

Price Strategy Bulletin

Are Parallel Import Savings Worthwhile? Another Report Fails to Convince

Introduction

'Unless parallel trade can operate dynamically on prices it creates inefficiencies because most, but not all, of the financial benefit accrues to the parallel trader rather than to the health care system or patient.'

Communication on the Single Market in Pharmaceuticals, European Commission, November 25th, 1998

Parallel trade's solitary justification for existence is to provide worthwhile savings to those who pay for prescription medicines in Europe. Such savings may arise directly, from parallel trade's lower price, or indirectly by stimulating a price competitive response from manufacturers. If lower prices fail to reach the payer – generally the social health insurance system/national health service and to a lesser extent the patient – in any significant amount then the reason for governments to manipulate the reimbursement system to either incentivise pharmacists to dispense parallel-traded forms or to penalize their non-use is questionable.

The size and destination of these savings have been hotly debated. A third multi-country, 72-page report on the topic has just been published by the University of Southern Denmark in Odense¹. This report, like the first one from the UK's University of York², was commissioned by the European Association of Euro-Pharmaceutical Companies (EAEPC), on behalf of parallel traders. In between, with the support of Johnson & Johnson, a study by LSE Health³ using different methodology reached completely different conclusions (see table).

Strong criticism of both the York⁴ and the LSE⁵ reports has appeared. This commentary will focus on the Odense study. This describes itself as 'a critical review of the theoretical arguments and empirical evidence concerning parallel imports', but is basically an update to 2004 of the York study. (Odense, incidentally, is the same city where Scandinavia's largest parallel importer Orifarm has its head office. Orifarm CEO Hans Bøgh-Sørensen is the current EAEPC President).

Table: Direct savings from parallel trade (€million)

| Country | York study* | LSE study** | Odense study*** |
|-------------|-------------|-------------|-----------------|
| Denmark | 16 | 3.0 | 14.2 |
| Germany | 194 | 17.73 | 145.0 |
| Netherlands | 32 | 12.76 | - |
| Norway | - | 0.56 | - |
| Sweden | 47 | 3.77 | 45.3 |
| UK | 342 | 6.89 | 237.0 |
| Total | 631 | 44.71 | 441.5 |

* estimates for 2002 (Denmark 2001)

** estimates for 2002 based on 19 molecules

***estimates for 2004

UK Savings Overestimated

At £160.7 million (€237 million), over half the total direct savings from the four countries in the Odense study are said to result from Europe's largest PI market, the UK. Yet this figure is a considerable over-estimate (as was to an even greater extent the UK figure in the earlier York report - it included discounts retained by pharmacies as savings to the NHS).

The Odense calculations are based on the UK government's average discount recovery (or clawback) of 10% on PI sales at reimbursement prices of £1,606.6 million in 2004. But what is ignored is that the clawback has separate components for domestic brands, unbranded generics and PI brands; each of these segments is calculated separately. A joint Department for Health (DoH)/PSNC (pharmacists) discount inquiry is used to estimate the separate savings from each. These are weighted by their sales value and summed up. Through such inquiries it has been determined that most of the weighting and hence most of the savings come from the discounts wholesalers give pharmacies for purchasing domestic brands. In contrast, the clawback contribution from PIs is relatively small.

Ostensibly on grounds of confidentiality, the DoH does not provide a breakdown of the current clawback, but figures obtained for 2000 are illustrative. At that time, based on the 1998 discount inquiry, the Department assumed PIs accounted for 4.63% of the market and offered average savings against NHS list prices of

17.43%. According to IMS, the total value of the Rx market in 2001 was £6,375 million, meaning the clawback attributed to PI use and recovered from pharmacy remuneration was just £51.5 million, a mere 0.8% of the NHS drugs bill. The bulk of the balance of clawback savings, over £500 million, came from recouping purchase profits made on domestic products - brands and generics.

Though parallel trade into the UK has grown greatly since 2000 this has not been reflected in a corresponding adjustment to the clawback scale. The most recent full discount inquiry in England was conducted in 2001. For years the mechanism of the clawback has been recognized as inefficient. Inquiries only used, via self-certification, a sample of 350 out of 10,500 pharmacies (with all Boots branches excluded). The parallel trade component was based on the difference between NHS list and PI market prices of just five products from five suppliers, whereas in reality there are over 30 active UK parallel traders each offering over 500 lines.

It is important to note that in the UK, in contrast with all other importing countries, the discount clawback is the only mechanism to realize direct savings from PI use. UK pharmacies are initially reimbursed the full list price of the domestic version irrespective of the source of the product dispensed.

UK government confirmation of the low level of PI saving was most recently given by Health Minister Jane Kennedy in a written parliamentary reply on June 6th, 2005: *'...from the data currently available, the Department estimates that parallel imports save the NHS in England approximately £60 million per year in the community sector.'*

Additionally, it is important to note that no saving at all from parallel trade reaches the UK patient

Other Countries

At €145 million, the Odense estimate for direct savings in Germany is described as 'exceptionally low due to temporary changes in the regulatory measures in 2004'. This apparently refers both to the increase that year in the manufacturers' rebate from 6% to 16%, which also had to be paid by parallel importers (it has now been reduced to 6% again) and to the demand that PI has to offer a 15% (or €15) saving to count towards the pharmacists' PI dispensing quota of 5% (though this requirement continues). A truly independent source, WIdO (the research arm of the Federal Association of Local

Sickfunds) calculated that PIs saved German statutory health insurance €56 million in the first half of 2002 (note that full year figures are not comparable due to regulatory changes during the year). Savings to patients were limited entirely to non-reimbursed lines.

Denmark and Sweden are much smaller markets, with commensurate tiny levels of savings from PI use. More importantly for the manufacturers concerned, PI usage is highly concentrated. Of the total Danish savings in 2004, one-third came from sales taken from the best-selling brand and 50% came from just three products. Similarly, the three top-selling products accounted for almost 40% of Swedish savings.

Despite it being PI's original market (with the trade achieving value penetration levels in double digits for decades) no estimate for savings from the Netherlands is given in the Odense report. This is unfortunate as even the York report found these to be small, with the average domestic product/PI product price difference as little as 3%.

While the York report relied on a few case studies to prove PI's competitive effect the Odense study attempts to quantify indirect savings for the top-50 best-selling products, but only for two countries: Denmark (€8.3 million) and Sweden (€16.4 million). How prices of domestic products would have developed in the absence of PIs is not known, the authors admit.

In these same two countries patients are said to financially benefit from parallel trade's lower cost, though it is arguable that under their "needs-based" co-payment structures this is not the case.

Valued-added?

Following criticism in the LSE report that parallel trade mainly benefits the traders themselves, the Odense study attempts to refute this by first developing a template of the value chain and then collecting price data on selected products in the four importing countries studied at different points along this chain.

"Value chain" is an unusual description of economically redundant and unnecessary activities such as re-importation, double transportation, removal, destruction and replacement of the original patient information leaflet and packaging material, regulatory re-examination, and duplicate

stocking of wholesalers' and pharmacies' shelves! Especially when there is no evidence that distribution by the originator of any product is insufficient to meet market needs.

The price margins at various levels in the parallel distribution chain (i.e. importer, wholesaler and pharmacy) are partly outlined. It was impossible to get good information from the exporting countries, so exporters' margins are missing. This is a serious deficiency. Anecdotal information suggests parallel exporters' gross margins are increasingly significant, in line with the rising problems they face in sourcing sufficient stock to meet importers' demands.

The case studies are anonymised and eyebrows might be raised at the claim that importers' price margins in the UK for more than half the products sampled are within the range 0-5%.

Implications for Strategy Development

Much of the past focus on the economics of parallel trade has been on how much is earned by the so-called "middlemen" – the parallel exporters, parallel importers, short- and full-line wholesalers, and community pharmacies. This has deflected attention from the small proportion actually saved by the healthcare system and especially by the patient. A 1% cut by manufacturers across Europe would more than offset the entire savings generated by PIs.

The PI trail can be long and convoluted – each participant wants his cut - and the costs faced by parallel importers – staff, premises, product search, legal and regulatory services, transport, repackaging materials, insurance, distribution, discounts and rebates to customers, write-offs, sales, administration, etc – can leave slim margins for the trade... and a few crumbs for the payer. Even these savings cannot be guaranteed, due to the difficulties of maintaining supply, price changes, and exchange rate movements outside the Eurozone.

Companies and their national associations should ensure payers realise they only recoup a small proportion of the wholesale selling price differential between the source and destination countries with parallel trade. Without adding value, the remainder is apportioned as costs and profits between the various actors in the parallel distribution chain.

Companies also need to react with a cool head to parallel trade and seek the advice of those who know the practice intimately.

Footnotes

1. The Economic Impact of Parallel Import of Pharmaceuticals, Ulrika Enemark, Kjeld Møller Pedersen & Jan Sørensen, University of Southern Denmark, June 2006. Available on the University's website at http://www.cast.sdu.dk/pdf/Parallel_import_rapport_13_06_1430_opdateret_final.pdf
2. Benefits to Payers and Patients from Parallel Trade, Peter West & James Mahon, York Health Economics Consortium, University of York, May 2003 (www.yhec.co.uk)
3. The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis, Panos Kanavos and others, LSE Health and Social Care, London School of Economics and Political Science, January 2004 (www.lse.ac.uk)
4. Parallel trade – the reality of payer and patient savings, Janice Haigh, Scrip 2858/5, 2003
5. LSE Study on Parallel Trade Seriously Flawed, Results Invalid, Says EAEP. EAEP press release March 25, 2004 (www.eaepc.org)

PriceSpective is an international firm of pricing strategy experts, focused on providing strategic guidance in pricing and reimbursement to the pharmaceutical and biotechnology industries. PriceSpective has specific expertise on a wide range of policy and practical parallel trade issues, including development and implementation of an effective methodology for supply allocation.

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