Counterfeit drugs: the impact on drug companies

Pharmaceuticals play a more prominent role in American healthcare than in any other nation. The North American market today comprises 47 per cent of the global prescription drug market, which now exceeds half a trillion dollars, with Americans spending approximately $251.8 billion annually on pharmaceuticals.

This is up significantly from a decade earlier, when American consumption represented approximately one-third of the world market. America's insatiable demand for prescription drugs has led to serious cracks in the drug supply chain of the world's leading pharmaceutical market.

The global epidemic of counterfeit drugs

The World Health Organization (WHO) estimates that as much as 10 per cent of the global pharmaceutical market – a half-trillion-dollar marketplace – is counterfeit. In some countries, the WHO estimates that 25 per cent or more of the entire drug supply is counterfeit. The New York City-based Center for Medicines in the Public Interest recently predicted that by 2010, counterfeit drug sales will reach $75 billion worldwide, almost doubling from the estimated counterfeit sales in 2005. The Federal Bureau of Investigation estimates that the financial impact of counterfeit drugs on US companies is $30 billion a year.

Why is there such unfortunate growth in counterfeit pharmaceuticals? The answer is multifaceted and complex, but the causal forces can be captured in:

- the profitability of the activity;
- the relative ease of it;
- the demand for drug products;
- the cost of prescription drugs;
- the web of country-specific regulations;
- the vast cost disparities between countries on products;
- the ease of transporting pharmaceuticals (which are generally shipped in cases, not pallets);
- the practice of relabelling, repackaging, and reimporting controlled substances; and
- the low prospect of being caught once the counterfeit pharmaceuticals are integrated into the drug supply.

Indeed, according to the US Department of Justice, the lure of counterfeit pharmaceuticals is so enticing that both organized crime and rogue entrepreneurs around the world are increasingly turning to the production and trade of fake, legal pharmaceuticals over narcotics and other illegal drugs.

The global pharmaceutical industry's counterfeiting problem is only exacerbated by the nature of its supply chain. In fact, the industry has been characterized as having "one of the world's most complex and opaque supply chains," producing "a web of legitimate, quasi-legitimate and illegitimate trade". With that, the sourcing of counterfeit drugs is now global, as fake pharmaceuticals have come from not only China and India, but also from Central and South American, African and European countries as well.
Counterfeit drugs in the USA

The USA has long thought of itself as being immune from the type of counterfeit drug problems found “over there” in areas of the world such as Southeast Asia and Africa. This is because in the USA, 90 per cent of all prescription drugs pass through the systems of just three drug wholesalers on their way to retail and hospital pharmacies. These are:

1. AmerisourceBergen.
2. Cardinal Health.
3. McKesson.

Pharmaceutical executives, retail pharmacies, and government regulators have relied upon these consolidated intermediaries as providing a straightforward chain that is the “gold standard” for control over the drug supply.

The number of actual prosecuted cases of counterfeit pharmaceuticals has risen dramatically in the past decade. While there was a slight decline last year, which has been attributed to the increased focus of law enforcement authorities on the problem of counterfeit drugs, the number of cases this decade is far above historical levels.

In fact, the FDA’s investigations of counterfeit medicines have increased by almost ten-fold since 2000. Even the FDA’s most conservative estimate – that approximately one per cent of our nation’s drug supply is counterfeit – amounts to some 35 million prescriptions a year. While this is far below the global rate of 10 per cent estimated by the WHO, it is still an astonishing figure.

The bottom-line impact of counterfeit drugs on drug companies

Counterfeit drugs cost pharmaceutical companies an estimated $46 billion annually. Considering the fact that pharmaceutical companies expend sometimes hundreds of millions of dollars to develop new drugs, this is a hit directly on their profits.

The average selling price of a patented medicine is many times the cost of its basic ingredients. This is because “sunk” costs associated with research, manufacturing and marketing must be recouped within a narrow window of time.

In fact, the marginal production cost of a new medicine will by definition be much closer to its ingredient cost, and its eventual generic price. Just making one additional batch of a product will typically require very little extra spending. Thus, counterfeit drugs take away incremental revenue from the pharmaceutical companies – the vast majority of which would have gone straight to their bottom-lines.

In actuality however, counterfeit drugs can have an even more dramatic impact. Bret Kinsella of ODIN Technologies stated that “in their most benign manifestation, counterfeit drugs are akin to placebos”. Yet, their very presence in the market weakens legitimate brands, as when patients and doctors fail to see results from the use of what are unknowingly counterfeit products, they will be less likely to use or prescribe that brand of drug in the future. Thus, counterfeit drugs do not simply take away from a fixed pie of sales for a particular brand or even an entire product line. Over the long-term counterfeits can weaken or kill a brand’s – and even a company’s – long-term image and prospects.

Progress in RFID tagging of pharmaceuticals

In 2006, there were significant developments in regards to RFID tagging of prescription drugs. Leading players in the pharmaceutical marketplace announced significant RFID-labelling programmes for three of the most sought after – both legally and illegally – drug products.

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Pfizer announced that by the end of the first quarter of 2006, all shipments of Viagra, the lifestyle drug for erectile dysfunction, would carry RFID tags. Likewise, the major drug wholesaler, McKesson, would use Viagra as the subject of its own RFID trial.

The privately-held Purdue Pharma green-lighted a significant pilot programme to apply smart labels to all shipments of OxyContin®, a narcotic pain-killer.

GlaxoSmithKline (GSK) began tagging all bottles of its Trizivir® drug for HIV infection.

For Pfizer, Purdue Pharma and GSK, the decisions to move to RFID on these specific items were based on the popularity of these specific products, both in the mainstream and grey markets. All are amongst the leading counterfeited and diverted prescription drugs today. For GSK, the choice of Trizivir was due to the fact that it was found to be one of the 32 most counterfeited drugs.

State and federal regulatory efforts

There have been significant developments in the area of RFID labelling of pharmaceuticals, as Pfizer, Purdue Pharma, and GSK all announced major RFID tagging programmes of their most counterfeited and diverted products in the early part of 2006. Despite these announcements from industry leading firms, both the federal and state governments initiated new regulatory efforts to tighten the pharmaceutical supply chain.

At the state level, attention has been focused on assuring the pedigree of the drugs being given to patients. Several states are beginning to enact their own regulations over the pharmaceutical supply chain. Florida’s drug pedigree law went into effect in 2006, and similar regulations in California commenced in 2007. Such laws call for an “e-pedigree,” providing the ability to track all controlled substances from the manufacturer to the wholesaler’s distribution centre, and ultimately, to the pharmacy.

A number of states, including Arizona, Indiana, Oklahoma, and Texas, are instead focusing on requiring at least paper pedigree information not on all prescription drugs, but rather those medications that are acquired from outside of what is being called the “Normal Distribution Channel”. This would generally focus on the third model of pharmaceutical distribution, where drugs come from outside the country or from atypical sources. Still, such pedigree requirements will not necessarily necessitate RFID, as most states’ requirements can be met through the use of paper records and bar codes.

At the federal level, the FDA has been consistent in its position that better control over prescription drugs is one of today’s most pressing public health and safety concerns. In a 2004 policy statement, the FDA advised that “use of mass serialization to uniquely identify all drug products intended for use in the USA is the single most powerful tool available to secure the US drug supply.” The FDA recommended that the pharmaceutical industry move to implement RFID-tagging throughout the supply chain for controlled substances by 2007.

Benefits

Pharmaceuticals are indeed likely to be one of the first consumer-level applications of RFID tagging of products. With all the concern over counterfeiting drugs amongst both regulators and the pharmaceutical companies, one would expect to see only rosy forecasts for RFID in the pharma sector.

RFID provides compelling benefits for the pharmaceutical sector in its ability to head off the explosion of counterfeiting going on today. By 2010, with or without government mandates, the pharmaceutical sector will – of necessity – move to RFID labelling of its products. If not, multibillion dollar investments in life-saving medicines could evaporate overnight, and worse, the lives of billions of people may lie in the balance, as our aging and growing populations depend on the ingenuity – and genuineness – of the pharmaceuticals that keep us alive.
December 2008.

This is a shortened version of “Genuine medicine?: Why safeguarding the pharmaceutical supply chain from counterfeit drugs with RFID is vital for protecting public health and the health of the pharmaceutical industry”, which originally appeared in Competitiveness Review: An International Business Journal, Volume 18 Number 3, 2008.

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