theory, especially when you consider that parallel distribution accounts for less than 2% of the whole European pharma market. I can't see we are that damaging, especially when much of the research is done by academia.'

Pfizer has been particularly vocal in blaming parallel distribution for the rise in counterfeit drugs. In a recent article the company cited research by the independent think tank SMF that said parallel distribution complicates the supply chain and leaves it open to abuse (*Manufacturing Chemist*, November 2005, p22). Freudenberg disagrees here too. No cases of counterfeit drugs have ever come to light via parallel importers, he says. He adds that despite reports in the press of convoluted supply chains, more than 90% of parallel distribution medicines come directly from the national laboratory via the wholesaler in the exporting state and a complete audit trail has to be maintained for every batch a parallel trader repackages.

audit trail

'We control things through batch numbers. This means that, whereas wholesalers would have to do a blanket recall, if we need to do a [batch] recall we can because we have all the records tracing it back to its European source. No one else in the industry, including the wholesaler, does that. So we say we add an extra level of safety to the supply chain.'

He even claims that the parallel trader will often filter out manufacturers' mistakes – products packed with the wrong leaflet or blisters with missing capsules – providing a 'secondary check'.

It is widely thought among parallel traders that Pfizer has an agenda to protect its investments in the US where parallel importation or re-importation is not yet legal but where there is a growing call for it.

'We believe there is political pressure in the US to force [parallel trade] through. Prices in the US are three to four times what they are in Europe, so a lot of socially deprived people can't afford medicines that are available freely to Europeans. There is mounting political pressure for the market to open up,' says Freudenberg.

While not all pharma companies may be as vocal as Pfizer, they are nevertheless keen to protect their margins and will attempt to restrict parallel trade in subtle ways. They may use trade mark and IP rights to prevent the importer from using the same product name, insisting they use the foreign name, or if a manufacturer finds a product being parallel traded it may stop selling that drug to a particular wholesaler.

Since about 2003, manufacturers have started to apply 'global supply strategies' that limit the amount of product in each market, providing just enough to satisfy purely the domestic market or restricting how much product wholesalers can buy. They may even close an account with some smaller wholesalers, claims Freudenberg. Such restrictive selling practices are regarded by the BAEPD and its sister body, the European Association of Euro-Pharmaceutical Companies (EAEPC), as an abuse of Articles 81 and 82 EC. The latter body has some 30 complaints before the EC waiting to be heard.

Most worrying of all is the recent introduction of dual pricing. In Spain, for example, there may be one drug price allowed for the domestic market and a higher price for export. Contracts are being introduced by one major manufacturer that specify that only if the wholesaler can demonstrate that it has sold all of its product on the domestic market will it get a rebate in line with the lower price of the drug.

> "We control things through batch numbers. This means if we need to do a recall we can because we have the records tracing a drug back to its European source"

'It's a very worrying development because, if they are allowed to get away with this, other manufacturers will follow suit,' says Freudenberg. 'The EAEPC has made a complaint to the Commission and we await their response.'

Meanwhile, the debate on pricing continues in the UK. Since the 1950s the Pharmaceutical Price Regulation Scheme (PPRS) has set the price that pharma companies can charge for their medicines and the UK government effectively caps that price.

Some time back a PPRS review requested a 7% blanket decrease in prices, but did not stipulate that this was to be across the board. This meant that the manufacturers did not have to take the same amount off every product: they could reduce the price of individual products as much as they liked, providing that overall they achieved the 7% drop. 'They used that modulation process to target parallel trade products,' claims Freudenberg. 'The Office for Fair Trading (OFT) is looking into the efficacy of the PPRS and we have made a recommendation that it is referred to the Competition Commission.'

On the other hand the ABPI, which represents UK pharmaceutical manufacturers, is fighting to maintain the status quo. Director general Richard Barker said recently: 'In our future discussions with the OFT we shall emphasise the case for stability in the UK market environment. A radical overhaul could fundamentally undermine the reputation for stability that has underpinned the UK's attractiveness as a location for global research and development investment'.

Whatever the outcome, the changing nature of the market is forcing parallel traders to broaden their range of products. 'A parallel trader lives by his licences; he has to refresh his portfolio all the time. A successful importer needs around 500 licences,' says Freudenberg.

Traders operating in the UK are being frustrated, however, by the time taken by the UK MHRA to grant an MA. The agency has seen its workload steadily increase and the accruing backlog has been exacerbated by the slow implementation of a new 'online' authorisation system.

MHRA backlog

The parallel traders have to pay the MA fees in advance, and the recent delays mean that the marketing opportunity may well have gone by the time the licence is granted.

'When they are performing to type we would expect [the MHRA] to issue around 250 licences a month.' says Freudenberg. 'However, they installed a new IT system called Sentinel in August last year, and since that time they have encountered all sorts of difficulties. In that time only a little over 300 licences were granted in total in the six months between August 2005 and January 2006.'

Freudenberg sees the MHRA's problem as largely one of resources, and the BAEPD wants to see a change in the way the MHRA operates. The agency is in the process of reassessing its working practices and is looking to improve its service, but for the BAEPD, it is just one more business hurdle to overcome. ■

Profit/expense comparison for 2003 (US$m)

2003	sales	profits	marketing expenses	r&d expenses
AstraZeneca	18,849	4,111	6,856	3,451
GSK	35,163	11,850	12,403	5,279
MSD	22,485	6,831	6,394	3,280
Novartis	24,864	5,889	7,854	3,756
Pfizer	45,200	3,910	15,242	7,684
Roche	22,650	4,525	6,553	3,649

(Source: EAEPC compiled from annual reports of pharma companies)

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