



THE ECONOMIC IMPACT OF PHARMACEUTICAL PARALLEL TRADE

A Stakeholder Analysis Key Study Findings

The LSE study showed that parallel trade has increased considerably over the period 1997-2002 for many products/therapeutic classes, and particularly those involving novel or patent protected molecules. With specific regard to the 5 key hypotheses identified by the LSE, the study's findings are as follows:

1. Cross-country effect: Parallel trade leads to price equalisation across countries – ‘arbitrage’ leading to more efficient market operation: There are significant differences between acquisition prices in source countries, and list prices in destination countries, and prices of parallel traded products are frequently marginally below those of locally sourced products; in source countries, concerns have been raised about medicine shortages due to parallel exports (e.g. Greece, which has a parallel export market valued at 21% of the retail market, and where the regulatory authority has issued circulars expressing concern over export impact and product availability). There are also signs of relative un-ease about the extent of parallel trade in other traditionally low-price countries, particularly Spain and France; both seem to be taking (or to have taken) measures to account for the extent of parallel exports from their territory. By contrast, traditionally high-price countries seem to have mature policies, which also enable them to benefit somewhat from this activity (especially the UK, the Netherlands, Germany, Sweden and Denmark). Overall, the study has found no evidence that arbitrage could lead to price equalisation across borders and to more efficient market operation.

2. Destination country effect: Increased price competition in destination countries reduces overall pharmaceutical prices, benefiting payers and patients: In destination countries, the average price spread between locally sourced and parallel imported products is small. The coefficient of variation does not show significant changes over time, pointing at no price convergence for the majority of products examined. Instead, there is co-movement between prices of parallel imported and locally sourced products over the 1997-2002 period. Different systems of pharmaceutical pricing and reimbursement additionally contribute to this scenario, as does the fact that parallel traders maximise their revenues by offering their products at a similar, or slightly lower price to that of locally sourced product in destination countries. As a result, health insurance organisations accrue only modest direct savings (which were as follows in 2002 and in €'000):

| | Norway | Germany | Sweden | Denmark | UK ¹ | Netherlands ¹ |
|-----------------------------|--------|---------|--------|---------|-----------------|--------------------------|
| € | 500 | 17,720 | 3,382 | 2,980 | 6,887 | 11,620 |
| € ¹ | - | - | - | - | 55,887 | 18,798 |
| % Total market | 0.35% | 0.8% | 2% | 0.6% | 0.3% | 2% |
| % Total market ¹ | - | - | - | - | 2.4% | 3.2% |

Note: ¹Includes estimates for the clawback.

3. Aggregate welfare effects: If price competition is the result of parallel trade, then the resulting price convergence may lead to overall welfare improvements for payers: The study finds modest direct savings to payers. Where administrative measures are introduced by institutional players to exploit price differences, these may violate EU competition rules (e.g. Sweden). In addition, prices of parallel imported and locally sourced products in destination countries show patterns of co-movement over the 1997-2002 period, suggesting that there is no price convergence and indicating that possible indirect benefits from parallel trade through long-term price competition range from weak to non-existent. The study thus shows no evidence of sustainable dynamic price competition in destination countries, with no corresponding indirect cost savings to payers. Pharmacists benefit only where pharmacy

margins are not determined by regulation, or where there is a financial incentive from dispensing a parallel-imported medicine. Measurable direct benefits are outlined below in € '000, although the extent of discounts from wholesalers to pharmacists cannot be known with precision and varies by product.

| | Norway | Germany | Sweden | Denmark | UK ¹ | Netherlands |
|-------------|--------|---------|--------|---------|-----------------|-------------|
| € | 500 | 0 | 0 | 0 | Positive | 5,902 |
| % of market | 0.35% | | | | | 1.2% |

Note: Excludes revenues for pharmacy from discounts on NHS price; these are product related.

4. Patient benefits: Patient access to innovative medicines is improved, with lower direct and indirect costs: With regards to patients, no clear benefits through lower prices were found. Even if price differences are visible and significant, the structure of cost-sharing arrangements in the study countries is such that the patient is not aware of the cost of medicines, and, therefore, s/he does not benefit from lower prices. In Denmark only are direct savings found but these are marginal. Consequently, patient access to safe, effective or innovative medicines is neither compromised nor enhanced through parallel trade.

5. Industry impact: Parallel trade has minimal impact on the pharmaceutical industry as a whole, in terms of profitability and potential to innovate, and indeed, improves overall industry efficiency: The study demonstrates that pharmaceutical manufacturers incur a significant loss of business in destination countries from the conduct of parallel trade. Parallel trade implies a transfer of producer surplus and reduces manufacturers' overall profitability, without necessarily increasing social welfare. Reduced profitability potentially affects the ability of industry to innovate and may be a contributory factor to downsizing in source countries over the medium term. The dynamic implications of continued trends in parallel trade may be that manufacturers will be reluctant to produce and/or launch in countries presenting significant parallel export potential. Over the long term, parallel trade may therefore force industry consolidation and the concentration of manufacturing and R&D into fewer locations.

6. Parallel traders: Overall, the study demonstrates that parallel traders are the main beneficiaries of parallel trade. Their direct (gross) maximum benefits (shown below in € '000, for 2002) exceed considerably those accruing to statutory health insurance organisations. These benefits are invisible to the latter.

| | Norway | Germany | Sweden | Denmark | UK | Netherlands |
|----------------------|--------|---------|--------|---------|---------|-------------|
| € | 2,832 | 97,965 | 4,707 | 6,108 | 518,013 | 47,688 |
| € ¹ | - | - | - | - | 469,450 | 40,692 |
| Mark up | 16% | 46% | 12% | 38% | 54% | 51% |
| Mark-up ¹ | - | - | - | - | 49% | 43% |

Note: Includes estimates for the clawback.

Summary

The lack of sizeable direct benefits to health insurance organisations, the absence of price competition in individual markets, the existence of reported product shortages in some member states, and the extent of benefits accruing to parallel traders, may force policy-makers at national and European level to re-evaluate the rationale behind parallel trade, the dynamic impact it may have on patients in some member states and on the research-based pharmaceutical industry in terms of location, manufacturing and research.