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Drug groups fear parallel trade

When the Greek government cut medicine prices sharply last month, pharmaceutical companies complained of a knock-on effect on pricing throughout the European Union.

Only Novo Nordisk and Leo Pharma, two Danish pharmaceutical groups, went as far as refusing to comply with Athens, which imposed a 27 per cent average cut in patented medicines as part of its efforts to tackle the country's budget deficit. But others, including Merck of Germany, are watching developments closely.

The pharmaceutical companies fear not only a hit in their Greek revenues, but a fresh surge in so-called " parallel exports " - estimated to account for a tenth of Europe's medicine trade - elsewhere across the EU, undermining their margins in many larger and richer countries.

Europe's hybrid approach of free trade across the EU, where countries are left free to manage their own healthcare systems and prices, has created an arbitrage, or "parallel trade", in drugs worth several billion euros a year.

Repeated legal rulings in Brussels have left pharmaceutical companies largely powerless in fighting parallel trade, by upholding the rights of intermediaries - pharmacists, drug distributors and other traders alike - to participate.

They arbitrage by buying up prescription medicines in countries where they are priced cheaply, and then reselling them profitably with a mark-up elsewhere, but still below the official price in the countries to which they import.

"The Greek prices would be loss-making and our medicines would travel to other markets in a completely uncontrolled fashion," says Lars Sorensen, the chief executive of Novo Nordisk, which has tried to impose a universal price for its latest generation insulin products for diabetics.

But a new analysis from IMS, the healthcare consultancy, suggests that the grey market cross-border trade in drugs may slow in the coming months, even as more cash-strapped authorities impose fresh discounts.

Data collected by IMS shows that most "parallel import" markets are the wealthier northern European ones where the local medicine prices negotiated with manufacturers are sold at higher prices.

Germany alone accounted for 61 per cent of the total trade in March this year: over the preceding 12 months imports reached €3bn, up a quarter compared to a year earlier. The UK and the Netherlands accounted for another 12 per cent each.

But Per Troein, a consultant at IMS, says that recent trends among the largest parallel importing countries will reduce their role naturally. The Dutch market has been been stagnant for three years. In the UK, a government imposed price cut and the weakening of sterling against the euro during 2009 meant that it was no longer a profitable market for arbitragers from other EU states for most drugs.

In fact, the relative shift in exchange rates made the UK - with some of the highest patented medicine prices in Europe - a net parallel exporter.

Similarly, Germany's domestic appetite for cheap medicines from Greece and elsewhere may also dampen in the months ahead, following newly introduced discounts that reduce the official prices agreed with drug companies supplying the country.

A requirement by Germany's healthcare funds for pharmacies to import about 7 per cent of their stock in order to reduce the drugs bill is also set to be abolished, further dampening demand.

But Mr Troein warns that these factors could be outweighed by new exchange rate shifts, which could stoke fresh demand for parallel imports elsewhere, including Sweden.

Some drug companies believe that recent price cuts in Greece, as well as in Spain, Italy and other low-priced markets, could help their case. They argue that while the cuts may boost parallel trade, they could at the same time highlight its iniquities, with richer countries benefiting and profits largely retained by traders.

The drug industry has done its best to stem parallel trade by imposing national supply quotas or exerting greater control over the drug distributors to whom they traditionally sell their products.

But in the end, direct intervention has achieved very little and pharmaceutical companies will hope that circumstances beyond their control dampen the grey market.

Financial Times 07/06/10

Special points of interest

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Asda to sell 'not-for-profit' cancer drugs, govt fund next April

The UK supermarket chain Asda says that it will sell all privately-prescribed cancer treatments at cost price, potentially saving thousands of pounds for sufferers.

The company, which is owned by US retail giant Walmart, says it is responding to the "three-pronged challenge" facing patients, the first being that a number of treatments have not been deemed to be cost-effective by the National Institute for Health and Clinical Excellence. Secondly, Asda refers to the problem of the 'post code lottery"; the latter has led to a situation where the annual spend per cancer patient across the 152 primary care trusts in England can vary by as much as 286% and determines the treatment people are eligible for on the National Health Service.

Thirdly, Asda says that its research compared the price of seven of the most common privately- prescribed cancer drugs available at the main high street pharmacies in the UK. This revealed mark-ups of up to 76%. The supermarket claims that Superdrug was found to offer the highest prices on four out of the seven drugs compared and marked up all seven by 50% over cost price. Prices at Lloyds Pharmacy and Tesco were consistently marked up by 20%, while at Boots, all seven drugs were marked up by either 50% or 27.5%.

Asda went on to say its research showed that 63% of people are unaware private prescription prices vary between pharmacies, and a "staggering 92%" have never compared the prices. The company went on to give examples, noting that AstraZeneca's lung cancer drug Iressa (gefitinib) is now available for £2,167.71 compared to £2,601.25 at Lloyds, £3,251.57 at Boots and £3,253.56 at Superdrug.

The supermarket added that it is working with suppliers to negotiate further discounts, with any savings passed directly on to customers as soon as they are available. John Evans, superintendent pharmacist at Asda, said that many people have had to spend their savings or re-mortgage to pay for essential drugs. Noting that "it's a small step in the right direction," he added that "we are the first retailer to recognise this injustice and to do something about it and we are calling on other retailers to follow our lead".

Tesco and Sainsbury's have responded quickly, saying they will match Asda's price, as has Superdrug. However, another major supermarket, Morrisons, told the *Wall Street Journal* said it has been retailing cancer drugs at cost price for two years already and therefore does "not need to engage in a price war".

Govt cancer fund to launch next April

The Asda announcement came just as Andrew Lansley, the new health secretary, confirmed that the coalition government will set up a £200 million Cancer Drug Fund, which will operate from April 2011 to improve access to treatments.

Mike Hobday, head of campaigns and policy at Macmillan Cancer Support, said "Asda's commitment is good news for people who can afford to buy cancer drugs privately but for the majority of cancer patients this simply isn't an option". He added that the government's fund "may go some way to ensuring fairer access to cancer treatments but wider reform is also needed to enable all patients to get the drugs their doctor recommends".

It has been reported that some 16,000 patients have been forced to pay for their own cancer drugs, though a spokeswoman for Asda told *PharmaTimes* that she could not confirm any figures.

Pharmatimes 21/05/10

WaveData — Top ten products

According to WaveData, these were the most commonly investigated products in searches of the online pricing data at www.wavedata.net

Both uk and pi prices were viewed for each product, giving some indication of where the focus was in May 2010

Omeprazole Caps 20mg 28

Gabapentin Caps 300mg 100

Losartan Tabs 100mg 28

Losartan Tabs 25mg 28

Losartan Tabs 50mg 28

Prednisolone E/C Tabs 5mg 30

Clopidogrel Tabs 75mg 28

Lansoprazole Caps 15mg 28

Losartan + Hydrochlorothiazide Tabs 50mg/12.5mg 28

Omeprazole Caps 10mg 28

Price falls are following a familiar pattern

Prices of generics after their UK launch have maintained a remarkably similar decay pattern over the past decade, according to recent research by WaveData. Price falls of some of the more recent launches may have seemed steeper - to reach lower prices relative to the brand more quickly - but the overall picture has remained similar for most of the bigger selling ingredients.

To see more go to

http://www.wavedata.co.uk/news2.asp and view our article from this month's Generics Bulletin.

Pharmaceutical Patent Intelligence

There is no question that patent protection on major products is a key issue in pharmaceutical circles. Some might say that it is the "king pin" of the whole industry. Without the protection of patents, which is merely a legal monopoly granted by the state, the pharmaceutical industry would not have flourished and developed into the success it enjoys today. The purpose of the patent is to grant the patentee exclusivity for a fixed period to enable return on investment and a reasonable level of profits. The period granted by most national patents is 20 years. In reality, because of the required interim procedures like clinical trials, licence submissions, etc., little over half of that time is actually available. Nevertheless, it has been sufficient to create a cash-rich industry. Because these initial and necessary procedures erode the patent duration afforded by most other inventions, legal mechanisms have been created to compensate for this shortfall. These are referred to as Pharmaceutical Patent Term Extensions which in Europe manifests itself as Supplementary Protection Certificates (SPC) and in the USA under Waxman-Hatch (Hatch-Waxman) legislation. Many countries throughout the world have adopted one or other of these systems. The net result is to provide up to an extra 5 years of patent duration.

Knowledge of these patents and their extensions is a vital piece of intelligence for those involved in the industry. The generic sector, which is one of the fastest growing areas in the industry, must treat this intelligence as essential. How many times have we seen in the press comments like ***"Pharma industry to lose $X billions in Y years through patent expiry"***. It is an emotive but inevitable truism that can be said at any time over the past several decades. The growth of the UK generic industry can be traced back to a provision in the UK Patent Act 1977 called "Licence of Right" which allowed access to patents prior to expectation.

With availability of such data becoming more extensive via the internet it is imperative that those needing such data not only have quick and accurate access, but are attuned to the significance of such data. That is where the professional investigator comes into the picture to provide such a service.

By Martin Paltnoi - 'Patent Expert' www.mpasearch.co.uk

UK may yank pharma's pricing power

Will drugmakers' ability to set their own prices in the UK soon come to an end? It could be, under a proposal now being floated by the new coalition government, *Pharmalot* reports. Officials say they're considering a "value-based pricing" model, but details of the proposal so far are scarce (or perhaps nonexistent).

The UK is one of the last markets on the globe where drug companies get to set their own prices. Under the country's current drug-pricing rules on the National Health Service, profits are regulated, not prices, *Reuters* reports. There's some downward pressure on prices, however, in the form of the National Institute for Health and Clinical Excellence, which evaluates medications for cost-effectiveness.

The new government says it's aiming to reform NICE and move to "value-based pricing." It's not yet clear just how those values would be determined, but analysts don't like it. "A price-control policy has not been fleshed out... but the fact that it has been mentioned... should be considered as the main--and perhaps inevitable--threat to the pharmaceutical industry in the U.K. going forward," IHS Global Insight analyst Milena Izmirlieva told *Reuters*.

The worry seems to be that value-based pricing could morph into full-on price controls. Morgan Stanley analysts called the idea "a wolf in sheep's clothing," saying it's bound to be negative for pharma in the long run. And depressed prices in the U.K. could have a ripple effects, as Reuters notes, because other countries often use U.K. prices as a reference point for setting their own.

Fiercepharma 25/05/10

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TIGHTENED DISTRIBUTION OF NOVARTIS LOW-VOLUME PRODUCTS BEGINS

Pharmacists will be required to order ten products direct from Novartis after the manufacturer announced it would streamline its supply chain.

From June 1 brands Aclasta, Afinitor, Exjade, Glivec, Myfortic, Sandimmun, Sandostatin LAR, Tasigna, Tobi and Zometa will need to be ordered exclusively through the manufacturer's Patient Priority Supply Service.

Novartis said the change would have "minimal impact on pharmacists" but would enable more effective management of stock of the medicines.

The shift had occurred because of the low volume of the drugs ordered in the community, with the list representing less than one per cent of Novartis products dispensed by the sector, the manufacturer added.

In April Novartis distribution arrangements came under fire from community pharmacists over demands for a faxed copy of a prescription before the manufacturer would despatch drugs in short supply.

Pharmacists can contact Novartis customer services on 0845 741 9442 with any queries.

CHEMIST AND DRUGGIST 01/06/10

This bulletin now goes out to1000 plus people, and it is growing each month.

If you would like to add or suggest any artcles/comments, please let me know by the 07th July 2010, as I will be issuing the next one on the 14th July 2010

If you have any colleagues who would like to receive this, please let them know about it.

You can view all copies of the Commercial Bulletin at www.wavedata.co.uk

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