

Price Strategy Bulletin

Factors Impacting Future Parallel Trade Growth

Introduction

The failure by the European Court of Justice (ECJ) in *Syfait* (case C-53/03) to follow its advocate general in clearing GSK in Greece of breaching EU competition rules came as a major disappointment to the industry. Together with an earlier ECJ decision in *Adalat* (C-2/01P & C-3/01P), the go-ahead to strangle parallel trade at source might effectively have been given. But it didn't happen, and the trade continues, as do other measures designed to inhibit it. This brief looks at some of the future drivers and restraints.

Impact of National and EU Institutions

Measures taken by national authorities will continue to greatly affect parallel trade either way. The requirement under the 2004 German healthcare reforms for parallel trade to offer a minimum 15% or €15 saving to fulfil the pharmacy dispensing quota had a marked negative effect on usage, as did the price modulation provisions of the 2005 PPRS in the UK. Conversely, the trade was boosted by new substitution rights in Finland and a Danish requirement to base reimbursement on the cheapest synonym.

The attitude of EU institutions is also likely to be mixed. A second Commission Communication on parallel trade was issued by the Directorate General (DG) Internal Market last year. This reaffirmed its legality and summarised case law on trade mark matters. Responsibility for enforcing the EU principle of free movement of goods has since passed from Internal Market to Enterprise and Industry, a DG with far less empathy for parallel trade; its Unit F2 also takes the lead on pharmaceutical issues. The Commission's DG Competition has been parallel trade's staunchest ally, but over the past few years it has been reluctant to act against manufacturer supply limitations, reportedly sitting on over 40 complaints, whilst awaiting judgements from the ECJ, first with *Adalat* and then with *Syfait*. There is no obvious champion for parallel trade within the European Parliament, and ECJ decisions are increasingly difficult to predict.

Factors Favoring Continued Growth

More Products Affected

Supply shortages with blockbuster brands are forcing traders to seek opportunities with a larger number of second tier products. Historically, parallel trade has disproportionately impacted a handful of manufacturers, but in the future a wider range of firms and products will be affected.

Fears have been expressed that the equivalence criterion between the domestic version and the import has been seriously weakened as result of ECJ rulings (C-201/94 & C-112/02), even to the extent that a generic drug, parallel imported from a country with no data protection, could be licensed to compete with an innovative brand. Another series of ECJ decisions (C-172/00, C-15/01 & C-113/01) have blocked the possibility of reformulation requiring the trader to withdraw the original.

More Destination Countries

All of the 28 states of the European Economic Area (i.e. the EU-25 plus Iceland, Liechtenstein and Norway), even traditionally low-price markets, are today targets for incoming parallel trade.

From its origins in the UK and the Netherlands, it first spread into Germany, throughout Scandinavia and into Ireland, but is found today in many other destinations as well, including Austria, Belgium, Cyprus, France, Greece, Italy, Malta, Poland, Slovenia and Spain. Sales are often limited in this latter group of countries by the small current number of parallel trade approvals and their non-reimbursable status, but the mere threat of parallel imports is used by traders there to lever more important supplies for parallel export out of local wholesalers.

Abandonment of the Single European Price

Industry had been hoping that visible price differences for the same product across the EU could be eliminated, along with the parallel trade that accompanies these differences, by a system that combines free 'facial' pricing with rebates paid directly to poorer states. While some countries, notably France,

offer limited opportunities for this approach, the prospects of achieving its pan-European roll out have receded. The future for other variants of dual pricing seem equally problematic, though much will depend on an appeal by GSK Spain against a 2001 Commission decision before the EU Court of First Instance (case T-168/01).

What remains clear is that price optimisation at the European, or increasingly at the global, level must continue to be part of the strategy of every multinational manufacturer.

Conditions for Repackaging Clarified

Repackaging has long been favored by traders. The alternative, over-stickering, meets customer resistance and is more labor-intensive in production. Manufacturers are legally entitled to be given advance notice of commercialisation of any new parallel trade product and to request a sample for examination. Much of the argument has centered on the necessity for repackaging and the impact on trade mark owners' rights. In a case referred by the UK Court of Appeal, the ECJ is expected to give a ruling soon that could greatly clarify the situation. While there is already considerable jurisprudence in this area, the ECJ has been asked to 'provide a single comprehensive code setting out all the rules'. For the first time it will look at over-stickering.

The requirement under the new human medicines Directive for the use of Braille on labelling is likely to be cited in support of re-boxing by parallel traders.

Factors Favoring Decline

Manufacturer Supply Restrictions

Over the past three years these have become increasingly common, and are viewed as being among the most effective counter-strategies, but need careful design and implementation. The aim is to allow fulfilment by wholesalers of only those orders necessary to supply the domestic market.

Tighter Regulatory Oversight

All parallel trade now requires a second regulatory assessment before marketing.

Each member state operates a simplified marketing authorization process for products that have received full marketing approval through the national route elsewhere. It should be noted that there are very large inter-state differences between these

schemes, with harmonisation not on the agenda.

Products approved centrally by the EMEA are by definition authorised for sale throughout the EU, but a linguistic compliance check on the labelling/patient package insert by the EMEA for those products distributed in parallel has been mandatory since May 2004. This checking process results in issuance of a parallel distribution notice. The marketing authorisation holder is informed of the notice by the EMEA, so it is possible to verify whether parallel trade forms of central approvals have been through the procedure or not.

Barrier to Sourcing from New and Candidate Member States

East-west parallel trade after 10 new member states joined the EU in April 2004 has been very limited. While this was the intention of the 'specific mechanism', written into the accession treaties of 8 of the 10 (Cyprus and Malta were exceptions), it has come about mainly as a result of legal uncertainty, as the wording of the mechanism is highly ambiguous. It is supposed to operate on a case-by-case basis as long as there are differences in patent/SPC protection between the incoming and older member states. Traders are fearful of putting it to the test. The Commission has declined to issue guidance and clarification may only come over time through the ECJ.

Both Bulgaria and Romania will be subject to the specific mechanism when they join in 2007, as will any subsequent EU entrant with lesser IP protection than the west. West-east parallel trade is unaffected, whilst the legality of that between the new member states themselves is one of many imponderables in the specific mechanism.

Growth of Generics

It is often forgotten that parallel trade is the least stable segment of the pharmaceutical market, and not just in terms of the total volumes traded. A trader's portfolio is constantly changing, with established lines being discontinued and new ones added. Apart from supply shortages, one of the main reasons behind product exits is patent expiry. Parallel trade is almost exclusively a business in original brands. It rarely survives for long a twin attack from innovators and generic copyists.

Manufacturers Regaining Control of Distribution

The role of wholesalers with parallel trade is vital. They are the main suppliers of it and the main customers for it. When full-line wholesalers began to stock parallel imports, first in the UK and later in Germany, marked surges in the level of trade were evident. Wholesalers gave the products respectability, ease of ordering and the convenience of twice-daily delivery. Whether for reasons of lower costs or higher control, there is now a trend for more manufacturers to review their channels of distribution.

Implications for Strategy Development

Parallel trade in Europe has been a thorn in the side of industry for over 30 years. Despite numerous efforts to curtail it, the business is still going strong, and affecting record numbers of countries and brands. With an all-time high EU market penetration of 5% it leads to an estimated annual net revenue loss of €2 billion (\$2.4 billion) for the R&D sector.

As well as direct sales losses in the more profitable markets, parallel trade – or just the threat of this -- constrains launch prices and price increases. Products and markets which previously would have been considered low risk may now be much higher risk. Most notably, the concept is being strongly promoted for introduction in the US.

It is wrong to think that nothing more can be done, but equally it can be very wrong to do something without thoroughly thinking through the strategy, implementation and follow-up. This can be wasteful, and even counterproductive, risking the huge expense and uncertainty of lengthy litigation. The parallel trade business, traders themselves argue with some justification, has been justified and built up largely from failed attempts to stamp it out.

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 in-depth expertise on price and non-price strategies to address parallel trade.

*Donald Macarthur, PriceSpective Ltd, U.K.
+44 1444 811888
dmacarthur@pricespective.com*

*Keiron Sparrowhawk, PriceSpective Ltd, U.K.
+44 1763 273949
ksparrowhawk@pricespective.com*

*Nigel Gregson, PriceSpective LLC, U.S.A.,
+1 610 862 6021
ngregson@pricespective.com*

*Stuart Tutt, PriceSpective Ltd, U.K.,
+44 1689 857 221
stutt@pricespective.com*