

**PARALLELIMPORTØRFORENINGEN
AF
LÆGEMIDLER**

Sundhedsudvalget
SUU alm. del - Bilag 676
Offentligt

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I dag offentliggøres en ny undersøgelse af det offentliges og patienternes besparelser som følge af parallelimport af lægemidler. Undersøgelsen, der er ledet af professor Kjeld Møller Petersen fra Syddansk Universitet, viser, at parallelimport giver betydelige besparelser for sundhedsøkonomien.

Men undersøgelsen dokumenterer også, at der er et fald i besparelserne i alle 4 lande. Besparelserne størrelse er blandt andet afhængig af forsyninger af produkter, men producenternes strategi med at afskære forsyninger, i flere tilfælde via ulovlige tiltag, er nu begyndt at virke.

Det er særligt bekymrende i Danmark, fordi regeringen og Folketinget jo netop har vedtaget regler for medicintilskud og –udlevering, der skal fremme salget af de billigste substituerbare lægemidler.

Vejen frem er en forstærket indsats mod producenternes kvoteordninger og dobbeltprissystemer i indkøbslandene, og et konstant pres på Europa-Kommissionen for effektivt at forfølge sådanne konkurrencehæmmende systemer.

Jeg vedlægger rapportens Executive Summary. I er meget velkomne til at rekvirere hele rapporten hos vores sekretariat eller downloade den på:

http://www.cast.sdu.dk/pdf/Parallel_import_rapport_13_06_1430_opdateret_final.pdf

Med venlig hilsen

Anders Norstrand
formand

PARALLELIMPORTØRFORENINGEN AF LÆGEMIDLER

Executive summary

Parallel trade in medicines is an important policy issue in Europe and is surrounded by controversy, due in part to contradictory stakeholder interests and in part to the lack of exhaustive treatment of the issue by 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, particularly the former, have dominated the debate on parallel trade in recent years. They draw opposing conclusions about the benefits of parallel trade. While the LSE report finds 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 closer to that of the York report, the present study finds that parallel distribution generates considerable savings. It estimates that direct savings to patients and health insurers in four countries - Denmark, Sweden, Germany and the United Kingdom - amounted to €441.5 million in 2004.

Estimated direct and indirect savings 2004 (€ Million)

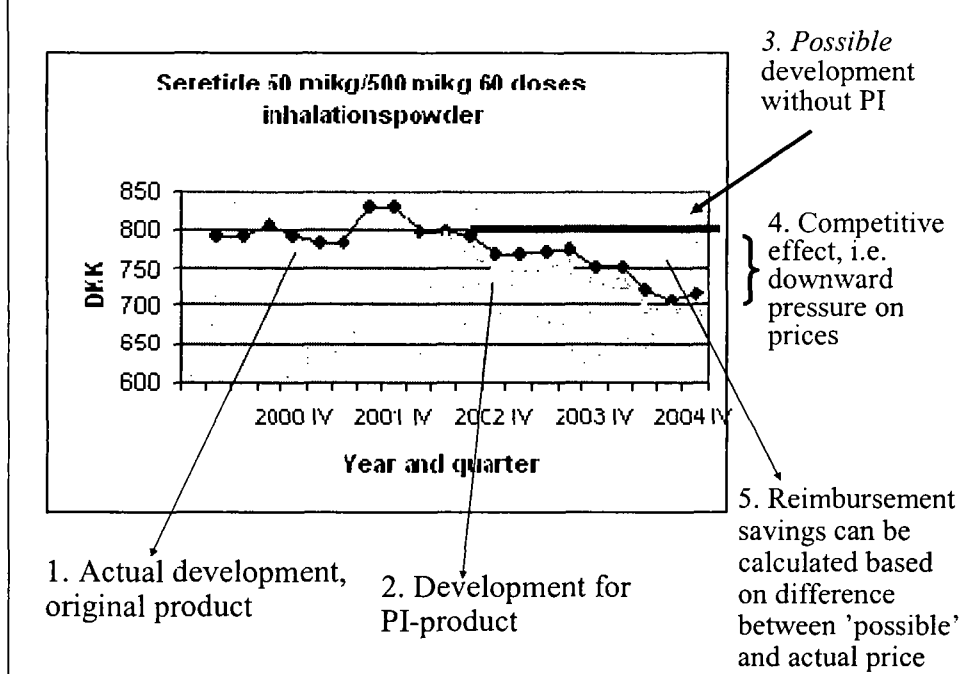
	Direct	Indirect
Denmark	14.2	8.3
Sweden	45.3	16.4
Germany	145.0	n.a.
UK	237.0	n.a.
Total	441.5	24.7

In addition, this study quantifies indirect savings for 2 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 in Denmark and Sweden amount to €8.3 million and €16.4 million respectively for 2004. According to these estimates indirect savings add another 58% to direct savings in Denmark, and another 36% in the case of Sweden.

Calculating direct savings is easier as they result directly from the difference in medicines prices between the more expensive direct imported product and the cheaper parallel imported product. Measuring indirect savings is more difficult as it requires making assumptions about how prices would have developed in the absence of parallel imports and about the causal link between parallel imports and declines in the price or the price growth of the direct import.

The graph below, taken from the study, shows how the study attempts 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



The main findings for 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 at €237 million for 2004. This amount would be larger if the savings which are 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 is available.
- The estimated direct savings due to parallel imports in Germany in 2004 amounted 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. Some direct patient benefits will also materialise from the reductions in absolute co-payment for prescription and non-prescription medicines.
- For Sweden direct savings were estimated at €45.3 million in 2004, and indirect savings at €16.4 million. Under the regulatory system in Sweden the savings will have directly benefited patients 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.
- For Denmark, direct savings amounted to €16.2 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 turnover in the four import markets.

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

Denmark	11.7
Sweden	20.4
Germany	4.5 - 5
UK	10

The level of savings and differences between countries depends to a large extent on the national regulatory frameworks, which provide different incentive levels for using the cheaper imported product instead of the direct import from the manufacturer. In Germany, for example, the government requires that a given percentage of pharmacies' turnover comes from parallel imported products. In the UK, on the other hand, a claw-back 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 healthcare system through the claw-back.

This study highlights these regulatory differences between national markets and their effect on the level and distribution of savings. By doing so, we illustrate 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.

Though the present study employs a methodology similar to that of the York study, it finds that compared to the 2001 estimates by York University, savings have decreased, most notably in Germany and UK. Changes in regulation, such as the strict price control in Sweden and the change in PI-quotas and the 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 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, frequent variations in marketing authorisation numbers, product differentiation (various pack sizes and brand names), multiple small batches and supply restrictions, ie. 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 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 value-added of parallel trade. While the data does not allow any specific results, the value chain approach does not suggest a supra-normal profit for parallel importers compared to other industries. In some cases it even appears surprisingly small.