

# Wholesale Bulletin

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## Novartis picks AAH and UniChem for supply deal

The pharmaceutical wholesale market could face an uncertain future if manufacturers continue to sign distribution deals with only the larger operators, European experts have warned.

Speaking at the annual general meeting of the European Association of Pharmaceutical Full-line Wholesalers (GIRP), Richard Barker, director-general of the Association of the British Pharmaceutical Industry, predicted more manufacturers would be striking distribution deals.

Dr Barker said economic pressure and a rise in counterfeiting were causing the companies to examine supply.

GIRP president René Jenny warned that if such deals "creamed off" margins for wholesalers on higher priced products, they would face problems funding distribution of lower priced generics.

He said: "This is our point of fear. We have to live with the market, that's clear, but we have to propose alternatives and other ways to continue to supply medicines, such as providing extra services."

UK wholesalers also expressed concern over the effect such deals could have on competition, and called upon the government to take action.

John Davies, retail services director of wholesaler Mawdsleys, warned a rise in deals with larger wholesalers could lead to "a lack of competition in the marketplace, which by now ought to be worrying the Department of Health very much".

Liam FitzGerald, CEO of United Drug, a wholesaler in Ireland, said changes would mean less choice for pharmacists

## Daiichi Sankyo acquires Ranbaxy

Japanese company Daiichi Sankyo is set to take over Ranbaxy, the largest manufacturer of generic drugs in India.

Ranbaxy will retain some autonomy as a standalone firm but handover nearly 40% shares in the deal at a cost to Daiichi Sankyo of up to \$4.6 billion.

The companies said uniting a generics and innovative pharmaceutical business will create a group that covers the full spectrum of the pharmaceutical sector, and open new opportunities for growth.

Takashi Shoda, president of Daiichi Sankyo, said the move

would help the company achieve its ambition of becoming a global leader.

He added: "This complementary combination represents a perfect strategic fit and delivers a considerable opportunity for the future growth of the new Daiichi Sankyo Group."

The deal allows Daiichi Sankyo access to Ranbaxy's low-cost R&D manufacturing facilities in India, which cut spending and improve margins on products.

The merged group anticipates its expanded global reach will provide new opportunities for the generic and branded side of its

business, in both mature and emerging markets.

Daiichi Sankyo, a company known for its high-blood pressure drug Benicar, also has an agenda to expand its presence in Europe. Last month it made the acquisition of U3 Pharma, a German biotechnology company focusing on research into antibodies for the treatment of cancer.

It has also recently purchased the European rights to the osteoporosis medication Evista from Eli Lilly.

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### Special points of interest:

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## Counterfeits are coming to a pharmacy near you.

Counterfeit medicines, generally made in China, India or the far east, are beginning to infiltrate the European supply chain, and might contain substances which might not just injure, but may kill patients in the UK.

Counterfeits have been found to contain toxic substances, no active ingredient, or the wrong amount of it. Prescription only medicines are increasingly being targeted, particularly expensive medicines for cancer, heart disease, psychiatric disorders and infections.



Counterfeits constitute between 40 and 50 per cent of total supply in Nigeria and Pakistan. In China, authorities have found that some products have a counterfeit prevalence ranging between 50 and 85 per cent.

Counterfeits often contain agents that are injurious to health, as for example when 89 people in Haiti died after swallowing cough syrup manufactured with diethylene glycol (a chemical commonly used as anti-freeze). This particular product was made in China, transported through a Dutch company to Germany, before winding up on the Haitian market. A similar case occurred in Nigeria in 1995, resulting in the death of 109 children and again in Bangladesh. The dangers of widespread counterfeiting were illustrated in 1996 during a meningitis epidemic in Nigeria. Some 60,000 people were inoculated with counterfeit vaccines, resulting in the deaths of 2,500 people.

"It is time for Europe to act as the driving force in the fight against this deadly crime," said EFPIA (<http://www.efpia.org>) Vice-President and Chairman of Sanofi-Aventis, Jean-François Dehecq. "Organized crime gangs operating on an international scale and playing with human lives in the name of profit must be dismantled through determined action, systematic prosecution and appropriate sanctions (civil and penal). Penalties in place in Member States today are inadequate. Administrative and operational tools and resources are required for effective law enforcement."

EU statistics released on 19 May 2008 show that a total of 4.081 million medicinal products (articles) were seized at EU customs borders in 2007. While internet-based sales are the main source of counterfeit medicines, these products are also appearing in the traditional supply chain.

Up until now the internet has been the main route into the high priced European market, but the counterfeiters have realised that if they can infiltrate the supply chain, they can sell a thousand packs at a time rather than one at a time on the internet.

Additionally the UK is the highest priced market in Europe, and thus the most profitable for the counterfeiters.

One essential component of any effective anti-counterfeiting strategy is the development of security features on medicine packaging. These security features include unique identification codes enabling the pharmacist to verify the origin of a medicine before dispensing it to the patient.

But under current EU rules, medicines can be re-boxed or re-labeled after they have left the factory or after importation into a new market. This means that efforts to put in place security features on medicine packaging are wasted.

The original package should remain untouched throughout the entire supply chain, from the time the product leaves the factory to the point that it reaches the patient. A ban on all forms of medicine repackaging is a prerequisite for an effective anti-counterfeiting strategy.

Liabilities should be more clearly defined for all involved in the distribution chain, including brokers, traders and agents.

Heavy penalties should be enforced for trafficking in counterfeits. Sanctions should be particularly severe when counterfeiting threatens public health. Medicines are not goods like others - fakes can kill instead of treating. The penalties should be at least as strong as for trafficking in narcotics (same criminal gangs switch from one business to the other).

Internet pharmacies are still the main source of counterfeit medicines; better consumer education is necessary as to the importance of purchasing medicines exclusively from the legitimate supply chain.

In addition to the development of security features on medicine packaging, individual companies are assisting authorities in different ways, for example by training officials to recognize fakes and by assisting with international police investigations.

EFPIA is making plans to launch a pilot scheme of a unique bar code system, which will enable the pharmacist to verify each medicine pack before dispensing it to the patient. This pilot will be launched before the end of 2008. The technology used - the 2 dimensional data matrix - is considered the best option today and could be used as an EU standard.

Another issue which has been raised, after the death of a Canadian woman whose internet purchase of counterfeits was found to be laced with heavy metals, is the possibility of terrorist attack on the west using toxic counterfeits.

If we are to avoid an attack which could make 7/11 look like a tea party, the supply chain will need to be counterfeit proof .



## **MHRA predicts more POM to P switches**

An MHRA director has signalled the UK medicines regulator's commitment to making more medicines available over the counter.

Drug reclassifications from prescription-only to pharmacy (POM to P) were "the most important innovation" in improving self-care, June Raine told delegates at a pan-European conference of the OTC industry.

The AESGP (Association of the European Self-Medication Industry) annual conference heard in Stockholm last week that the proposed POM to P switch of azithromycin was "looking very positive indeed". The MHRA post-licensing director highlighted pilots for the supply of OTC Viagra via local patient group directions, saying: "Let's watch this one."

Ms Raine also hailed the introduction of OTC nicotine replacement therapy, emergency hormonal contraception and simvastatin as "landmarks for public health".

## **Cough Drug Warning**

The Royal Pharmaceutical Society of Great Britain (RPSGB) has told pharmacists that they have two years to prove that they can properly control the sales of certain cough and cold medicines. Products containing pseudo ephedrine/ephedrine can be used to manufacture crystal methamphetamine (crystal meth) and according to the RPSGB, the process is relatively simple for anyone with knowledge of medicinal products. The Medicines and Healthcare products Regulatory Agency (MHRA) has said that if evidence emerges that the illegal manufacture of crystal meth has not been contained, then the cough and cold medicines may be reclassified as prescription only drugs in July 2009.

## **CATEGORY M 'RELATIVELY STABLE' THIS QUARTER**

Category M remained relatively stable this quarter, generics experts have said.

The heads of both Teva Generics and Sigma Pharmaceuticals expressed hope that the July tariff, published by the DH last week, indicated increased stability for generics reimbursement in the future.

Teva director Kim Innes said: "We noted that category M was flat overall, and in general there were no surprises."

She added: "We believe that what pharmacy and its suppliers need is some certainty, and we hope that the relative stability in the quarter three reimbursement level is indicative of the future."

Sigma managing director Bharat Shah agreed that changes were mostly "reasonable" and added it was "good news" that some money had been put

back into commodity generics. But he said: "Hopefully it is not 'the calm before the storm' in October."

Though changes from April were minimal, Mr Shah said the tariff still made "depressing" reading when compared to the tariff this time last year.

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