UK parallel trade – unparalleled change

Carol Alexandre and Nigel Seear at IMS Health discuss the challenges posed by recent developments in parallel trade to patients and the pharmaceutical industry

Dizzying developments in global financial markets have masked the radical changes also taking place in European pharma markets where dynamic changes in cross-border trading are creating risks to patients’ lives and posing additional challenges for pharmaceutical companies and regulatory bodies alike.

Across Europe, parallel trade, worth an estimated €4.7bn per annum (UK, Netherlands, Belgium, Denmark, Norway, Finland and Sweden), is now growing at five per cent a year – faster than the overall growth (3.9 per cent) of the European pharma market (source: IMS European Parallel Trade Database, August 2008). The trade occurs as distributors arbitrage the price differences across the European Union and repackage medicines intended for use in one country for sale in another country.

Price differentials in medicines across European countries have combined with the sharp dip in the value of sterling to make the UK one of the cheapest countries in Europe to buy pharmaceuticals. As a consequence a large, viable, albeit controversial parallel export (PE) market has developed out of the UK, which has also witnessed a sharp decline in parallel imports (PI). A new generation of trading...
pharmacists (IMS estimates that around 10 per cent of the UK’s 12,500 pharmacists are now exporting products either directly or indirectly through third-party license holders) have joined other parallel exporters including wholesalers to create a mixed model (PI and PE) market place.

WHAT’S HAPPENED TO UK PIs?
Traditionally the UK has been the largest PI country in Europe – at their peak parallel imports into the UK were valued at around £1.7 billion. Today, although the UK remains the largest market for PI in Europe in volume terms, in the last few months it has taken a big step towards being a ‘mixed’ market with PI and PE co-existing but with PI becoming much less significant. IMS forecasts this trend will continue for at least the next 18 to 24 months as the new PPRS is introduced and the exchange rate continues to weaken against the Euro.

As the exchange rate has declined, IMS reports that the top 20 PI products in the UK have witnessed a dramatic decrease in market share falling by more than 30 per cent in the latest six months. This fall in PI market share followed the decrease in the Euro/sterling exchange rate (see graph 1 below).

It is no surprise then that wholesalers are struggling to source PI products with a suitable margin.

Some of the larger importers took early advantage of the currency changes and hedged their options by buying Euros. As the strength of sterling declined, their margins were covered by the fact that they had a significant holding of foreign currency so enabling them to offset the lost margins on future imports. These forward-thinking importers also seemed to have the view that they would be able to take advantage of smaller importers going out of business and so they increased their import volumes while they had the opportunity. This planning paid dividends in the short term, but it won’t be possible to roll this activity forward without further major currency fluctuations. With foreign currency reserves dwindling, IMS anticipates that PI will continue to fall.

While parallel importation into the UK has slowed and will continue to fall, IMS nevertheless expects the trade to remain attractive to some importers, which include pan-European wholesalers. Drivers for this continued trade include:

• Differing pricing and reimbursement policies within the EU, with price differentials aggravated by increasingly tough pricing policies in several markets; furthermore there is no real sign or prospect of price convergence in the EU.

• The clawback system that encourages retail pharmacists to dispense parallel imports – although pharmacists are the main beneficiaries of parallel trade, the UK authorities will be reluctant to discourage it because of

1. GBP/EUR EXCHANGE RATE V PI SHARE FOR TOP 20 PI PRODUCTS*

*Top 20 PI Products BPI Sept 08
the savings generated for the NHS through the clawback.

- The sophistication of the trade, which is a well-established business run by major operators including, but certainly not limited to, vertically integrated pan-European wholesaler/pharmacists.
- The speed and efficiency of the UK licensing system for parallel imports.
- Increasing use of parallel imports by hospitals. Products previously thought immune to parallel trade, (eg, injectables, products requiring cold chain distribution, specialist products and hospital-only products) will be increasingly targeted by traders, especially as these products tend to be high-priced and as manufacturer tactics restrict supplies of major retail brands.
- Legal endorsement of the right of parallel importers to repackage original products.

Currently wholesalers are legally able to move pharmaceuticals across the EU’s open borders - subject to ensuring the correct language is used on packaging and information leaflets. This may, however, be set to change. Günter Verheugen, EU Trade and Industry Commissioner, has recently proposed the introduction of repackaging controls as a means of clamping down on the trade in counterfeit medicines.

It remains to be seen though whether growing concerns in some quarters over counterfeiting will hinder parallel trade. Manufacturers are pushing for a number of changes to combat counterfeiting that would also have an adverse impact on parallel importers. A new, industry-funded organisation, the European Alliance for Safe Access to Medicines (EAASM), claims that the trade represents a danger to European patients and that any added value from parallel trading goes largely to intermediaries, not to patients or payers. It further maintains that repackaging undermines the security of the supply chain. However, recent reports suggest that the legislation’s process concerning these proposals may be delayed until June 2009.

**WHAT IS DRIVING THE EXPORT BUSINESS?**

Although the exporting of pharmaceuticals by wholesalers is nothing new, the emergence of pharmacy level exporting is a new phenomenon in the UK. IMS estimates that around 10 per cent of pharmacies in the UK are now involved in exporting pharmaceuticals either directly or indirectly. The value of these pharmacy level exports is estimated to be £15 to £20 million per month. This is being driven largely by trading pharmacies purchasing additional low volume products in order to avoid manufacturer quotas and selling the product on for export purposes - the ‘skimming’ effect.

Rational, profitable trade arrangements between local traders and UK pharmacists – in some cases trading through a third party wholesalers’ dealers licence holder – have been stimulated by a combination of economic factors. Broadly this form of trade is driven by the price differentials across countries (patent medicine prices vary in different countries). Traders buy ‘low’ in these countries, transport the products, repackaged them in the language of the importing state, and sell them there at a higher price.
THE FALL OF STERLING
The credit crunch and the prospect of a recession in the UK sent sterling into virtual free fall. There have been four significant reductions in sterling’s value against the Euro in the last 12 months (see graph below) with sterling’s value falling some 20 per cent since August 2007. This decline meant that the 10 per cent price differential - considered as the margin at which parallel trade becomes viable - between the UK and Euro-Zone countries was breached and normal trade flows went into reverse, with Germany as one of the principal beneficiaries.

ECONOMIC PRESSURES ON UK PHARMACIES
Currency movements have coincided with growing economic pressures on UK pharmacies to seek new ways of generating income, which, as we highlighted above, has encouraged many to export stock either directly or indirectly.

The UK’s Pharmacy Contract, for example, which de-emphasises the volume and throughput of prescriptions in favour of the quality and range of patient services expected of community pharmacies, is currently the most well developed concept for a new, broader role of pharmacies. Whatever pharmacists may feel about expanding their advisory responsibilities, the development of enhanced services requires considerable additional investment in systems, time and training, and is not compensating for the reductions in supply profit underway. This adds to the growing financial pressure many pharmacists face arising from other trends in the market, particularly:

• Progressive erosion of over-the-counter (OTC) margins: Although pharmacies have maintained a majority position in the OTC market, IMS estimates that their market share may now have fallen to around 50 per cent and that most pharmacies now generate only between 10 and 20 per cent of their income from this source. Furthermore, the pre-discount OTC margin has been reduced from a traditional 33.3 per cent on return to as low as 20 per cent, in the case of some products, over the last 20 years. The prescription margin is below cost (negative) for branded ethnicals, although still around 40 per cent on return for generics.

• Potential blocking of discounts: There is growing debate around the ability of pharmacies to receive additional discounts, especially in relation to generics which in countries like the UK are essential to pharmacy profitability. The payer will allow certain discounts but will then take them into consideration when setting pharmacy remuneration, and ‘claw back’ a substantial portion.

• Growth of mail order: Although still in its infancy in Europe compared to the US, where 22 per cent of prescription sales are filled via this route, mail order is starting to build up in the region. While mail order prescriptions in the UK are still unable to offer a competitive advantage to consumers in the UK, as there is no co-payment for ethical prescription products, the threat remains from both ethical and unethical internet suppliers. UK pharmacies have been responding to this by steadily moving into this space where they are...
being subjected to close monitoring. Most internet-based businesses, however, operate outside of the UK and so remain beyond the reach of UK regulatory bodies, with no impact on UK NHS dispensing.

**CHANGES IN THE SUPPLY CHAIN**

Distribution networks are changing, becoming more complex, and as a result more aggressive forms to make money are emerging. As well as the growth of mail order, direct-to-pharmacy (DTP) arrangements such as those introduced by AstraZeneca and Pfizer are emerging which not only challenge the business model of traditional wholesalers, but effectively allow manufacturers greater control over their commercial terms with pharmacies. Despite this, manufacturers with DTP schemes have not been immune to the effect of PE (see graph 4 above).

**NEW PPRS**

The Pharmaceutical Price Regulation Scheme (PPRS) applies to all branded medicines sold in primary and secondary care. Under the PPRS, companies have the freedom to set a price for a new drug on entry to the market, with the proviso that there is not an unreasonable delay or discouragement of the production of generic forms when the patent ends. Companies that don’t join the scheme are subject to statutory price or profit controls, which include the power to make price reductions.

When the new PPRS comes into effect at the beginning of 2009, manufacturers will modulate their prices in order to maximise their return. However, in all likelihood they will not announce those price changes until the last moment. This creates price uncertainty for wholesalers and pharmacies who will then take the decision to de-stock in the lead up to the beginning of the year in order to avoid the commercial losses arising from holding stock. Lower prices under PPRS will further stimulate the export trade and compound the shortages of stocks.

Although the Department of Health has delayed a key part of the new PPRS, the move is unlikely to go far enough to allay fears that the country will face drug shortages this winter. The DH has said that it is delaying new PPRS rules relating to off-patent medicines, which were set to start in January along with rest of the agreement. The new PPRS, which was agreed between the UK government and the Association of the British Pharmaceutical Industry (ABPI) in September, will force companies to reduce the prices of off-patent branded drugs if generic equivalents exist.

**THE IMPACT**

PE is not in itself a new trade - it can be traced back to the mid 1970s - what is creating the renewed interest and raising concerns in the industry is the impact of the increasing scale of this activity in the UK. The volume of PE is now generating many more unknowns, or risks, for the healthcare market.

Without effectively quantifying wholesaler and these pharmacy imports and exports, manufacturers are exposing themselves to:

1. Consequences of not meeting domestic (UK and export) demand
• Loss of product sales (to switched patients and missed new starts)
• Risk to patient health through non-compliance
• Damage to corporate reputation.

2. Consequence of not knowing true UK local demand
   • Inappropriate brand and portfolio strategies
   • Inefficiencies in sales and marketing resourcing.

Increases in PE - that began around April 2008 coinciding with the fall in sterling/Euro exchange rate - have accelerated and are now having a dramatic impact on stock levels held by wholesalers and pharmacists. Stocks of some drugs at UK pharmacies are now so low that some manufacturers have recently reported a very sharp increase in telephone enquiries from pharmacists trying to obtain additional supplies of potentially life-saving products to meet the needs of their patients.

As the pattern of PE evolves, so IMS is continuously looking at ways to ensure it keeps pace with these developments and find ways to measure accurately the size of local markets.

IMPACT ON PATIENTS
Although legal, parallel trade is controversial because it may contribute to medicine shortages that may then deprive some patients of their treatments. With stocks of medicines at UK pharmacies being diverted to overseas markets - and parallel imports continuing to fall away - severe shortages of some drugs are anticipated by many stakeholders in the UK this winter, particularly of those most commonly prescribed.

These shortages are likely to be compounded by the fact that December is the busiest time of the year when demand is at its highest with patients stocking up to cover the Christmas to New Year period. At the same time, wholesalers will de-stock in December so as to avoid huge financial losses as a result of PPRS.

Industry insiders are claiming that the gravity of this situation has not yet been registered by the Department of Health or indeed by some manufacturers. Jeff Bulmer, Pharma Services Director at AAH Pharmaceuticals said: “Manufacturers may not have seen the scale of a problem which is growing by the day, but now is the time to recognise the problem and act.”

While PI trade into the UK will continue for the reasons given, there are major hindrances to increasing parallel importing into the UK to deal with the shortages foreseen in the near term. These include:
• Manufacturers’ continued pursuit of the supply quota strategy, especially after legal rulings in the EU have rejected challenges to this.
• Dual pricing - Pfizer and GlaxoSmithKline have taken this approach in Spain, although the issue is still being fought in the European courts and this will be a risky strategy pending final resolution of the legal challenges.
• The continued weakness of sterling against the Euro.
• Adoption by manufacturers of direct-to-pharmacy distribution schemes.
• Further patent expiries on leading products.
• The possibility of a ‘weighted’ price cut, especially if a renegotiated PPRS were to retain the ability for manufacturers to modulate prices across their product ranges.

**IMPACT ON MANUFACTURERS**

UK patients are not the only group to feel the impact of these developments. The effect on the pharmaceutical industry itself is already highly significant. IMS has concluded that more than 50 of the top 200 products have shown evidence of parallel exports. And with many brands experiencing unanticipated demand for product for export, questions arise about whether the industry will be able to meet its ‘duty of care’ to its UK patients and increase production of UK packs to meet demand.

Where the supply of a product to wholesalers and pharmacists fails to keep pace with demand there is evidence of prescribers switching to other products (see graph 6 above). For some manufacturers such loss of brand loyalty may be hard to recover from, or worse, reputational damage may follow.

Manufacturers need to recognise that the nature of demand in the UK has changed and therefore the assumptions on which their quotas are based need to be reviewed urgently.

Unfortunately, the historic market data available to manufacturers does not highlight the changes in demand that are taking place in practice and so not all manufacturers may see the scale of the problem in the way wholesalers can. Yet the need for manufacturers to recognise the problem is pressing if they are to have sufficient time to react and mitigate the risk of shortages this winter. It will take time to ensure they have sufficient production capacity for UK demand and they may have to shift capacity from one country to another.

Increasing production to meet this exceptional demand in the UK is not the simple win-win solution some suggest though. As one manufacturer recently said: “Increase production... by how much?” This question highlights the principal concerns of manufacturers. As they lose visibility around the real size of the domestic market so production, distribution, as well as compensation and performance processes become harder to manage efficiently. Furthermore, since they can no longer be sure in which country their original product is used, they become further removed from the patient and arguably less able to provide them with an appropriate level of service.
WHAT DO MANUFACTURERS NEED TO DO?

There are five clear steps that need to be taken. Manufacturers need to get visibility of the current PI and PE levels. Production planning needs to take into account the true local demand that includes UK consumption and exports. In addition to this, a measure of stock levels at both wholesaler and pharmacy can be used as an early predictor of out of stocks. Planning for risk scenarios will ensure that companies have plans in place to ensure that the stock flow is maintained and patients’ access to vital drugs is secured. There are challenges to achieving a smooth UK supply:

- Effective production planning requires a robust measurement of PI and PE at both a pharmacy and a wholesaler level.
- Effective stock monitoring requires measurement of stock risk at a pharmacy and a wholesaler level.
- Effective scenario planning to mitigate event risks requires analogue studies and primary research to assess size, timing and likelihood of risk.

A simple structured approach is needed (see table 7 above).

CALL TO ACTION

The time to act is now. Parallel exporting is on the increase and will be further impacted by PPRS and potential further weakening of sterling.

Only by understanding the current dynamics can pharmaceutical companies plan for the future and minimise the risks to their business in such critical areas as forecasting, strategic planning, stock management and compensation. Pharmaceutical companies are entering a new world where the penalties of the wrong decision or non action will be severe.

Despite the complexity of the market, IMS has recognised the issues and is seeking ways of partnering with the pharmaceutical industry to help deal with the emerging problems. Information and intelligent insights remain critical to helping to resolve the current crisis in parallel trade. By bringing stakeholders together to build a deeper understanding of the picture of local demand, IMS will play a key role in helping to find solutions that are acceptable to all stakeholders.

To learn more about how parallel trade could affect you, please email your questions to answers@uk.imshealth.com