Spaghetti Junction

When the jar of pasta sitting in your pantry is more reliable than the pack of heart disease tablets tucked inside your medicine box, something has gone wrong. Julian Mount, senior director of European trade for Pfizer, believes that the convoluted system of parallel trade is compromising the security of the drug supply chain and it's only going to get worse.

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Julian Mount is concerned. As senior director of European trade for Pfizer, he's keeping a close eye on the supply chains that weave their way across Europe and he doesn't like what he sees. A lot of drugs now make their way from the manufacturer to the patient by the legal practice of parallel trading — ostensibly in the interest of saving customers' money while providing the middlemen an income for their trouble. Mount believes that the patients do not actually save money obtaining drugs by this route and are in fact endangering their safety.

Mount is among those who tellingly use the phrase 'grey trade' instead of 'parallel trade.' He explains how a license from the Medicines and Healthcare products Regulatory Agency (MHRA) can verify little more than that the medicine was originally bought in Spain and is destined for the UK. "It doesn't ask how it was purchased in Spain; how it was transported in Spain; how many countries it went through before it came to the UK," says Mount. "You can actually get medicines that are bought in Spain, transshipped to Germany, put in the UK and there is no record of their previous movements."

It's those movements in-between the start and finish line that concern Mount. "140 million packs of medicine in Europe are transhipped by grey traders," says Mount. "Each one of those packs of parallel-traded medicine has to be opened and repackaged by a third party. So, when they leave our factory we're sure from a quality-inspected point of view that that medicine is safe and has been manufactured under the most technically-controlled discipline. After it leaves our factory gates, who knows how it's being repackaged, who knows how many hands, who knows whether it's getting transported in a temperature controlled lorry or the boot of somebody's car."

And these are not hypothetical fears. Pfizer has seen its own medicines parallel-traded. "We've got numerous examples of very poorly packaged medicines — packs in Greek language with over-stickering, blisters that have been cut with scissors." Mounts says that Pfizer conducted an audit of parallel-traded medicine in 2004. Of the 300 medicines surveyed, 80% failed for legal and trademark reasons, 50% failed because of poor quality and 25% failed for safety reasons. "I wouldn't be so confident having this position if we didn't have the facts," he says. "But we have the facts and the quality of the parallel trade repackaging can be very poor."

Last year, counterfeit Cialis and counterfeit Reductil were found in the largest UK full-line wholesaler, in hospitals and pharmacies. This incident is linked to a report in a Dutch Pharmacy journal where a local parallel trader, Fisher Farma, was identified as the source of counterfeit Cialis entering the legitimate Dutch supply chain. Mount fears that the counterfeit Cialis and Reductil are simply foreshadowing bigger and scarier things bound for Europe. Two years ago, across the Atlantic, Pfizer was the subject of the largest drug counterfeiting case in the world. In the US, 18 million counterfeit tablets of Lipitor were found in more than 20 states and had to be withdrawn from the market. "Are we really going to fool ourselves and say 'it's happened in the US, but it won't happen here'?," Mount asks. "It could be any of the multinational pharmaceutical companies."

This stance is not built on scaremongering, Mount insists. "We just want to give the information to government and regulators to say, 'There's a risk. Do you know what you're doing? This explosion of grey trade is creating a free trade spaghetti map in medicines. If something went wrong, how could you trace it?' We have independent sources telling us that a recall of medicine in Europe would be virtually impossible."

Critics of this stance have suggested that the industry is playing up the counterfeiting issue to get tighter controls over parallel trade. To this, Mount poses the question: how much is patient safety worth? "We're not saying this is an explosion waiting to happen. We're saying that there is a rising threat."

An explosion of grey

Mounts looks back fondly to a time when there was a manufacturer who sold to a wholesaler, who sold to a pharmacy: three players in the mix for bringing a product to the patient. "Now, with the advent of the European Union, the Treaty of Rome and the free movement of goods, we, as a manufacturer, don't know how many hands our medicine goes through before it arrives at the pharmacy."

The growing size of the EU has further complicated things, Mount believes. "When we had fifteen countries, it was bad enough in terms of how would you track product movement across fifteen countries. There are 25 countries now." He points to a World Health Organization (WHO) statement made in 2003 that estimated that 10% of the global supply in medicines is counterfeit. The largest counterfeit market with close proximity to the EU is Russia, where it is estimated that 12% of medicines are counterfeit. "Now the EU has thousands-of-miles of land border with Russia," says Mount. "Are we really sure that all these fake medicines are going to stay that side of the border?"

When Mount entered his current role in 2001, there were approximately 250 licenses for parallel trade of Pfizer medicines in the UK — licenses the MHRA had granted for Pfizer medicines to be imported into the UK. Three years later that

JULIAN MOUNT

Mount joined Pfizer as engineering manager in the UK in 1989. He then spent 4 years in China developing and running a GMP approved production facility for Pfizer before becoming business development director for China and Hong Kong. Mount then moved to New York (USA) to work as director of pricing strategies for Europe before taking up the position of strategic planning director for Asia, Africa, Middle East, Japan and Australia for a subsequent 3 years. His next move was to Indonesia to serve as country manager for Pfizer, looking after the five business units there. In 2001, Julian came back into the UK and took up the role as senior European director for trade policy and operations.

figure is 3500. He attributes the rapid growth to a wider recognition of the money that can be made by selling drugs from one country to another. "The UK has the Pharmaceutical Price Regulation Scheme; Germany has a reference pricing system; France has a price volume system," Mount says. "Each government puts in methods of capping prices of pharmaceuticals. So, you can sell at any price; however if you want to be reimbursed for your medicines, you have to sell it at the government's price. This means that if a trader can buy their Pfizer product at $2 in Greece, and sell it for $3.99 in Sweden, that's almost 100% increase." Mounts adds that IMS projects the European parallel trade market to be worth close to $8 billion in 2006.

Show us the money

Despite the philosophy behind the birth of parallel trade, the savings allowed by parallel trade is questionable. Doctor Panos Kanavos and a team from the London School of Economics (LSE) published a peer-reviewed study at the end of 2003, which estimated the savings parallel trade gave to government payers. Kanavos concluded that a savings of approximately £30–50 million a year was realized in the UK each year, which is less than 0.5% of the drugs budget. This is a similar to the £60 million figure that the UK Government publicly stated it saved from parallel trade. "Parallel trade doesn't save the consumer money," says Mount. "It doesn't save the government money. What it does is make these grey traders a lot of money indeed. The same LSE study highlighted that parallel trading profits are estimated to be in excess of £325 million each year.

"In the UK, the consumer still pays his £6.40 on his prescription, regardless of whether he receives an English language, safety-sealed authentic manufacturer's pack, or if he receives a really poorly repackaged Greek pack, over-labelled with sticky labels and Sellotape. Parallel trade does not intrinsically save money, but what it does do is lower the standard of the supply of medicines."

Pfizer fighting back

Although a company cannot control whether its products are parallel traded, Pfizer scrutinizes its potential traders. "We object where the law allows us to object," says Mount, "but we can't stop anybody from parallel trading a medicine of ours." Mount points out that the European Commission says that a pack of medicine is the same as a pair of Levi jeans. "Vans can ping pong through countries, drugs can be stored in non-temperature controlled storage conditions — anyone can do anything they like in the movement of medicines."

Pfizer is heightening its involvement in the supply chain; the wheels have been set in motion for a change in Pfizer's distribution structure, beginning in Spain. Mount says that there had been a very fragmented distribution chain there, one whereby Pfizer was supplying to some 170 wholesalers. Pfizer are now rationalizing that into a limited few, re-taking control of their medicines. "Medicines again will be supplied to Spanish patients and Spanish pharmacy," says Mount. "We can better serve the supply chain in terms of the security and reliability of that supply." In the US, Pfizer is already experimenting with radio frequency identification technology to track and trace the supply chain, which provides visibility of the product once it leaves the factory. By improving visibility Mount expects these initiatives to allow Pfizer a better understanding of how products move through the external supply chain — "how much, where it is, how it's being stored and whether it's in the correct place at the right time."

As for the actual medicines packaging, Pfizer is introducing tamper-evident packaging that will make it evident if the carton has been opened, and is marking its products with a colour-shifting ink label. Patients and pharmacists will be able to determine whether a carton is authentic by viewing the colour-shifting ink label through a special filter that Pfizer will supply to pharmacists. "This technology is borrowed from bank notes — very difficult to copy."

Unfortunately for those pharmaceutical companies who, like Pfizer, are investing significant time and resources to such integrity-assuring changes, current law allows that when a medicine is parallel traded and repackaged, such devices can be removed. A frustrated Mount points out: "Anything you put on to protect the patient, a parallel trader can take off."

More than good packaging

Despite being the subject of such a significant counterfeiting case, Lipitor remains one of the world's largest selling drugs. This continued success, Mount believes, is a testament to Pfizer's handling of the situation: "The transparency, awareness, the recall, the social and corporate responsibility around the issue — Pfizer handled it in such a way that it didn't have a great effect on the product." Lessons were learned, however. "It really brought home the fact that this is the twenty-first century and we have to deal with things like this now," he says. "This is not a game of one guy in a shed making some tablets. This is organized crime, this is pan-national."

Not all companies, it seems, are as comfortable with publicizing cases of supply chain mishaps or findings of counterfeit medicines. "To me, it's a dangerous game to play," says Mount. "If you're trying your best to produce safe medicine and somebody takes it out of your control downstream, you have to tell the whole story. The more you cover that up, the more it looks like you've got something to cover up." Mount believes that industry is

OVER-PACKAGING WINS?

Whereas repackaging can involve removing critical components of a packaged medicine, over-packaging keeps the original manufacturer's product intact. "If we had to continue with parallel trade," says Mount, "over-packaging would be an appropriate solution. It will allow the manufacturer's box to stay intact, keeping originally packed medicines safe and secure."

It sounds so simple; the parallel traders stay in business and the patients can restore their faith in the medicines they're receiving. Why aren't the industry, the government and the regulators collectively leaping on the idea? "I don't know," says Mount. "To me it's a great solution. I think it's something they should do."

going to have to form a more unilateral position in terms of how these issues are treated. "The more open and transparent you are about your information, the more you force the regulator to do something about it. Now, if he only hears the Pfizer voice, he's going to get pretty bored of that."

Other voices

Last year, the Social Market Foundation (SMF) published a paper on parallel trade, highlighting many of the same points that concern Mount. "That paper basically proved Dr Kanavos' conclusion that there really isn't a fiscal benefit of parallel trade," says Mount. The paper was lauded by most of the industry, including the Association of British Pharmaceutical Industry (ABPI), who welcomed the report's proposal that pharmacists should advise patients when a parallel traded medicine is being offered to them.

But is anything happening as a result of the paper, other than groups such as ABPI nodding their heads in agreement? "We would like to see more action," says Mount. "In the UK, for example, Pfizer would be happy to work with MHRA, the Department of Trade and Industry (DTI) or the Department of Health (DOH), either through the ABPI or directly as Pfizer. We would be very happy to work with anybody to address these concerns — to safeguard patients' safety."

Mount believes that with industry bringing the issue to the table, Regulators have to take the leading role. "Regulators such as the MHRA in the UK can take the initiative themselves, or can be prompted by government, DTI or DOH," says Mount. "But either way, it's the regulators that have to take the lead on this, to recognize that they have a problem and that this problem is growing." Mount would like to see the establishment of a patient's charter for medicines. He proposes a patient can expect the packaging to be in his or her own language, transported in a temperature-controlled environment, with proper record keeping, delivered in its original manufacturer's pack with a tamper-proof seal. "These are all things the patient should have a right to with his medicine."

Obviously, MHRA is acting, so why is Mount so concerned? He doesn't think it's doing enough. "MHRA has sixteen medicine inspectors for 12000 pharmacies, more than 100 pharmaceutical wholesalers, more than 100 pharmaceutical companies and this is not counting all the commercial laboratories there are in the UK. If Pfizer had 3500 parallel import licenses for its medicines, then you can only use a multiplication factor to think how many there are in total in the MHRA. Are these being appropriately and diligently scrutinized in the same way that the manufacturer is?"

The patient's role

In comparing consumers' attitudes towards groceries with their attitudes towards medicines, Mount concludes that most patients are not proactive enough. "If you were in the supermarket and your jar of pasta sauce didn't have a tamper proof seal on it — would you buy it? Probably not," he says. "But when you go a pharmacy, you'll accept a medicine that's been repackaged by somebody, possibly cut by somebody, in a different language. As consumers we can be very happy by taking poorly repackaged medicine, but we won't accept poorly packaged pasta sauce."

Mount wants patients to inspect their medicines, not just to take that white bag and walk out of the pharmacy. "Go back to your pharmacist and say 'I want an English language pack with the safety seals still on,'" he says. "That's your right." Getting patients to do this requires greater public awareness, says Mount. "I think the industry, and the industry associations, such as ABPI, need to be more active in informing patients." Mount believes grey trading can lead to patient compliance issues as well. "If a patient who hasn't checked their medicine goes home, puts it on the counter and sees that it's poorly packaged, they may say 'that doesn't look right. Maybe I won't take it.' It's a very serious issue. If an epileptic misses his medication just once per day, he could have a seizure; he could be driving a car and cause an accident — or worse."

Man on a mission

Julian Mount seems to be a man on a mission. He recites statistics about grey trade as easily as the days of the week, he's part of a company with cutting-edge anticounterfeiting measures in place and more on the way, and he doesn't hesitate to point fingers at those who he thinks are not doing enough. He's genuinely indignant about the state of today's pharmaceutical trade industry — and it's not too difficult to see why. "People are taking medicine because they have a vision of the pharmaceutical plant with men in white coats and air conditioning and stainless steel machinery — and that's how they leave our factory," he says. "But they're tampered with before they get to the pharmacy, and we don't feel right about that. It's patient safety and our brand integrity." ■