + pharmacy price margin	n.a.	Estimates based on pharmacy purchase price, so this should be added.
Ganslandt & Maskus (9)	1994-99	Sweden	n.a.	Significant price effects. Price reduction of 4% for goods subject to competition by PI. Taking market contestability into account: originator prices cut up to 19%.	50 highest selling products in 164 forms. For a subset also detailed prices for exporting countries.
Linnosmaa et al. (18)	2001	Finland	4.9 million € (incl. indirect savings)	No price effects found	Assumes that all price changes after PI started are caused by PI.

2.4.2.   Distribution of savings

Both the LSE study and the York study analysed the distribution of the savings. The LSE study raised the question about increased access to medicine and reduced prices to consumers and concluded that 'It does not directly transpire that parallel trade enhances patients' access to medicine or reduces price to consumers'. It is, however, not clear in what terms patient access is measured. The focus on reduced prices paid directly by consumers also appears slightly out of context. In health care systems that provide comprehensive cover with low cost-sharing requirements, cost sharing is primarily functioning as a measure to reduce moral hazard.

The two reports have different conclusions on the distribution of benefits. For Denmark for example, the York study reported a 60/40 government to patient split of savings, while the LSE report reported a 100/0 government to patient split of savings. It is not clear how the latter arrive at this split. In Denmark there is substantial co-payment of drugs. Furthermore, it must be assumed that even if savings primarily fall on the government or insurer side, it will be of benefit to the patient if greater value for money can be achieved.

2.4.3.   Competitive effects

The competitive effects of parallel trade have been analysed in both the York and LSE studies, but also in a few other studies.

The York study used time series data where such were available, i.e. for Denmark, Germany and Sweden. The method of analysis included visual inspection as well as statistical analysis to isolate competition effects by studying average price changes and price variance over time with and without parallel importing. The inspection of the time plots suggests limited price competition. For on-patent drugs without competition prices have increased over the period 1997-2002, while for on-patent drugs with parallel imports in the market prices have decreased.

Similar to the York study, the LSE study used time series data for a five-year period. The method of analysis included graphic inspection. Furthermore, in order to test competitive price effects the study tested the null hypothesis of co-movement of prices, i.e. equal price changes over time, against a hypothesis of no co-movement. The hypothesis that the mean change in price is the same was tested for each of the 19 products using a t-test with unequal variance. Based on the acceptance of the null hypothesis it was concluded that there are very limited competitive effects. However, it appears to be a very small sample of products from which to generalise.

Acceptance that there is co-movement of prices of originator and parallel-imported products does not necessarily imply that there is no price effect. In fact, if competition works one would expect to see co-movement in prices. If either the originator price or the PI price is reduced in order to increase the market share, other manufacturers will follow immediately to preserve their market share. Of course, co-movement in prices may also reflect lack of competition as one stakeholder with monopoly power can dominate the market and constrain market supplies.

The LSE study found the small average price spread to be a problem. But if the PI share is low because the supply of parallel imports is low, then the parallel importer would have an incentive to set prices high as increased demand could not be translated into sales. On the other hand a small price spread could also reflect that competition is working.

In line with the two studies described above, a Finnish study did not find any evidence of price competition. Linnosmaa et al. (18) estimated the short-term and medium-term competitive price effect of the introduction of parallel trade and the direct and indirect savings. The study included sales data for the period 1998 to 2001 for 169 pharmaceutical products, although not all of the products were on the market for the entire period. The study concluded that there was no statistically significant relationship between the originator prices and the parallel import price. The study was undertaken at the very early beginning of the parallel import in Finland, however.

Contrary to the other studies mentioned, a recent study of the Swedish experience 1994-1999 (9) was specifically aimed at analysing the potential for parallel trade to generate significant price competition in high-price countries. It was based on a dataset including quantity and price of the 50 highest selling products in 164 forms during a period in which there was considerable growth in parallel imports. The initial findings included a 4% decrease in prices in the import market relative to products not subject to parallel import. However, panel data regression with endogenous entry into the market suggested that originator prices were cut by up to 19% due to the introduction of parallel trade.

2.4.4. Long-term effects on research & development and access to medicine

Some studies have attempted to assess the effect of regulation on research and development and access to medicine. Such regulation includes regulation of parallel trade. However, no study has focused on the possible effects of PI on research and development. The empirical evidence is thus at best circumstantial, i.e. the effects of relative price differences on new drug launches. This is partly due to inherent differences in time span: PI has particularly increased in the new millennium, whilst any effects on research and development will only show up after a considerable time lag. The effects of PI on profits in the research-based pharmaceutical industry may not necessarily translate into cuts in research and development, but might equally likely affect other cost areas, e.g. marketing or administration.

One study covering 25 countries and 85 new chemical entities launched over the period 1994-98 analysed the effect of pharmaceutical price regulation on delays in new drug launches (21). Low price in one market may spill over to others through parallel trade and price referencing. Manufacturers may thus prefer longer delay or non-launch rather than accepting a low price. The hypotheses were, therefore, that in markets that can be separated, differential pricing will be used and new drugs launched promptly, while in non-separable markets prices will converge and delays in the launch of new products will occur in low-price countries. The data analysis suggested that within the EU, the likely parallel-exporting countries in Southern Europe have fewer launches of new chemical entities and a longer average delay in the launch of new products. Furthermore, launch delay appeared to decrease with increased market size and expected price. When

controlling for national income the effects were smaller but still significant. These results are, however, merely indicative and do not address the issue of the effects of parallel importing on research and development.

The most appropriate statement about empirical evidence of the effect of PI on research and development would seem to be that there is no convincing evidence available.

2.5. Conclusion

The methodology applied in the York study for estimating direct savings on drug expenditures is the most appropriate. Generally, there is little disagreement about the relevant principles for calculating the benefits, but the difference seems to lie in the selection of products for analysis.

Taking into account the differences in methodologies between the empirical studies (and specifically adjusting for the fact that the LSE study due to its other objectives was based on a sample of varying representativeness in the countries studied), it appears that the savings estimates would be much less different between the two studies than may appear at first glance.

None of the two larger studies have attempted to quantify indirect savings. The Swedish study that did so used a crude assumption that did not take into account price trends, but rather the static prices. With regard to competitive price effects the study by Ganslandt & Maskus 2004 (9) was specifically aimed at testing the effects of entry of parallel imports into a market and found that there were significant reductions in originator prices associated with the introduction of parallel imports in the Swedish market.

3. What benefits? Assessment of savings associated with parallel imports

3.1. Introduction

Economic theory suggests that the short-term effects of allowing parallel trade of drugs would stimulate direct savings to purchasers of pharmaceuticals in importing countries as parallel imports would be sold at a lower price than the originator price. As outlined in the preceding section, economic theory is less clear as to what extent any competitive pressure will be sufficient to result in lower originator prices, especially if the parallel traders experience supply restrictions and the market is characterised by one large manufacturer and one or a few parallel importers.

The empirical literature is limited to a few studies, as described in the previous section. There is some disagreement about the magnitude of the savings as well as about the existence of price competition.

The focus of this section of the report is on the short-term effects of PI in four countries in which PI is of significance and where previous data are available for comparison. The purpose of this section is to provide an estimate for the direct savings and to analyse the likely contribution to savings from competitive effects – the so-called indirect savings.

3.2. Material and methods

3.2.1. Material

Four countries with relatively large and mature markets for parallel importing of drugs, i.e. Denmark, Germany, Sweden and the United Kingdom, were included in the study. The time frame for the estimation of direct savings was 2004. For indirect savings, a five-year time frame (2000-2004) was used for the time series analysis of prices and competitive parameters. For each country the time series dataset included information on the 50 products that were the highest selling products in 2004.

The variables included for each specific product were quarterly prices of domestically produced or directly imported drugs and prices of parallel imports for the same products. Pharmaceutical retail prices were used. This is the most appropriate price variable for comparison of savings as it represents all the price elements included at the point of consumption by the end-user (however financed), including distribution costs and taxation.

The competitive parameters included the number of suppliers in the therapeutic market (therapeutic competition[2]), the number of suppliers of the same product (generic competition) and the market share of parallel imports. Time lines for each product, including time for application for import permission, time of import permission granted and time for start of parallel importing, could unfortunately not be established. Such information would have been useful in developing indicators for changes in the contestability of a product market and could have been used to analyse price effects (as

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[2] The number of drugs in the ATC5 category was used as an indicator for therapeutic competition. Therapeutic competition refers to compounds that are chemically distinct but are used to treat the same indication.

an entry deterrence measure) before parallel importing started or even when it did not materialise in the case of successful deterrence of entry or for other reasons. Background information on the regulatory environment in terms of price regulation, payment mechanisms, substitution policies and incentives was also provided.

Data material for savings estimates, price trends and competitive parameters were supplied by members of the European Association of Euro-Pharmaceutical Companies (EAEPC), through country representatives in the four countries, based on a questionnaire that specified the generic data requirement and methodology. With regard to the price time series the questionnaire further specified how to select the 50 products for which information should be provided. For some countries it was not feasible to supply all data over the preceding five years. Further details on the data provided from each country are provided below in the country-specific sections. It should be noted that the national associations of parallel importers do not always include all local parallel importers; as the data are based only on submissions from members there may thus not be complete coverage of the market. Membership coverage is lowest in the UK, while Germany is covered by two organisations. As information on direct savings is based on IMS or IMS-equivalent data for the full market, however, these differences will not affect the savings estimates. As for the supply of price series information for selected drugs there is no reason to believe that it will produce any significant bias in the data.

Given that EAEPC members could have an interest in the outcome of the savings estimates there is a risk that the data could be biased. An attempt has been made to overcome such potential bias by specifying the analytic method, the data to be supplied and the selection criteria for products, where samples were needed[3]. Furthermore, the data from Denmark and Sweden have been certified by an auditor and some cross-checking with official sources of information has been undertaken, e.g. in collaboration with the Danish Medicine Agency.

3.2.2. Methods

For Denmark, Germany and Sweden the <u>direct savings</u> were calculated by multiplying the quantities of parallel-imported products sold by the retail price difference between domestic/directly imported products and parallel imports of the same products. This straightforward procedure was based on an implicit assumption that there is no quantity effect of the reduction in prices, i.e. the consumption of a drug does not increase as cheaper PI products become available. This seems to be a reasonable assumption as price is not likely to be a main determinant for either prescription or consumption. Prescribers are not involved in the selling of drugs and consumers of prescription drugs at most pay a modest co-payment (most of the payment is through a third party). Any bias that would arise from this omission would tend to be an overestimation of direct savings. Furthermore, it was assumed that the cheapest product is made available to consumers – otherwise savings will not materialise; as the estimates were based on actual quantities sold this does not in practice constitute a problem.

The above method could not be applied to the UK market because the pharmacies in that market are reimbursed the same amount for the same products irrespective of whether they are direct or parallel imports. Savings are instead realised through a

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[3] In the interest of transparency, researchers who are interested in analysis of the data are invited to access the data upon request.

clawback system, in which the NHS retains a percentage corresponding to the estimated savings (see the section on the UK for more details). In the current study, savings were estimated on the basis of total sales and the realised clawback percentage for 2004.

<u>Indirect savings</u> may arise either because competition results in price decreases (or reduces the price increases below the level expected without competition) or because the potential competition leads to limit pricing (where the manufacturer chooses to reduce the domestic price to a level at which it is less profitable for parallel importers to enter the market).

In principle, indirect savings are calculated from the quantity sold of the original product multiplied by the price differential between the original manufacturers' product as it would have developed in the absence of competition from parallel imports and the actual development after introduction of parallel imports in the market. It is not known, however, how prices would have developed in the absence of parallel imports.

Two methods were used to assess the competitiveness of the market and hence the existence of indirect savings. One method analysed the price series for the 50 products mentioned above taking into account the development in prices over time, while the other method produced an estimate for the full market using specific assumptions about the development of the originator price with and without competition from PI. This second type of analysis was only carried out for Denmark and Sweden, however.

The first analytical method was applied for all four countries and was based on the price series for *50 products*, which obviously only represent part of the PI market, albeit a significant part. Based on the time series data, regression analyses for individual products were undertaken using the following very basic model to test whether the entry of parallel imports to the market affected the originator price:

$$P_o = \alpha_0 + \alpha_1 * \text{time} + \alpha_2 * \text{entry} + \alpha_3 * \text{time} * \text{entry}$$

where P_o is the price of the originator product and entry refers to entry of the PI product into the market. It was not possible to estimate price equations for all the products, however, due to some products having short time series, and no or very limited price changes for some products.

Panel data analysis was applied for each of the included products within a country. For this purpose the price series were normalised to 100 in the base year. The set of potential explanatory variables included market size, number of competitors, entry of parallel imports in the market, and price changes on parallel imports. A time trend variable was included to capture any remaining price trend. The key explanatory variables showed little variation over time, however, and thus fixed effects estimation or first differencing would produce less robust estimators. Consequently, a random effects model was used. All regressions were estimated using the statistical software STATA. This procedure does not lead to an estimate of specific amounts of indirect savings, but can only detect the presence of a competitive effect of PI.

The second analytical method estimated the amount of indirect savings for Denmark and Sweden for the *full market*. The basic idea is illustrated in Figure III.1 using a specific product as the point of departure. For the Danish data the Average European Price (AEP) was used as an indicator of the price level that would likely have emerged had there been no parallel import. For the Swedish data the originator price at the date of first PI entry was used as this corresponded to the maximum approved price from the Swedish Medicines Board for the original product at that time. The calculations were made using fortnightly (Denmark) or monthly (Sweden) data and the figures have been verified by an auditor. In both systems drugs would have been reimbursed up to these maximum price levels. Any difference between the originator price and the maximum reimbursable price was assumed to be due to the competitiveness of the markets in which parallel importers operate. The rationale behind this is that the originator products in the absence of competition from PI can be reimbursed up to the maximum price and any deviation from this maximum in markets with PI competition can therefore be attributed to competitive effects from PI.
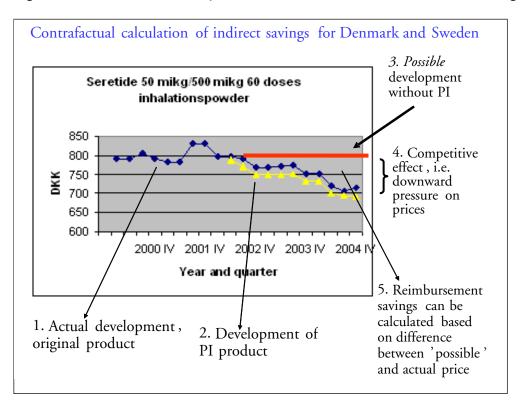
Figure III.1 Illustration of analytical method 2 for calculation of indirect savings

The advantage of this analytical approach is that it includes *almost the full market* for PI. The calculations are made for products for which PI exist and where generics do not exist. As PI and generics sometimes coexist this might lead to a slight underestimation of the quantities. Such coexistence is mostly of short duration, however, as parallel importing tends to be less profitable once the patent expires and generics enter the market, putting the parallel import under the same competitive pressure as the originator product. At the same time the effect of contestability on products for which PI does not (yet) exist, may lead to further underestimation. A further limitation in the

case of Denmark is that the AEP was not available for all products, which would also result in a downward bias in the savings estimates.

The assumption that any decrease in originator price compared to AEP or originator price at the time of PI entry is caused by PI competition may on the other hand lead to an overestimation of savings. There could be other reasons for changes in prices and especially in relation to the Swedish estimates, where some time could have elapsed since the first entry of PI (and thus since the reference price date), thus increasing the uncertainty of the estimate. Furthermore, it could be argued that a rule of symmetry should apply such that any change in price would be attributed to the change in competition. In principle, the entry of parallel imports into the market with more or less full penetration of the price-sensitive market segment could result in an originator pricing strategy of increasing the price for any price-insensitive market segment in order to recoup profits lost on the price-sensitive market segment. In practice, this may not happen so often. If there are other reasons for price decreases, for example that the originator price is already following a downward trend due to other factors, the indirect savings will be overestimated using this method. Overall, this analytical approach probably provides a reasonable estimate of the indirect savings, but also most likely a maximum estimate. The risk of overestimation is likely to be larger for Sweden than for Denmark.

Currency conversions have been made using average annual exchange rates reported by the Central Banks in the four countries.

3.3. Denmark

3.3.1. Brief description of the market

The first approval for parallel import of a drug was given in 1990 and since then marketing permission has been granted for 6-8,000 products in Denmark. Over the period 1998-2004 the share of the total drug expenditure spent on parallel-imported products has remained more or less constant at slightly above 12% of the total sales of prescription and non-prescription drugs in the primary health care sector. The expenditure on parallel-imported medicine in the hospital sector amounts to only 2% of the total expenditure on drugs in the hospital sector (22).

Price regulation
There is free pricing for both reimbursable and non-reimbursable products. However, in practice a reference pricing system has been in place. The Danish Association of the Pharmaceutical Industry (Lif) had originally guaranteed that for the period of one year (from 25th June 2001) the pharmacy purchase price would not exceed the average European price (AEP). The AEP is the average of the prices in 11 EU states (Austria, Belgium, Finland, France, Germany, Ireland, Italy, the Netherlands, Norway, Sweden and the UK), plus Iceland, Norway and Liechtenstein. The guarantee was originally made in return for corresponding amendments to the basket of countries used to calculate the AEP for reimbursement purposes, and was subsequently extended for a further year and then two more years – up to 25th June 2005. The pricing system has, however, changed from the 1st April 2005. There are no controls on over-the-counter (OTC) prices.

Before 1st April 2005 the system operated as follows:
- Products with no generic or parallel-import competition were reimbursed up to the lower of the Danish price and the AEP.
- Multi-source products (generic and parallel-import competition) had their reimbursement capped at either the price of the cheapest product in the group (if the group consists only of products with Danish prices) or the lowest European price in the group (if a European comparator price exists). A substitution scheme was, and still is, also in place if the price difference is significant.

Pharmaceutical companies are obliged to inform the Danish Medicines Agency of the pharmacy purchase prices (excluding VAT) for the individual product in the reference countries every six months. The lowest Danish price is taken from the Medicine Agency's fortnightly Price List.

Payment mechanism
The Danish Medicines Agency (DMA) takes decisions concerning reimbursement status on the basis of advice from its Reimbursement Committee. General reimbursement is granted for products 'with a certain and valuable therapeutic effect when used for a well-defined indication'. Furthermore, the price of the product must be 'proportionate to the effect compared to other reimbursable drugs'. In order to justify a high price, the company can voluntarily submit a pharmacoeconomic evaluation. Nevertheless, in 2003, 4 out of 6 refusals for reimbursement were made because of the drug's high price (7 out of 12 in 2002). When general reimbursement is granted for a product the Medicines Agency includes it on the positive list.

Reimbursement on a named patient basis is possible upon individual applications.

All reimbursable medicinal products have equal status from the point of view of reimbursement. The reimbursement rate depends on the patient's prior consumption of reimbursed pharmaceuticals within a period of one year from the date of first purchase.

Substitution policy and incentives
There is a substitution policy for doctors' prescriptions. There is no obligation for doctors to prescribe an active ingredient, but there is an obligation not to put 'no substitution' on the prescription, unless there are strong reasons to do so. It is then up to the pharmacies to substitute the cheapest product. In recent years, doctors have experienced considerable pressure from the Public Health Insurance to prescribe cost-effective drugs. The Institute for Rational Pharmacotherapy has developed a national list of recommendations that doctors are expected to follow. Furthermore, most counties also have a list of recommendations for drug prescription that the doctors are supposed to follow.

In the context of fixed price differences, pharmacies have to inform patients about low-cost alternatives. It is mandatory for pharmacists to dispense cheaper parallel imports or

generics if savings reach a certain level[4] and unless substitution is blocked by the prescribing doctor or not accepted by the patient.

The Danish Medicine Agency must be notified about the pharmacy purchase price and companies may change their prices every fortnight when the Agency publishes its Price List of Proprietary Medicinal Products. This information gives pharmacists the opportunity to compare the retail prices of products and offer the cheapest of the products to patients.

3.3.2.   Material and methods

The direct savings were calculated by the PFL (Parallelimportør Foreningen af Lægemidler - the Danish Association of Parallel Importers of Drugs) using the methodology outlined above: a simple multiplication of the quantity sold and the price differential based on fortnightly data. The figures used were verified by an auditing company, which should provide some confidence that the results are unbiased. All PI products in the market as of 1st May 2004 or entering the market during 2004 were included. The prices used were pharmacy sales prices.

The dynamic savings or indirect savings caused by reductions in originator product price were estimated by PFL using the assumption that the difference between the European pharmacy sales price and the Danish pharmacy sales price was due to PI competition. The calculations were made for products for which PI exist and where generics do not exist, i.e. largely for patented products.

3.3.3.   Direct savings due to PI

The direct savings were estimated to be 106 million DKK in 2004. This corresponds to €14.2 million using the average DKK to EUR exchange rate for 2004. The calculations were based on pharmacy sales price to be paid directly out-of-pocket by patients and/or by the health insurance scheme. These savings are thus the total savings for users/insurance. The direct savings amounted to 7.4% of the value of total PI sales in 2004. Compared to the total sales of medicine for primary health care the direct savings amounted to almost 1%[5].

Compared to 2001, when savings amounted to 121 million DKK (€16.2 million), there has been a decrease of 12% in nominal savings. A definitive explanation is not easy to provide. The decrease in savings could be due to narrowing of the price differential either by increased prices on parallel imports or reduced prices on domestically manufactured/directly imported drugs. The latter could imply that the increased competition from parallel imports has resulted in a downward pressure on prices, thus

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[4] The levels that should result in substitution are 5 DKK (€0.7) price difference for prices less that 100 DKK (€13); 5% for prices between 100 and 400 DKK (€13 to €54); 20 DKK (€2.7) for prices above 400 DKK (€54). Conversion to €based on 2004 annual average exchange rate.

[5] Total sales available from
www.laegemiddelstyrelsen.dk/db/filarkiv/5047/salg_laegemidler2000-2004.pdf

resulting in unquantified indirect savings. Alternatively (or simultaneously), the decrease in direct savings could be caused by a decrease in the quantity of parallel-imported drugs sold. Thus, it could reflect the effects of supply restrictions on the part of the manufacturers, which would result in decreased volumes available for parallel importing – in which case similar development would be expected in other markets. It could, however, also reflect a convergence of prices resulting in a decreased price differential.

Of the direct savings in 2004, 70% were accounted for by the top 10 products sold and 60% by the top 5 products. The highest selling product accounted for one-third of savings and the three top-selling products accounted for more than 50% of the savings. This picture is similar to the situation in 2001. The strategy applied by parallel importers thus appears to remain focused on a few products. The two top-selling products that accounted for more than 40% of the direct savings were the same in both years, but the other products on the top ten list differed, probably reflecting a shift towards products where the price differentials and thus potential gains were larger. Other explanations could be that for some products the patent period had expired, thus increasing the competition from generics and squeezing the profitability of the parallel import. Despite the focus on drugs where arbitrage is profitable, the large parallel importers tend to have a broader portfolio of drugs in order to be able to supply the market and to be considered a reliable source of drugs.

3.3.4. Indirect savings due to PI

Using analytical method 2, the estimated indirect savings in 2004 amounted to 62 million DKK (€8.3 million), which corresponds to an additional saving of 58% of the direct savings.

As PI and generics sometimes coexist, the exclusion from the calculations of products in markets with generics might lead to a slight underestimation of the quantities. Such coexistence is, however, mostly of short duration as parallel importing tends to be less profitable once the patent expires and generics enter the market, putting the parallel import under the same competitive pressure as the originator product. At the same time the effect of contestability on products, for which PI does not (yet) exist may lead to further underestimation. Finally, the AEP has not been available for all products and the omission of such products from the analysis may further bias the estimate downwards. On the other hand, the assumption that any price difference is caused by PI competition may be an overestimation.

But has the existence of parallel imports had an impact on pharmacy prices? Is there a competitive price effect? These questions are investigated using analytical method 1 (the statistical approach).

Danish time series data were available for originator products for the full period and for parallel imports as they entered the market. It was thus possible to compare the time trends in originator prices before the parallel imports entered the market with the price trends after parallel imports had entered the market. The basic question was whether the entry of a parallel importer into the market changed the price development of the originator product, either in terms of a decrease in the price or a reduced price growth. The price development prior to market entry was used to estimate and forecast the likely

price development for the time after entry of the parallel import into the market. Sensitivity of the price to the time immediately preceding the entry of parallel imports into the market was also tested, although this would only be an indicator of unsuccessful entry deterrence for those markets where parallel imports occurred despite price decreases.

For 10 of the 50 products the model yielded statistically significant results, cf. Table III.1. It appears that except for products 39 and 46 the entry of the parallel-imported product into the market reduced the average price increase for originator products over time, while for products 30 and 50 the average price reduction in originator price increased over time.

Table III.1. Results of individual regressions for 10 products, Denmark

Product	3	9	13	17	28
Basic model					
Time	3.15	1.16	3.46	38.00	2.27
Entry	100	55	73	338	28
Time*change	-11.0	-5.3	-6.8	-51.3	-5.07
Constant	783	770	665	3519	544

Product	30	39	44	46	50
Basic model					
Time	-1	-71	5.6	-17.8	-4
Entry	77	-329	154	-125	155
Time*change	-4.4	67.0	-14.8	18.9	-5.8
Constant	370	1573	702	684	1397

Note: For all coefficients $p < 0.05$. For all models Prob > F is less than 0.05.

Product key: 3=Seretide 50 µg/500 µg 60 doses inhalation powder
9=Cozaar Comp. 50 + 12.5 mg 98 tablets
13=Zyprexa 5 mg 28 tablets
17=Aricept 10 mg 98 tablets
28=Seretide 50 µg/500 µg 60 doses inhalation powder
30=Insulatard FlexPen 100 IU/ml 15 ml inj., suspension
39=Casodex 150 mg 30 tablets
44=Berodual 100 + 40 µg/caps 100 inh. powder in capsules
46=Meronem 1000 mg 10 vial inj. substance
50=Meronem 1000 mg 10 vial inj. substance

The price trends for two of the products are illustrated in Figure III.2 below. Price trends for all products can be found in Annex 1.
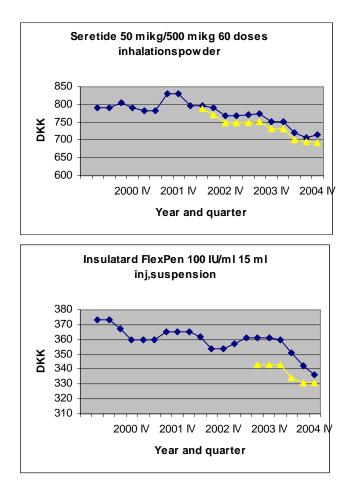
Figure III.2. The observed price trends for two products 2000-2004, Denmark

Finally, a panel data regression was undertaken. The panel data regression of price index for originator product (Po), on parallel import price (Pi), number of suppliers (n), a dummy variable for entry of parallel imports (E) and time (t) in quarters showed that

$$: Po = 78 + 0.1\ Pi + 1.9\ n + 1.3\ t + 4.3\ E - 1.4\ t * E$$

This indicates than on average for the 50 products there would be an increase in the originator price of a factor of 1.3 per quarter as long as there was no parallel import in the market. After entry of a parallel import there would be a small decrease in the quarterly originator price, suggesting that entry of parallel imports would decrease the time-dependent growth in originator prices by a factor of 1.4. Even if prices may not decrease, it appears that on average prices would have grown more had there been no entry of parallel imports. This suggests that there might be a competitive effect when the parallel-import products enter the market.

3.3.5. Summary

The estimated direct savings in 2004 due to PI in Denmark amounted to 106 million DKK (€14.2 million).

The indirect savings using analytical method 2 were estimated to be 62 million DKK based on the earlier mentioned assumptions, mainly that originator price would have been set at the Average European Price had there been no PI competition.

Using analytical method 1 it was shown statistically that competitive effects are likely in terms of an average reduction in the growth of originator prices following entry of PI. At the individual product level significant changes in price trends after entry of PI product could only be observed for 10 out of 50 products, but the analysis of the combined cross-section and time-series data showed that, on average, there was a downward shift in the price trend.

Under the Danish regulatory structure the estimated savings will benefit the consumers directly through lower co-payment as well as indirectly through savings to the Public Health Insurance scheme.

3.4. Sweden

3.4.1. Brief description of the market

When Sweden became an EU member in 1995 parallel importing of drugs from other EU countries became an option and the first parallel-imported drug was available on the market in 1997. Parallel trade increased rapidly in Sweden. The market share of 1.9% in 1997 had increased to 6.1% in 1998. By 2000 the market share was 8.6% and reached 10.4% in 2004. The market share has been volatile within this range for the period 2000-2004 (23).

Price regulation
Both original manufacturers and PI can set prices freely, but in order for patients' costs to be reimbursed, the prices have to be accepted by the third party payer. Until 2003, the Swedish National Social Insurance Board had to accept the prices set. The Pharmaceutical Benefits Board (LFN) that was established in 2002 determines whether the drug will be subsidised. In 2002 a new act of pharmaceutical benefit came into effect. Drugs for which a sales price had been established were no longer automatically reimbursed. Following negotiations with the manufacturer the LFN also determines what a reasonable price for the drug is.

Payment mechanism
For most medicines on prescription the patient does not have to pay a total of more than SEK 1800 (€197) per year. Within these SEK 1800 there are four discount steps. Up to SEK 900 (€98) the patient pays 100% of the actual cost. Between SEK 900 and 1300 (€142) there is a 50% discount, between SEK 1300 and 1700 (€186) the discount rate is 75%, and between SEK 1700 and 1800 it is 90%. Consequently, when the patient pays SEK 1800, the actual cost of the medicines is SEK 4300 (€471). All savings accrue to the state via the county councils.

Substitution policy and incentives
For several years state-owned pharmacy monopoly has been instructed to dispense the lowest priced equivalent product when possible. As of October 2002 the law mandates generic substitution, i.e. pharmacists are mandated to dispense the cheapest generic drug. The pharmacist should substitute the drug prescribed by the doctor with the cheapest product available with the same active ingredient. If the doctor thinks substitution could be harmful to the patient, he/she has the possibility to disallow substitution on the prescription. This was followed up in the spring of 2003 by mandatory stock-keeping of the cheapest alternative drug. At the same time the reference price system introduced in 1993 was abolished (24).

Drug budgets were decentralised in 1998 and counties have developed their own models. By 2002 only three county councils had implemented decentralised responsibility for prescription expenditures, although the long-term plan in most county councils are to integrate expenditure on prescription drugs with the existing budget responsibility for other health care inputs (24).

3.4.2.   Material and methods

The direct savings were calculated by the FPL (Föreningen för Parallelldistributörer av läkemedel – the Swedish Association for Parallel Importers of Drugs) using the standard methodology outlined in section 2.2, i.e. a simple multiplication of the quantity sold and the price differential based on monthly data for 2004. The prices used were pharmacy sales prices. Figures were verified by an auditing company.

FPL provided an estimation of the dynamic savings as a result of price competition. The same method was used for the Danish estimations (see section 3.3), except that the estimate for expected originator price in the absence of PI was the originator price at the time of PI entry into the market (retrospective). The calculations were made on monthly data and these figures were also verified by an auditing company.

The price dataset for Sweden was generated from a variety of sources due to difficulties with the data structure in the FPL database. The price series comprised pharmacy purchasing prices (AIP) rather than pharmacy retail prices. This is not expected to make any significant difference when looking at price series trends, however. The use of different data sources meant that some indicators for competition were not available for all products and the exact number of suppliers was slightly uncertain as exit from the market was not recorded.

3.4.3.   Direct savings due to PI

The direct savings were estimated to be 414 million SEK in 2004, corresponding to €45.3 million. This represents a 12% increase in nominal savings compared to 2001 when direct savings amounted to an estimated 370 million SEK (€40.0 million). For 2004, the estimated direct savings amounted to 15% of the total PI sales or 1.4% of the total sales of pharmaceuticals for human consumption (25).

Of the direct savings in 2004, 64% were accounted for by the top 10 products sold, and 48% by the top 5 products. The three highest top-selling products accounted for almost 40% of savings. This picture is similar to the situation in 2001, although there may be a slight tendency to reduced concentration in the market. The strategy applied by parallel importers appears to have remained focused on a few main products. The top-selling product is the same in the two years, but in total only 4 of the products on the top-selling list in 2004 were also on the list in 2001. As in the case of Denmark, this probably reflects a shift towards products where the price differentials and thus potential gains are larger, underlining the arbitrage nature of parallel trade.

3.4.4.   Indirect savings due to PI

The estimated indirect savings amounted to 150 million SEK (€16.4 million), corresponding to 36% of the estimated direct savings. This reflects a smaller impact on prices of originator products by parallel trade as compared to Denmark. The Swedish pharmacies are organised as state enterprises and the pharmacy price margin is relatively low, which would result in lower indirect savings for the same pharmacy purchase price differences between originator and PI products than in the other countries.

The pharmacy purchase prices for direct imports in the Swedish dataset for the 50 highest-selling products have the peculiarity of being almost constant for all 50 products throughout the period 2000-2004. While the price for parallel-imported drugs has varied, only 12 of the 50 products have changed price over this time and of these only 7 have changed prices during the period in which parallel imports have existed in the market. This limits the meaningfulness of a regression analysis. The price series for the seven products are illustrated in Figure III.3.

Figure III.3. Seven products for which Swedish domestic prices have changed over the past four years

Prices of direct and parallel imports for same products
Product 44

Prices of direct and parallel imports for same products
Product 46

Prices of direct and parallel imports for same products
Product 50

PRODUCT KEY
Description
Sinemet Depot MSD, 100 tabs
Zoloft PFZ, Filmdr. tabl. 100 mg, TRP 98 tabs
Pravachol BMS, Tabl. 20 mg, TRP 98 tabs
Selokenzoc AZN, Depot tabl. 100 mg, pack 100 tabs
Orudis AVE, Gel 2.5%, 60 g
Stilnoct SNF, Filmdr. Tabl. 10 mg, 100 tabs
Norvasc PFZ, Tabl. 10 mg, TRP 98 tabs

Visual inspection of the graphs leads to the following observations (see product key in Figure III.3):
-       For six of the seven products where the *originator price* has changed during the period 2000-2004, it has decreased (product 32 being the exception)
-       For six products, the *price difference* between originator product and parallel import has reduced over the period (except product 31)
-       For five products (24, 27, 31, 44, 50), the *price of parallel imports* has decreased over the period
-       For one product (no. 32) both the originator and the parallel import price has increased

The development in competitive pressure as represented by market shares and prices can be illustrated by a few case studies, see Box III.1. It should be remembered, however, that while there seems to be some relationship between the competitive pressure and prices in these cases, there are also a number of products for which the competitive pressure has changed, yet no price changes have resulted.

Box III.1. Summary of price trend and competitive parameters in three case studies

Case 24 (Sinemet depot MSD, Depot tablets 100 st): Over the period 2000-2002 the market share of parallel imports increased from 6% to 22%. By the end of 2002 the originator price had fallen to the same level as the parallel import price, and both fell at the same rate in early 2003. After that the parallel import price fell further and both prices were stable until the last quarter in the series. The market share of parallel imports was stable at 9-10% for 2003-4.

Case 27 (Zoloft PFZ, Tabl. Filmdr. 100 mg, TRP 98 st): Over the period 2000-1 the parallel import market share increased from 37% to 49%. By mid-2001 the originator price fell to just above the price level for parallel imports. The parallel import market share remained at 47% in 2002. By mid-2003 both prices fell (it is not known which fell first). The PI market share then fell to 24% in 2003, but was back at 47% in 2004, despite stable prices since 2003.

Case 44 (Orudis AVE, Gel 2.5%, 60 g): The parallel product entered the market at the beginning of the period at 40% of the originator price. Over the period 2000-3 the parallel import market share increased to 23%. By end-2003 the parallel import price was reduced and its market share increased to 38% in 2003. In early 2004 the originator price fell considerably, while the parallel import price continued to drop slightly. Throughout 2004 the originator price fell, while the parallel import price stabilised at a lower level. The parallel import market share in 2004 was 13%.

These results for Sweden are in some ways surprising, as two other studies (9;19) found evidence for considerable price effects, although for a different period (the 1990s). This was a period during which parallel trade started up and there was considerable growth in parallel imports. Originator price adaptation may therefore have mainly taken place at that time.

Another contributing factor to the lack of response to parallel imports in the market in terms of price adjustments could be the regulatory changes in Sweden. The required justification for price adjustments to be approved by the financing agency provides an incentive not to enter into price competition with a view to driving parallel imports out of the market. Once prices have been reduced it is likely to be difficult to find acceptable justifications for increasing them again. Price increases above the price ceiling have to be justified to LFN. Since the price ceiling is the highest price in the market, which is usually the originator price, the originator has little incentive to reduce this price.

3.4.5. Summary

The direct savings were estimated to be 414 million SEK in 2004. Using analytical method 2, the indirect savings for the entire market were estimated to be 150 million SEK (€16.4 million) based on the stated set of assumptions (mainly that in the case of no competition the expected originator price would have remained at the same level as before entry of PI into the market).

Regarding the statistical analysis of possible competitive effects it was noted that competitive price effects have been observed in the past, but there was a surprising absence of price changes on originator products in the sample of 50 products during the study period. A possible explanation may be the strict price regulation that creates a disincentive for the price leader in the market to reduce prices.

Under the Swedish regulatory system the savings will benefit patients directly through reduced payment under the co-payment limits and indirectly as and when savings on the county and state budget translate into more and better services.

3.5. Germany

3.5.1. Brief description of the market

Parallel trade has existed in Germany for several decades. Over the period 1998-2003 its market share of the total pharmacy sales increased from less than 2% to around 7% in 2002-2003. In 2004 the parallel import market share again decreased to around 5%.

Price regulation
While there is in principle free pricing of drugs in Germany, wholesalers and pharmacies are obliged to comply with maximum profit margins that are calculated based on manufacturers' sales prices. Pharmacies are allowed a price margin of 3% plus a fixed prescription fee (currently €8.10, less €2 in a mandatory discount for sickness funds). In addition, VAT is added to reach the pharmacy sales price.

The mandatory manufacturer's rebate to sickness funds was temporarily increased from 6% in 2003 to 16% only for 2004 because of the poor financial situation of the sickness funds. The mandatory rebate has, however, again been reduced to 6% for 2005.

Payment mechanisms
There is a modest co-payment of €5-10 on drugs. Co-payment is 10% of the retail price with a minimum of €5 and maximum of €10 per pack. This means that for retail prices between €50 and €100 the lower price of PI drugs or of competitive prices of originator products is reflected in a lower co-payment by the end-user. The sickness funds reimburse the pharmacists for prescription drugs and the users will thus also benefit indirectly from lower prices due to parallel imports as savings accrue to sickness funds.

Due to this payment mechanism any savings due to parallel imports will accrue mainly to the sickness funds and indirectly to users, but also to patients who buy drugs within the above-mentioned range and who buy non-prescription drugs.

Substitution policy and incentives
As doctors have a capped drug budget, there is an incentive to prescribe the cheaper drugs.

Before 2002 the pharmacies were obliged to dispense parallel-imported products if the price difference was more than 10% and parallel imports were available. Since April 2002, however, the pharmacies have been obliged through an agreement between the sickness funds and the pharmacy association to dispense a certain quota of parallel-imported drugs. This quota was initially 5.5% of sales, but was increased to 7% in January 2003. Later, however, it was reduced to 5%.

Furthermore, as of January 2004, if the price of a parallel-imported product is more than 15% cheaper than the original (for values less than €100) or if the price difference exceeds €15 (for values greater than €100), then the pharmacist is required to dispense the parallel-imported product; the sale of parallel imports should amount to at least 5% of its total turnover. At the same time the pharmacist has to ensure that the required savings through PI dispensing generates a 10% overall reduction (€15 on an expensive product can be much less than 15%). This stimulates the dispensing of parallel-imported drugs.

The pharmacists do not as such have direct financial incentives to dispense parallel-imported drugs, but are under pressure to meet the 10% savings target. Furthermore, if the sales of foreign sourced drugs do not meet the quota, the reimbursement from the sickness funds to the pharmacy is automatically reduced by such an amount necessary to generate the required 10% savings within the 5% quota fulfilment. On the other hand, a pharmacy can also develop credit (equivalent to the amount of savings that exceed the required minimum) that is transferable once from one quarter to the next.

3.5.2.   Material and methods

The direct savings were calculated by BAI (Bundesverband der Arzneimittel-Importeure e.V.) using the standard methodology outlined in section 2.2, i.e. a simple multiplication of the quantity sold and the price differential based on monthly data for

2004. The prices used were pharmacy sales prices. Data were sourced from IMS (sales data), IFA (public databank of the German Pharmacy Association) and GAmSi (public databank of the Association of German Sickness Funds).

The price dataset for Germany included quarterly prices for 14 quarters covering the period 2001 (third quarter) to end-2004. These data were provided by kohlpharma. Prices for domestic/directly imported products were available only for products which at the same time were available as parallel imports. Prices provided in German Marks prior to 31/12/2001 were converted into Euro[6]. Prices were further transformed into indexes in order to allow cross-product analysis. The time trends in prices for 50 products are presented in Annex 2.

Indicators of the level of competition included the number of competitors in the same product market as well as in the market for therapeutic substitutes[7]. It was not possible with the available data to analyse the effects of entry of parallel imports. Furthermore, market share data for parallel imports were only included in the dataset for 2003 and 2004.

3.5.3. Direct savings due to PI

Parallel imports accounted for 7% of the total turnover in the market in the first half of 2003, but only for 4.5-5.0% of turnover in the first half of 2004. A main reason for the decline is probably the reduction in the mandatory dispensing of parallel imports from 7% to 5% at the end of 2003. Furthermore, as of 1st January 2004 the parallel importers' mandatory discount to sickness funds on the ex-factory price was temporarily increased to 16% as compared to 6% earlier. This increase was limited to one year. BAI estimates that it resulted in up to a 30% decrease in turnover in 2004, as PI companies were forced to withdraw approximately 1/3 of their PI products from the market because they could not sustain the additional 10% cost increase. With the PI portfolio reduced by such an amount the pharmacies association claimed that they were unable to fulfil a 7% quota. As a consequence of this the quota was reduced to 5%.

Correspondingly, the estimated savings from pharmacy selling prices decreased from €213 million in 2003 to €145 million in 2004. This coincides with the temporary reduction in the increase in the mandatory discount to sickness funds and the reduction of the PI quota from 7% to 5% in 2004. On this basis it is not surprising that estimates for 2005 suggest that the 2004 figure for direct savings is exceptionally low. In addition there will be some direct savings to sickness funds as they reduce reimbursement of drugs dispensed in pharmacies that have not fulfilled their savings quota.

For 2004 the estimated direct savings amounted to 10.5% of the total PI sales in Germany.

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[6] The official conversion rate was used: 1 German Mark to 0.51129 Euro.

[7] Identified by the same ATC5 code.

3.5.4. Indirect savings due to PI

Price changes in domestic/directly imported products
Of the 50 products, 41 were on the market throughout the period from third quarter 2001 to fourth quarter 2004. The average growth in price of domestic products/direct imports for this period amounted to 2.1% (0.35% annually). This price development should be compared to the overall price development in the pharmaceutical market.

For 61% (i.e. 25) of the 41 products, the domestic prices decreased over the period, on average by 6.9%, corresponding to a 3.0% annual price decrease. For 18 products the price increased, on average by 15.8%, corresponding to an annual price increase of 5.4%. This price increase was in particular due to two products for which the price almost doubled over the period.

Difference in prices of domestic/directly imported products and parallel imports
At the beginning of the period the price of parallel imports on average amounted to 91% of the price of domestic products/direct imports. There was no significant difference at the end of the period, where the average PI price amounted to 90%. This is in line with an earlier finding that on average the lowest priced parallel-imported product was 10.0 % cheaper than the directly imported product in September 2002 as compared to 10.2% in September 2001 (3).

For 22 products the price difference between domestic/directly imported products and parallel imports decreased over the period, on average by 27%, and for 18 products the price difference widened, on average by 66%.

Competitive price effects
The domestic price would be expected to depend on the cost structure and general market conditions, and to some extent reflect the previous years' prices. The price is also likely to depend on the extent of competition, i.e. whether competition exists, the degree to which competitors (especially parallel importers) have penetrated the market and the aggressiveness of the parallel importers in terms of price competition.

In the case of Germany, all the products for which price series were supplied already faced competition by parallel imports. The question then is to what extent this competition was effective in putting competitive pressure on prices. Are price differences smaller for product markets in which

- There are many competitors?
- Penetration by parallel imports is high?
- Parallel importers follow an active policy?

Regression analysis was undertaken at individual product level with a view to examine the relationship between domestic price and competition parameters. A panel data regression was also undertaken using the indexed prices.

The results of the fitted panel data regression showed a positive association between change in the price of parallel imports and manufacturers' domestic price. A decrease in the price of parallel imports was associated with a decrease in the domestic price.

However, the causal relationship cannot be established as the data would need to be considerably disaggregated to identify who moves first. According to Model 1 (shown in Table III.2) there is also a negative effect on domestic prices from the increased market share of parallel imports. This would suggest that on average there is some response to increased competition. The coefficient is fairly low, however, with a market share of 10% resulting in a less than a 1% price decrease.

When no effect of these competitive measures can be found the question arises as to whether this is a reflection of parallel imports being ineffective in putting pressure on prices. Essentially, the system is not demand-driven but rather supply-driven, and this supply is in the end controlled by the manufacturers.

No direct estimation of the indirect savings was available for the German market.

Table III.2. Estimated effect of competition from parallel imports on manufacturers' prices based on a cross-section of 43 products over a period of 14 quarters

Variable	Model 1 - RE	Model 1 - FE	Model 2 - RE	Model 2 - FE
PI market share	-0.072 **	-0.067**		
Number of suppliers in market			1.345***	1.413***
Competition (>2 suppliers)	92.178***	92.882***		
Price difference in previous quarter	0.049*	0.069**		
Change in PI price since previous quarter	0.102***	0.097***	0.143***	0.137***
Time trend			-0.427***	-0.427***
Constant	11.322**	10.199**	95.021***	95.021***
Observations	554	554	554	554
Products	43	43	43	43

Notes: Hausman's test was used to test that the differences in coefficients were non-systematic; the null hypothesis was accepted. RE: Random effects estimation; FE: Fixed effects estimation.
* Associated p-values significant at 10% level
** Associated p-values significant at 5% level
*** Associated p-values significant at 1% level

3.5.5. Summary

The estimated direct savings due to PI in Germany in 2004 amounted to €145 million. This estimate is not representative, however, of the 'normal' situation as 2004 was characterised by a temporary increase in mandatory rebates resulting in withdrawal of a number of parallel-imported products. There are indications of small effects of competitive pressure by PI. It should be kept in mind, however, that the price series dataset largely represented product markets in which PI already existed and thus did not allow testing for effect of entry. No estimates were available for indirect savings.

Due to modest co-payment on drugs, any savings will mainly benefit consumers indirectly through savings realised to the sickness funds. As membership contributions are determined by the members' overall health care expenditure, savings in pharmaceutical expenditure will help to contain membership contributions at a lower level than would otherwise have been the case. Some direct patient benefit will also materialise from the reductions in absolute co-payment for prescription and non-prescription drugs.

3.6.   United Kingdom

3.6.1.   Brief description of the market

Parallel importing of pharmaceuticals has existed for decades in the United Kingdom. The UK market has the highest level of penetration of the four countries studied. In 2003 parallel imports were estimated to account for 17% of the pharmacy market sales.

Price regulation
Prices are regulated through the Pharmaceutical Price Regulation Scheme (PPRS) – an agreement between the Department of Health and the ABPI (manufacturers), for the purposes of section 33 of the 1999 Health Act. Essentially there is free pricing for new active substances, but PPRS seeks to limit the overall profit a manufacturer may make, after allowing for certain costs, especially research and development costs. Price increases on existing products must be negotiated and agreed with the government. The prices of reimbursed products are published monthly in the Drug Tariff. The PPRS is renewed every five years, most recently in January 2005.

Payment mechanism
Full reimbursement is given for drugs on the positive list, i.e. included in the Drug Tariff. There is co-payment for patients, but this is a means-tested payment. The large majority of patients do not pay any substantial co-payment.

Substitution policy and incentives
Doctors have no legal obligation to prescribe a brand or an active ingredient. In practice, doctors are 'encouraged' to write a prescription using the generic name of the product and to prescribe cheaper products. About 80% of prescriptions are written generically.

If the prescription is written by reference to the brand name, the pharmacist may only substitute the brand for a parallel import. If the prescription is written by reference to the active ingredient (generic), then the pharmacist may substitute a generic, if one exists, or a parallel import. The decision is only subject to economic considerations, as there is in neither case an obligation to make such substitutions.

The pharmacist and the wholesaler have strong incentives to substitute brands with parallel imports, however, due to the particular reimbursement system used in the UK. The government operates what is called the 'clawback' system. Pharmacies are reimbursed the full list price of the domestic brand drug according to the Drug Tariff, irrespective of the source of the product dispensed. However, under the assumption that pharmacies are able to obtain discounts and to buy a certain part of the sales using cheaper parallel imports and generics, the government adjusts the reimbursement to

each pharmacy through the Discount Recovery Scheme (or 'clawback') the following year. On the basis of a discount enquiry to a representative sample across the NHS, the government assesses the savings materialised on the purchases of domestic brands, parallel imports and generics and determines a level of reimbursement reduction by which it recovers a share of the putative savings which the pharmacist can enjoy from the competitive market. This clawback is applied across the board, whether or not the pharmacist uses PIs and generics, and currently stands on average at around 10%.

There is an incentive for the pharmacist and wholesaler to purchase supplies from the cheapest possible source, as they are directly reimbursed by the government. If the cheapest source is a parallel-imported product this is likely to be chosen, if such supplies are available.

3.6.2. Material and methods

The UK data included information on list prices for domestic brands and parallel import prices for the period 2001-2004. Data on the number of suppliers and the PI market share in both the therapeutic market and the product market were available for 2003-4. The data further contained information on total sales and clawback percentages. Illustrations of price series are presented in Annex 3.

3.6.3. Direct savings due to PI

IMS data for 2004 indicated that the total value of parallel-imported products in that year, at reimbursement prices, was £1,606.6m. As the clawback rate for 2004 was 10%, the government savings from the clawback were some £160.7m in 2004 (€237 million). This figure does not include any savings beyond the clawback that contribute to the profits of the pharmacies. It is difficult to asses the size of such a contribution. The choice in this study has been to adopt a conservative approach in estimating the direct savings – as opposed to the York study that included such savings accruing to pharmacies. The York study from 2001 suggested that the total value of the discounts would be of a magnitude of 17%, of which the clawback would be approximately 10% (3). The basis for this suggestion is unclear. However, although such discounts basically finance the operation costs of pharmacies and are therefore necessary for maintaining a certain distribution level, it can also be argued that they do not represent a direct benefit to the government. The York estimates for savings, with pharmacy savings excluded, amounted to approximately £200 million (€322 million). There appears, therefore, to be a decrease in the savings realised from 2001 to 2004.

3.6.4. Indirect savings due to PI

Due to the peculiarities of the UK market and regulation of pharmacy profits through the clawback system, increased competition from parallel imports will not directly materialise into reduced pharmacy sales prices. The pharmacy will continue to be reimbursed the full list price according to the Drug Tariff. Increased competition will show up as competition on discounts. Indirectly, such increased discounts would result in increased assessments of the year's savings made under the Discount Recovery Scheme that would then increase the clawback rate, effectively resulting in lower net ex-

post reimbursement rates to pharmacies. The clawback rate has, however, remained more or less stable around 10% for the past five years.

The indirect price competition could be reflected in the price difference between the parallel import price and the list price. Although this does not say anything about the responses of manufacturers to the competition, the assumption is that an increased price difference is likely to indicate the presence of competition and that this competition would also affect effective prices of originator products (i.e. list prices net of discounts). It can further be hypothesised that the price difference would also depend on the amount of competition in the market, i.e. the number of suppliers. The average change in price difference for 35 products in the market from the beginning of 2002 to the end of 2004 was, however, negative at -4.7%, i.e. on average there was a decrease in the price difference to the list price. The number of suppliers in the market was statistically significantly higher for the products that experienced increases in price differences than among the group of products that did not.

In this context it should be noted that there is no motivation for parallel importers in the UK to lower prices if not forced to, as 'price reductions' in the form of raised discounts make PI more attractive to the pharmacy buyers due to the clawback system.

Finally, another element of dynamic price competition is related to the negotiations for the PPRS, which is agreed for a period of 5 years. This may limit the competition on a year to year basis, but competitive effects would be reflected in the changes in the PPRS. The PPRS was fixed for the period covered by the price series of the present study, but was renewed in 2005. It has been reported that price reductions in the renewal process tended to target products with high PI market shares in order to deliver the 7% price reductions that had been agreed.

3.6.5.   Summary

The estimated direct savings due to PI in the UK in 2004 amounted to £161 million in 2004 (€237 million). This amount would be larger if the savings to pharmacies were included.

There are signs of some effects of competitive pressure by PI and the regulatory environment is very conducive to PI. But since competition is primarily on the discounts given to wholesalers and pharmacies and information on such discounts is not available, it is hard to determine the exact effects. Thus, no estimates were available for indirect savings.

Since the clawback percentage is taken by the national health authorities especially with a view to recouping the savings made by pharmacies through the sale of generics and imported drugs, the savings will benefit consumers indirectly.

3.7. Conclusion

The total direct savings due to parallel importing of drugs have been estimated for four countries – Denmark, Germany, Sweden and the UK. These countries have relatively large and mature markets for parallel imports. The results are summarised in Table III.3 and show that there are considerable savings in the four countries. The figure for the UK would be larger if savings made by pharmacies were included. Similarly, the inclusion of savings by sickness funds on pharmacy bills to pharmacies that do not meet the PI quota would increase the estimated German savings. The direct savings figure of €441.5 million can thus be regarded as a fair, but conservative estimate.

Table III.3. Estimated direct and indirect savings (million €) in 2004

	Direct	Indirect
Denmark	14.2	8.3
Sweden	45.3	16.4
Germany	145.0	n.a.
UK	237.0	n.a.
Total	441.5	24.7

Furthermore, a comparison with previous results from the York Study (notably based on 2001 data) shows decreasing savings over time and most notably in Germany and UK (Table III.4). In Germany direct savings declined by 32%, while in the UK the estimated direct savings were reduced by approximately 20%. Regulatory changes that have taken place in recent years have contributed to this decline in savings, e.g. the strict price control in Sweden and the change in PI quotas and mandatory rebates to sickness funds in Germany. Thus, for Germany the savings are exceptionally low in 2004 due to the temporary but significant increase in the mandatory discounts to sickness funds, which led to withdrawal of about one-third of the PI products. Estimated savings for Germany in 2003 amounted to €213 million and the 2005 figures will be higher than for 2004. Other explanations for the apparent decrease in savings could be that prices have converged so that the savings per quantity sold are lower, or that supplies have been increasingly restricted and therefore sales have gone down.

Table III.4: Comparison with the York study estimates for 2001 (3), million €

	Direct	Indirect	York study: Direct savings
Denmark	14.2	8.3	16
Sweden	45.3	16.4	47
Germany	145.0	n.a.	194
England	237.0	n.a.	342
Total	441.5	24.7	599

Indirect savings may occur as originator prices are decreased or as the growth rate in originator prices is decreased as a result of competitive pressure by parallel imports. While there were some signs of such downward competitive pressure on prices for some products, and also on average prices, the picture for many products is that such pressure is remarkably absent. Contributing factors could be an increasingly supply-restricted

market or restrictive price regulation. Such an interpretation could be supported by the seemingly modest competitive price effect observed across countries. This cannot be determined decisively on the basis of the currently available data, however. Estimates of the indirect savings have been made for Denmark and Sweden, based on assumptions about the likely originator price in the absence of parallel importing. These estimates suggest that such indirect savings are not insignificant.

The results of the statistical analysis of competitive effects of PI are summarised in Table III.5.

Table III.5. Summary of results from statistical analysis by country

	Competitive effect of PI on prices
Denmark + present	There are probably competitive effects in terms of an average reduction in the growth of originator prices following entry of PI. At the individual product level significant changes in price trends after entry of the PI product could only be observed for 10 out of 50 products, but the analysis of the combined cross-sectional and time-series data showed that, on average, there was a downward shift in the price trend.
Sweden - absent	Regarding the statistical analysis of possible competitive effects it is noted that competitive price effects have been observed in the past, but in the study period the apparent absence of price changes on originator products in the sample of 50 products is surprising. A possible explanation is the strict price regulation that creates a disincentive for the market's price leader to reduce prices.
Germany + present	The results of the fitted panel data regression show that there is a positive association between change in price of parallel imports and manufacturers' domestic prices. A decrease in the price of parallel imports is associated with a decrease in the domestic price. There is also a negative effect on domestic prices from an increased market share of parallel imports. This would suggest that on average there is some response to increased competition. The coefficient is fairly low, however, with a 10% market share resulting in a <1% price decrease.
The UK Difficult to estimate; maybe absent	Difficult to establish due to the clawback system. Various attempts could not firmly establish a competitive effect.

Due to differences in the methods used no direct comparison is made with the LSE study (2). However, aspects of the present study and the York and LSE studies are summarised in Table III.6.

The LSE study found no competitive, i.e. indirect effects. Two approaches were used. The first method involved a review of the competition patterns for five of the highest selling PI products in Germany, the Netherlands and the UK. Based on this material it was concluded that 'there may be little competition in products subjected to intensive parallel distribution' p. 776. It is added, however, that this is by no means conclusive evidence and that it may suggest that arbitrage is keeping prices and price increases within a certain range. In the LSE study there was no explanation for including only three of the study's six countries, apart from describing them as mature markets – and the limitation to 5 products rather than all 19 is not explained.

The second method was used to answer the question: Does parallel trade promote price competition in destination countries? Panel data for all products for 1997-2002 were used in a random effects model. No evidence of price competition was found in the four different models estimated.

Disregarding the question of the econometric method employed – a relevant methodological approach was undoubtedly used – the crucial questions then become whether the results may be sensitive to a) the overall model specification and b) whether national markets are too unique to be pooled in one analysis as was done in the LSE study.

As regards the first question it may be a possibility but is difficult to pursue in the present context. Regarding the second question the rather different regulatory situations in the various countries point towards a strategy in which analysis is undertaken on a country-by-country basis, rather than on a pooled dataset, in order to avoid overriding possible effects in individual countries, e.g. effects in Denmark and (at least earlier) in Sweden.

Table III.6: Comparison of three studies

	Time period	Product range	Countries	Statistical model
York (3)	*Direct savings*: 2001 Germany 2002 *Indirect effects/competitive effects*: 1997-2002. No explicit calculation.	*Direct savings*: the whole market *Competitive effects*: selected products. The Netherlands & UK not analysed.	Denmark Germany The Netherlands UK	Simple time plots and simple statistical tests; no regression model
LSE (2)	*Direct savings*: 2002 *Indirect savings/ competitive effects*: 1997-2002. No explicit calculation	*Direct and indirect savings*: Six product categories (19 products)	Denmark, Germany Netherlands Norway Sweden UK	Random effect pooled analysis of all countries
Odense	*Direct savings*: 2004 *Indirect savings*: 2000-2004. Explicit calculation for Denmark & Sweden	*Direct savings*: the whole market *Indirect/competitive effects*: 50 highest selling products	Denmark Germany Sweden UK	Random effects model, analysis of individual countries

In the LSE study much is made of the fact that parallel importers make a profit out of their activities. It is also claimed that the parallel importers are the main beneficiaries of the PI activities. The issue of how much parallel importers gain is addressed in the following section of the present study by using a value chain approach. When looking at the gains from parallel trade, however, one must remember that ultimately all patients pay for health services through contributions, taxes and direct fees. Since all countries have some form of co-payment, price reductions due to PI result in direct gains to patients, but citizens also experience indirect gains through savings accruing to the national health or insurance system that in principle enable the purchase of more or better health services to the benefit of patients.

It is somewhat puzzling that the intuitive idea of a competitive effect seems to be difficult to trace. In a recent paper on 'strategic responses to parallel trade' Kyle investigated non-price responses by pharmaceutical firms (4). Non-price responses in general are adjustments in product offerings, such as slight changes in brand name or dosage form, i.e. something different from the restrictions on supply mentioned in section II.

Kyle used the most comprehensive data set so far, with the inclusion of a total of 30 countries (including some non-EU countries) and all drugs assigned to 36 therapeutic classes (measured at the 4-digit ATC level) for 1993Q1 to 2004Q3. This was a subset of the IMS Midas database.

Kyle found evidence that the behaviour of EU pharmaceutical companies with respect to their product portfolios is consistent with attempts to reduce parallel trade. Kyle noted that this may at least partially explain why parallel trade has not yet resulted in significant price convergence across EU counties. The implication is that accounting for non-price strategic responses may be important in assessing the welfare effects of parallel imports.

4. Value chain analysis

4.1. Introduction

An issue that has received some attention is the question of who benefits from parallel trade. The LSE study (2) concluded that patients do not benefit directly, that pharmacists realise modest financial benefits and that benefits accruing to health insurance organisations are at best modest. The study concluded that the main beneficiaries are the parallel-importing companies, indicating that there are supra-normal profits in the parallel-import industry.
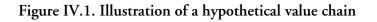
In the previous section it was concluded that benefits from parallel importing of drugs will be passed on to the payer in the form of savings if and when the incentives are correctly set in the regulatory environment. The market structure, the number of suppliers and the organisation of the (national) market are additional factors that determine the way in which reductions in ex-manufacturer purchase prices translate into savings for end-users.
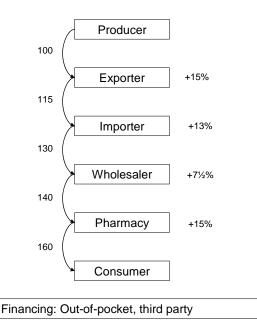
The issue of who gains can be discussed in the context of the regulatory environment. It can also be illustrated through the concept of value chains. In this section an attempt is made to develop a template for such an analysis of the translation of savings in ex-manufacturer prices into savings at the point of consumption. The value chain describes how value is added to the product along the distribution chain from the point of manufacturing or import to the point of sale to the consumer. It has the potential to analyse how savings generated from the parallel trade of drugs accrue at the different stages of the distribution chain.

4.2. Material and methods

4.2.1. The value chain approach

The principles of the value chain approach are illustrated in the example in Figure IV.1. **It should be noted that the numbers used are purely illustrative**. The figure shows various levels in the distribution chain from the manufacturer in a country A to the user in another country B, with an indication of the transaction price between two levels and the added price margin. It is important to keep in mind that the *price margin is different from the profit margin* as the various distribution levels will need to finance a number of operating costs. For example, the parallel importer carries the costs of registration, transport, repackaging and relabelling as well as an increased market risk as products cannot be returned if the market collapses.

Figure IV.1. Illustration of a hypothetical value chain

```
          ┌─────────────────┐
          │    Producer     │
   100   ╱└─────────────────┘
        │ ┌─────────────────┐
        └→│    Exporter     │   +15%
          └─────────────────┘
   115   ╱
        │ ┌─────────────────┐
        └→│    Importer     │   +13%
          └─────────────────┘
   130   ╱
        │ ┌─────────────────┐
        └→│   Wholesaler    │   +7½%
          └─────────────────┘
   140   ╱
        │ ┌─────────────────┐
        └→│    Pharmacy     │   +15%
          └─────────────────┘
   160   ╱
        │ ┌─────────────────┐
        └→│    Consumer     │
          └─────────────────┘

┌──────────────────────────────────────┐
│ Financing: Out-of-pocket, third party │
└──────────────────────────────────────┘
```

The price margin is defined as the difference between sales price and purchase price in relation to the purchase price. In the fictive example in Figure IV.1, a product is sold by the manufacturer to the exporter at a price of 100. The exporter needs to pay for the product and to cover the costs of transport, storage, marketing, etc. as well as generate a surplus for the continued survival of the business. In this example the exporter resells the product at 115 having added a price margin of 15%. Similarly the importer, in addition to the buying price of 115, needs to recover operational costs as well as to generate a surplus. The importer in this example sells at a price of 130 having added a price margin of 13%[8] on top of the purchase price of 115. Finally, the wholesaler and pharmacy will likewise add to the price. Note again that operating costs at each level would have to be paid out of this price margin. At the point of consumption, the product will be paid for either directly out-of-pocket by the consumer or by a third party payer.

Another way of looking at the value chain is to look at the contribution to final price at various distribution levels. Using again the hypothetical example of Figure IV.1, the final price at sale to the user (whose purchase may be subsidised by any third party) is 160, an increase of 60 price units since the product left the manufacturer. The 'add-on leading to the final price', i.e. the price increase from the time of sale by the manufacturer until the time of purchase by the end-user, is thus 60%. Of this total value added, 15 price units or 25% of the total value addition were contributed at exporter level, another 15 price units or 25% at the importer level, 17% at the wholesaler level and 33% at the pharmacy level. It appears that although the price margin is the same at the exporter and pharmacy level, the contribution to the final price is higher at the pharmacy level, because the price margin is applied to a higher purchase price at that level.

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[8] Calculated as (130-115)/115.

The value chain in Figure IV.1 relates to a parallel-imported product. Figure IV.2 illustrates how this value chain compares to that for a directly imported or domestically manufactured product.
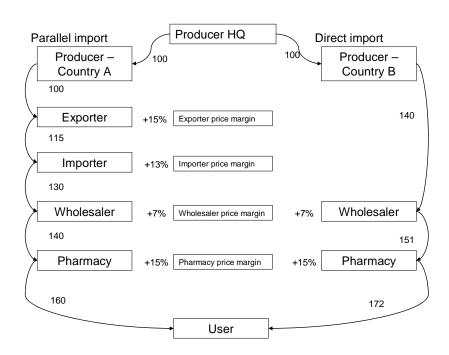
Figure IV.2. Illustration of two hypothetical value chains for parallel and direct imports

The same drugs can reach the consumer in country B through two distribution channels. Figure IV.2 illustrates the difference in the value chains for directly and parallel-imported drugs. The same purely fictive prices as in Figure IV.1 are used for the supply chain of parallel-imported drugs. Since the price of direct imports is usually slightly higher, a 7.5% price difference is arbitrarily assumed. It is further assumed that pharmacy and wholesaler percentage price mark-ups are the same for both scenarios.

The supply chain is shorter in the case of the direct import, implying that the producer's sales price can be considerably higher yet result in the same or in this purely fictive example a higher price at the point of end-use. Figure IV.2 illustrates that if the pharmacy margin, the pharmacy purchase price and the wholesaler price margin are the same across markets (parallel and non-parallel) then the producer's sales price (and profit) will be considerably higher in the case of direct import.

The ex-manufacturer purchase price differs in the two scenarios due to price differentiation by the manufacturer. As such there are 'savings' by buying in Country A rather than in Country B. But do these savings reach the consumer in country B and to what extent? In the preceding sections it was argued that there are direct savings at the point of consumption that benefit the consumer either directly or indirectly depending

on the third party financing arrangements. The question remains, however, to what extent the manufacturers' losses translate into consumer gains.

In the above fictive example, the manufacturer loses 40 currency units by selling to the exporter in Country A rather than to the wholesaler in Country B. The exporter in Country A and the importer in Country B will need some payment for transport, storage, administration, repacking, etc. In the present example this amounts to 30 currency units in total. Thus, at wholesaler level, there is a difference in price of 10 currency units whether a parallel or directly imported product is purchased. Assuming that the wholesaler and pharmacy levels apply a percentage mark-up on their purchase prices, then the consumer would further 'save' on smaller costs at these levels of the distribution chain, in this example 1 currency unit at each level resulting in a total price saving of 12 currency units at the point of consumption. If the wholesaler and pharmacy levels apply a fixed mark-up in absolute terms then the savings at the level of consumption would remain as the difference in the wholesaler's purchasing price.

4.2.2.   Case material

Based on the above-described value chain model, data were collected to provide an empirical case illustration of the value chain. Data were collected on price at different levels in the distribution chain for a selected number of PI products. The levels included

- Exporter in third country: estimated purchase price
- Parallel importer: price at purchase in third country (import price)
- Wholesaler in import country: wholesaler's purchasing price
- Community pharmacy's purchasing price
- Community pharmacy's sales price

Products were selected based on criteria set by the research team and included the highest selling parallel-imported products in various dispensing form (tablets, fluids, inhalers). Data were obtained for Denmark, Germany, Sweden and the United Kingdom.

The prices would ideally be averages for the year, but as this presented a number of practical difficulties, end of year prices were used instead. The prices were transformed into an index. Furthermore, in the interest of confidentiality requested by some of the respondents in view of the competitive market situation, the product names are blinded for presentation by the research team. An attempt was also made to include an estimate for the exporters' purchase prices in exporting countries in order to get the full picture of the value chain. It was, however, only possible to get some estimate from two countries and those were deemed to be very inaccurate, both due to lack of good information as well as the fact that importers source from many different exporters in various countries and it would be difficult to come up with one consolidated and meaningful figure. Such figures have therefore not been included.

The available data do not include information on the value chain for the originator product. Comparisons between the two value chains and the distribution of beneficiaries from the 'savings' in ex-manufacturer price at various levels in the distribution chain cannot be determined directly.

If fixed mark-up percentages are applied either at wholesaler or pharmacy level or both, then the higher the pharmacy and wholesaler margins, the larger the potential savings at the point of consumption.

4.3. Findings

This sub-section presents the findings for each of the four countries in turn. There are between-country variations in both the information available and the national context, and hence also in the way in which the results can be presented. Given these variations, cross-country comparisons are not made.

4.3.1. Denmark

For Denmark information was provided for six products, here denoted A-F. The market share for these six PI products in their specific dispensing form, strength and package size was in the range of 50-75% in 2004 and there were 3-5 importers (direct and parallel) of the products. Products A-C represent high-selling products with turnovers of 2-3 times that of products E-F.

Table IV.1 shows the price margin between purchase and sales prices at each distribution level, expressed in per cent of purchase price. This allows an analysis of the level of importer's price margin compared to other levels in the supply chain. The importer price margin ranges from 6-66% and is relatively low (6-12%) for products B, C, D and F and relatively high (34-66%) for products A and E. A slightly different pattern emerges for the pharmacy price margin, which is relatively low (13-14%) for products A-D and relatively high (25-27%) for products E and F. This could imply that products E and F represent a more specialised market. There does not appear to be any relationship with market share.

Table IV.1. Price margins at various levels in the distribution chain for 6 products, Denmark

	Product					
Price margin at	A	B	C	D	E	F
Importer	34	6	11	7	66	12
Wholesaler	7	7	6	7	7	7
Pharmacy	13	14	13	13	25	27

Note: Price margin = (Purchase price – Sales price)/ Purchase price

Figure IV.3 displays the composition of the final sales price by the contribution from the price additions at the various levels in the distribution chain. It appears that the import price contributes less to final sales price for products A and E than for the other products. Furthermore, the contribution to the final sales price at community pharmacy level is higher than at wholesale and importer level for products B, C, D and F, see also Table IV.2.
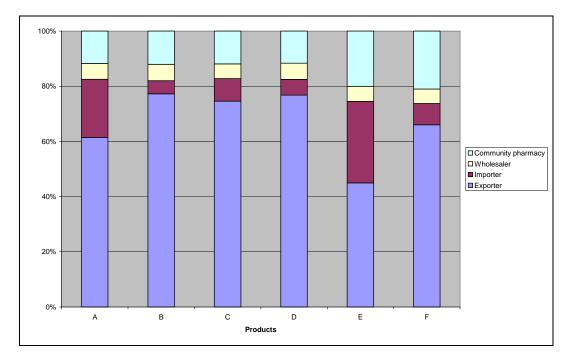
Figure IV.3. Contribution to final sales price by levels in the distribution chain

Table IV.2. shows the percentage of the total price margin that has been added to the export price at various levels in the supply chain. Looking only at % price margins at each level in the supply chain may in a way be misleading as 7% added in the bottom of the chain will be a lot less than 7% added at the top (which also includes 7% of all other additions that have been made to the price). It appears that almost half of the total price difference from point of import to consumer purchase is added at the pharmacy level. That would imply that to the extent that lower ex-manufacturer purchase prices for PI do not translate into lower consumer prices, the 'savings' are largely retained at pharmacy level.

Table IV.2. Percentage of total price margin added to import price by level in value/distribution chain, Denmark 2004

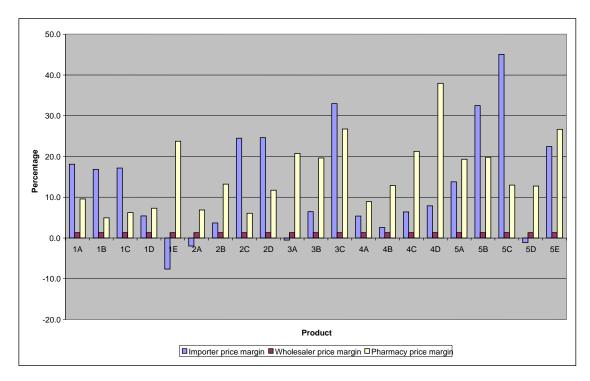|	A	B	C	D	E	F
Importer	55	21	32	25	54	22
Wholesaler	15	26	21	26	10	16
Community pharmacy	30	54	47	50	36	62
Total price margin	100	101	100	101	100	100

4.3.2.   Sweden

For Sweden information was provided for 21 package types in 5 product categories. The market shares are very high for products 2-3, high for product 4 and lower for products 1 and 5, although this may not apply to all package sizes. More products are thus available for analysis for Sweden as compared to Denmark. Table IV.3 summarises the available information on price margins for the various product categories. It presents the

unweighted average price margin[9] for importers and the range of price margins within each product category. It appears that in some cases the importer's price margin is negative. This can be explained by the use of estimated import prices and end-of-year prices. The price margins vary from -8% to 45% and likely reflect the spot market nature of the market with volatility in the availability of supplies as well as in purchase prices. Also noteworthy is that the variation in price margins on packages within product seems to be as high as between products, see also Figure IV.4.

Table IV.3. Importer price margin variations for 5 product categories, Sweden 2004

Product	No. package sizes	Importer's price margin		
		Unweighted average	Range	Span
1	5	10%	-8% to 18%	26 %-points
2	4	13%	-2% to 25%	27 %-points
3	3	13%	0% to 33%	34 %-points
4	4	6%	3% to 8%	5 %-points
5	5	23%	-1% to 45%	46 %-points

Figure IV.4. Price margins by distribution level, Sweden 2004

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[9] The unweighted average price margin is the simple average of price margins for each package size within the product category. It could be considered to calculate an average weight for market size.

The variation in importer price margins appears to be fairly low for product 4 and relatively high for product 5. At the same time the variation in pharmacy price margin appears to be largest for product 4. Product 4 has a low average price margin and also a fairly narrow range of variation in the price margin. Product 5 with a high average price margin at the same time has a wide range of variation in the price margin. Pharmacy price margins and importer price margins tend to vary considerably and appear to be almost similarly volatile. The low price margin and the low level of fluctuation in price margins at the wholesaler level reflect the Swedish system with a state company, Apoteksbolaget, acting as wholesaling agent.

Figure IV.5 shows the composition of the total value added to the import price by level in the distribution chain[10]. It appears that for one-third of the cases (7 packages) the largest share is retained at the importer level, and for two-thirds of cases (14 packages) the largest share is retained at pharmacy level. Thus, to the extent that lower ex-manufacturer purchase prices do not translate into low consumer prices for PI, the benefits accrue mainly to the pharmacy level. If the pharmacy price margins are representative of the general level of pharmacy price margins in percentage terms, i.e. if similar percentages are added to the pharmacy purchase price (=wholesaler sales price) for originator and PI products, then the lower wholesaler sales price for PI products as compared to originator products will also result in less price addition at the pharmacy level.
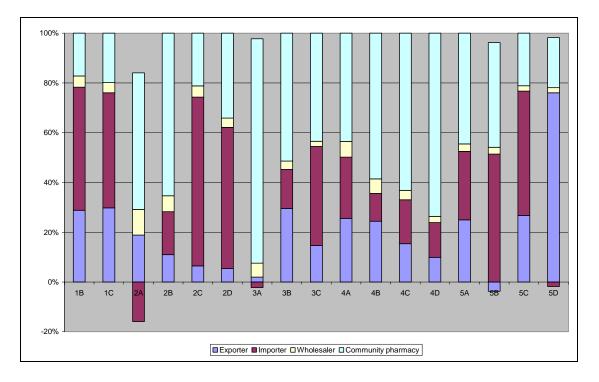
Figure IV.5 Percentage value added to import price by level of distribution, Sweden 2004

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[10] Calculated as the percentage of total price margin (final sales price – import price) that is retained at each level in the distribution chain.

4.3.3. Germany

For Germany information was provided for five products, in total including 50 variants with specific package size, strengths and dispensing forms. For each product category, the variation in terms of price margins between package sizes by various levels in the supply chain is illustrated in Figure IV.6 (Product 1-5) below.

There appears to be a large within-product category variation in the price margins at the importer and pharmacy levels in the supply chain, while the price margins do not vary much at the wholesaler level. Within one product category the importers price margin can vary considerably, e.g. for product 2 the price margin for the 10 product variants varies from 19% to 57% with an average of 35%. Similarly, the price margins for pharmacies vary, e.g. for product 2 from 22% to 84%.

It may be surprising to find parallel imports even for product variants where the price margins are relatively small. In some cases this may reflect a shift of the market away from certain package sizes and illustrates the risks that suppliers have to take into account in their pricing strategies. In some cases it reflects the strategy of the larger parallel-importing companies to maintain a broad portfolio of drugs in order to be considered reliable as a source of drugs.
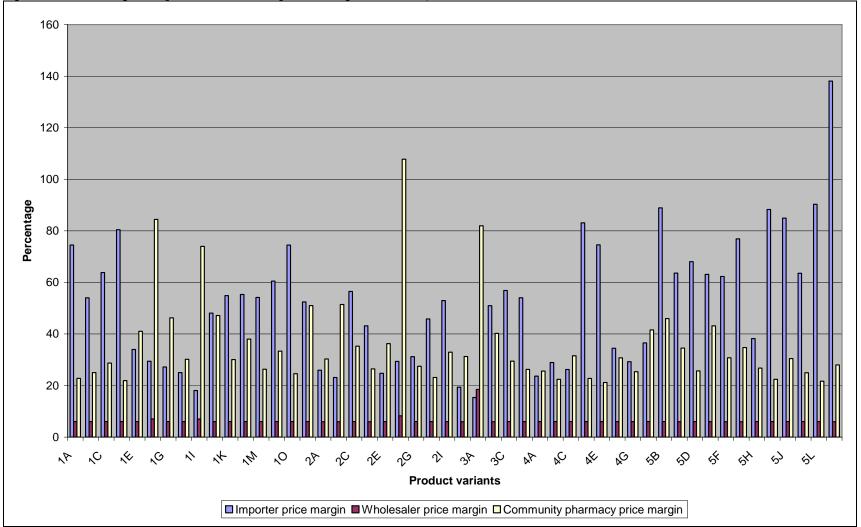
Figure IV.6. Price margins for product variants in 5 product categories, Germany 2004

From Figure IV.6, it appears that the price margins are almost consistently higher at the importing level in the distribution chain compared to the pharmacy retail level. Table IV.4, however, shows the percentage contribution at each level in the distribution chain to the add-on to import price resulting in the final sales price.

Table IV.4. Distribution of price addition to importing price by level in distribution chain (%)

Product	Variants	Distribution level		
		Importer	Wholesaler	Pharmacy
1	15	42 (15-60)	8 (6-10)	50 (32-75)
2	10	36 (15-51)	9 (6-11)	55 (40-79)
3	4	38 (10-51)	10 (7-14)	52 (40-75)
4	8	44 (35-60)	10 (8-11)	47 (32-57)
5	12	53 (43-62)	8 (6-10)	40 (30-51)

It appears that the percentage of the addition to the importing price at each level can vary considerably and generally seems to be higher for the pharmacy retail level than for the importing level. In other words, while the percentage addition to the price as represented by the price margin is higher for the importing level than for the pharmacy retail level, the absolute addition in terms of money appears to be higher at the pharmacy retail level than at the importing level.

4.3.4.   United Kingdom

For the UK information was provided for five products covering 40 different variants in terms of package size, strengths and dispensing forms.

The variation in price margins within product categories and for the different levels in the distribution chain is shown in Figure IV.7. As the fifth product category contains only one product variant the figures present only results for four product categories.

Figure IV.7 illustrates the variation in price margins within and between products for various parts of the value chain. A considerably larger price margin is consistently found at the level of the community pharmacy (illustrated in the last column for each product variant). This reflects the special characteristics of the UK pharmaceutical retail market in which the pharmacies are initially reimbursed the list price of the domestic brand and where the clawback system for estimated excess benefit due to a lower estimated acquisition price is in operation. Thus, the bars in the figure reflects the prices before the clawback. Even if a 10% clawback is assumed for the community pharmacies, the larger price margin appears to be at the pharmacy level.
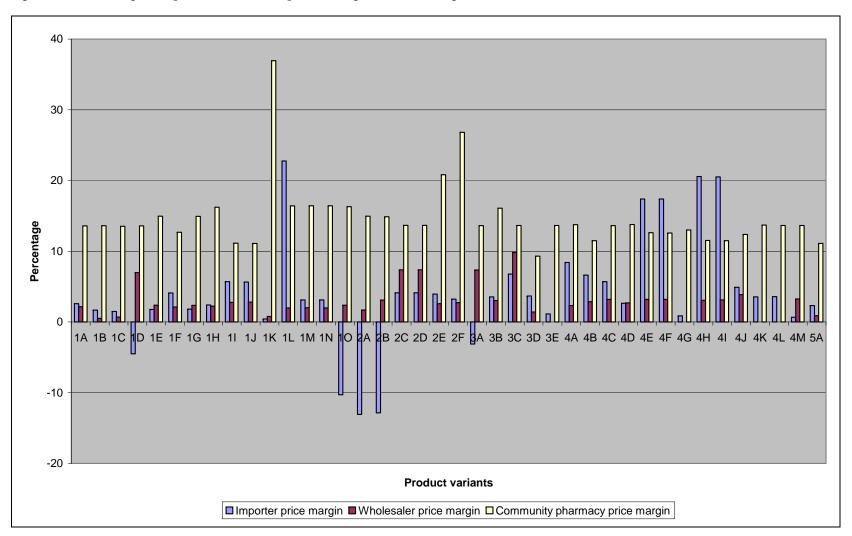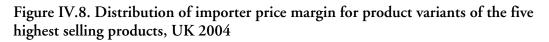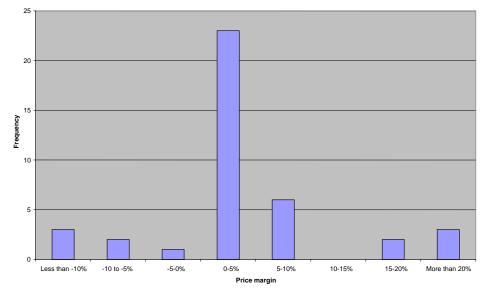
Figure IV.6. Price margins for product variants in 5 product categories, United Kingdom 2004

As for the other countries, the price margins for importers vary considerably and at times are negative. However, most frequently the price margin is within the range of 0-5%. This is the case for 58% of the product variants; for almost three-quarters (73%) of the product variants the price margin is in the range 0-10%, see Figure IV.8.

Figure IV.8. Distribution of importer price margin for product variants of the five highest selling products, UK 2004

It is further noticeable that the importer price margins appear to be relatively low except for a few products, and at times even negative.

4.4. Conclusion

Patients benefit from any savings that may materialise at the point of consumption. However, the LSE study also raised the question of who else benefits from the savings arising from PI. In this relation 'savings' refer to the manufacturer's losses due to price differences in ex-manufacturer prices for different markets. Value chains can describe how the value or price for a product develops through the distribution chain from the point of manufacturing to the point of consumption and would for the purpose of studying distribution of 'savings' ideally involve a comparison of value chains for both directly and parallel-imported products.

Based on case studies in the four countries attempts were made to develop value chains from the point of import to the point of consumption for parallel imports. The results presented above are merely an attempt to illustrate how the value chain approach can be used to tackle the question of who in the supply chain gains from the savings generated by parallel trade. A more systematic and comprehensive data collection would be needed to produce more generalisable findings, preferably including value chain data for direct imports for comparison.

Comparisons across the four countries should only be undertaken with great care as the methodologies of data collection and the national contexts may not be completely comparable. However, while there may be inconsistencies in reporting across countries,

the reporting of data within each country is consistent. The selection of the products has been based on objective criteria (the five highest-selling product categories, various product variants) and there is no reason to believe that there would be a subjective selection of drugs. There could be a bias in using highest turnover as a selection criterion, as it could be expected that a lower profit margin was accepted on products with high turnover. This would, however, hold equally for non-parallel imports.

The variation in the values added at the wholesaler level in the chain suggests that prices respond to variations in the competitiveness of the market. Another explanation could be a wide variation in the price differentiation between countries, e.g. where there is a high price difference between importing and exporting market, there is scope for larger profits. Due to the nature of parallel trade, the profit is determined more by supply side changes than by demand, and sales prices do not fluctuate much. The large variations in price margins may well be a reflection of variations in supply availability. The larger parallel importers survive by selling a portfolio of products and ensuring a varied and reliable supply. This requires a mix of products and package sizes of which some produce no or very little profits, while others are sold in large quantities or at higher price margins.

The price margin at the importer level has to cover the costs of registration, transport, repackaging and relabelling as well as the distribution margins to other levels in the supply chain and a risk premium on stocks that cannot be returned. The split of the overall price margin between the various stakeholders in the distribution chain as illustrated above, does not, however, suggest a supra-normal profit compared to other industries. In some cases it even appears surprisingly small.

5. Overall conclusion

Parallel trade in pharmaceuticals is an important policy issue in many countries and is surrounded by controversy, in part due to the many contradictory stakeholder interests, but also because the theoretical literature shows conflicting results and the empirical literature is still scant, albeit growing.

The present study is a new attempt to provide empirical evidence of direct and indirect benefits of parallel trade in pharmaceuticals. The study aims were i) to briefly assess previously documented evidence, with particular focus on two major studies undertaken recently, i.e. the York (3) and LSE (2) studies, ii) to estimate the savings from parallel trade in four countries (Denmark, Germany, Sweden and the UK) and iii) to develop a template for a value chain for parallel trade in drugs.

Potential welfare effects
Total welfare is defined as the sum of consumers' surpluses net of the public expenses, and profits of both the drug manufacturer and the parallel importers.

Short-term welfare benefits of parallel trade to importing countries are likely to occur in terms of lower drug expenditure, provided that lower costs are transferred to the consumers of pharmaceuticals. Such benefits may occur through two mechanisms. The availability of cheaper PI of the same brand products as currently in the market will translate into direct savings, as parallel imports enter the market at lower than the originator price. The level of such savings is an empirical issue.

Furthermore, to the extent that parallel trade puts competitive pressure on the originator price, thus resulting in price decreases or a deceleration of price increases, there will be indirect savings in drug expenditures. However, the response to parallel trade in the market may not necessarily be to enter into competition. To what extent that happens is an empirical question.

On the other hand, it has been argued that in the longer term, research and development could suffer from reduced profits in the pharmaceutical sector. It has also been shown, however, that this is not necessarily the case under all circumstances and there is so far no convincing empirical evidence.

The distribution of any savings in drug prices will depend on the regulatory environment and health care financing system. Ultimately, however, all patients pay for health services through contributions, taxes and direct fees and therefore gain either directly or indirectly, if savings materialise.

Previous studies
Two recent studies conducted by independent research organisations have produced contradictory results concerning the net benefits of parallel trade in drugs. The York report concluded that direct and indirect savings from the parallel trade of pharmaceuticals have helped contain public health care expenditure and that due to the nature of the national health systems, the users of health services benefit from such savings. The LSE report, on the other hand, concluded that the lack of sizeable direct benefits, the limited price competition in individual markets, the existence of reported product shortages in some member states, and the size of absolute and relative profits accruing to parallel traders may force policy-makers to re-evaluate the rationale behind parallel trade.

The disparities in the savings estimates in these two studies are mainly due to methodological differences. Taking these methodological differences into account (specifically adjusting for the fact that the LSE study due to its other objectives was based on a sample of varying representativeness in the countries studied and that the savings reported only pertained to this small section of the market), it appeared that the savings estimates would be much less different between the two studies than may appear at first glance.

Few studies have attempted to quantify the indirect savings and none of them very comprehensively. Increased competitiveness of the market would, however, indicate the presence of indirect savings.

The LSE study found no competitive effects, but it is uncertain whether the approach of pooling data from national markets with very different regulatory frameworks may not contain a risk of washing out possible effects in individual countries. The York study also found only limited signs of competitive effects. However, one Swedish study that was aimed particularly at analysing market competitiveness in response to PI found significant reductions in originator prices associated with the introduction of parallel imports into the Swedish market over the period 1994 to 1999.

Empirical findings

The present study, in line with the previous studies, includes estimates of direct savings from PI and assessments of competitiveness of the markets in four countries. However, in addition, the present study presents estimates of indirect savings for two countries and illustrates the use of the value chain approach to trace supply chain gains.

Direct savings
The total direct savings due to parallel importing of drugs were estimated for four countries (Denmark, Germany, Sweden and the United Kingdom). The result showed considerable direct savings of €441.5 million in the four countries. This is a conservative estimate, however. The UK estimate would be larger if savings made by pharmacies were included. Similarly, the inclusion of savings by sickness funds on pharmacy bills to pharmacies that do not meet the PI quota would increase the estimated German savings. Finally, the figures for Germany are believed to be exceptionally low due to a temporary increase in 2004 of the mandatory rebates to sickness funds. The direct savings for 2005 are thus likely to be higher than €441.5 million.

In comparison to previous results, notably the 2001 estimates from the York study, there appeared to be decreasing savings over time and most notably in Germany and the UK. Explanations vary between countries but could be that prices have converged, that the supplies have been increasingly restricted and that changes have been made in the regulatory environment, e.g. the strict price control in Sweden and the change in PI quotas and increased mandatory rebates to sickness funds in Germany in 2004.

Indirect savings
Estimates of indirect savings were made for Denmark and Sweden, based on assumptions about the likely originator price in the absence of parallel importing. These estimates suggested that such indirect savings are not insignificant. The indirect savings for the two countries were estimated to be €25 million compared to €60 million in estimated direct savings.

Indirect savings may occur as originator prices are decreased or as the growth rate in originator prices is decreased as a result of competitive pressure by parallel imports. The analysis revealed signs of such downward competitive pressure on prices for some products, and also on average prices, but the picture for many products is that such pressure is remarkably absent. Some competitive effects were found for Germany and Denmark, but were absent in Sweden and they were difficult to establish for the UK due to the clawback system. Contributory factors could be an increasingly restricted supply market or restrictive price regulation.

It is somewhat puzzling that the intuitive idea of a competitive effect seems to be difficult to trace. A recent paper on 'strategic responses to parallel trade' investigated non-price responses by pharmaceutical firms and found evidence that the behaviour of EU pharmaceutical companies is consistent with attempts to reduce parallel trade. As noted by the author of this paper, this may partially explain the absence of significant price convergence across EU counties. The implication is that accounting for non-price strategic responses may be important in assessing the welfare effects of parallel imports.

Distribution of gains
An important factor in the level and distribution of any savings and resulting welfare effects is the regulation of the market and the payment mechanisms in place. Since all countries have some form of co-payment, reduction in prices due to PI results in a direct gain to users. Most countries also have some form of third party financing either in terms of a tax-financed national health system, a premium-based insurance system or a combination of these. Savings on drug expenditures for third party payers may in principle result in indirect benefits to citizens by enabling a combination of reduced premiums and taxes and/or purchase of more or better health services. The balance between co-payment and third-party financing broadly determines the balance between direct and indirect benefits to consumers.

Patients clearly benefit from any savings that materialise at the point of consumption. However, the LSE study raised the question of who else benefits from the savings from PI. In this context 'savings' refer to the manufacturer's losses due to the differences in ex-manufacturer prices for different markets. Value chains can be used to describe how the value or price of a product develops through the distribution chain from the point of

manufacture to the point of consumption. For the purpose of studying distribution of 'savings' such an approach should ideally involve a comparison of value chains for both direct and parallel imports.

Based on case studies in the four countries studied, attempts were made to develop value chains from point of import to point of consumption for parallel imports. One consistent finding was the very large variation in price margins at all levels in the distribution chain, except where regulations restrict price margins. Importer price margins are at times even negative. According to the case studies developed, the pharmacy level often contributes more than importers or wholesalers to the total price addition from import price to final sales price.

The split of the overall price margin between the various levels in the distribution chain does not suggest a supra-normal profit compared to other industries. In some cases it even appears surprisingly small considering the costs of registration, transport, repackaging and relabelling as well as the distribution margins to other levels in the supply chain and a risk premium on stocks that cannot be returned.

In conclusion

- Empirical evidence of welfare effects of parallel import of pharmaceuticals is scant, especially with regard to dynamic competitive pressure and impact on research and development
- Disparities in the findings of previous studies are mainly due to methodological variations influenced by differences in study focus
- There are considerable direct savings from parallel importing in the four countries studied
- The estimated indirect savings are not negligible, yet the apparent difficulties of tracing competitive effects are puzzling and may call for the inclusion of non-price strategic responses in the analysis
- The value chain analysis can provide useful insights. Case studies show large variations in price margins at all levels in the distribution chain and there are no signs of supra-normal profits.

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7. Annex

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Annex 1 – 3 are available in a separate document:

The economic impact of parallel imports of pharmaceuticals
Annex 1-3