400
300
200
100

On the Right Track

Akan Oton at Catalent Pharma Solutions analyses the impact of track-and-trace technology on the reduction of pharmaceutical counterfeiting

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Counterfeit drugs are an adverse symptom of the complexity of the pharmaceutical distribution network. Products change hands as many as 10 times, making penetration of counterfeit medications into the supply chain possible. This invariably has an impact on the safety of patients as well as on the bottom line of legitimate pharmaceutical manufacturers.

When companies manufacturing drugs conclude that they can effectively address the patient safety challenges posed by counterfeiters, as well as address the financial losses that counterfeiting creates, they will increasingly adopt track-and-trace solutions across the globe. However, regulators and legislators are not providing manufacturers with the luxury of time to arrive at that conclusion independently. Increasingly, local jurisdictions are taking action.

California's ePedigree law, mandating item-level serialisation by January 2009, and the recently-passed United States Federal legislation (slated to take effect within 30 months from September 2007) will require the implementation of track-and-trace technology. These technologies provide a solution to the problems of counterfeiting, shrinkage and parallel trade. Mandating item-level serialisation with track-and-trace capabilities can significantly minimise the supply of sub-standard pharmaceuticals, which are expected to comprise $75 billion of the global market by 2010.

TARGETING FAKE PRODUCTS

Consumers reliant on prescription medications have suffered health consequences by consuming fake drugs. Counterfeits look like the authentic product, but contain inadequate active ingredients or contaminants that are potentially dangerous to the consumer's health, or they may be placebos and equally unsafe for patients with serious illnesses. California's legislation is gaining public support as advocacy groups, legislators and pharmaceutical companies are acknowledging the severity of the issue. Documenting drug manufacturing and distribution through the supply chain has immediate consumer benefits as authenticity, confidence and the prime driver – consumer safety – are improved.

At the other end of the economic spectrum, track-and-trace induced velocity, visibility and adaptability

Figure 1: Track-and-trace technology options compared

	Pros	Cons
2D barcodes	• Inexpensive to set up and use • Use around biologic drugs • Can be printed on any substrate	• Need line-of-sight to be read
RFID	• Preferred by distributors because it simplifies their operations • Does not need line-of-sight to be read	• Expensive to set up and use • Failure rate of tags • Low read rates around liquids and metals • Cannot be used around biologic drugs (FDA decision)

will generate long-term benefits for pharmaceutical manufacturers. With virtual information flow, the right drugs are produced at the right time and delivered to the right location, reducing operational costs and ensuring product availability. A 2004 study by the Healthcare Distribution Management Association (HDMA), entitled 'Adopting Electronic Product Coding in Healthcare: Costs and Benefits' finds that the economic benefits attributed to tracking range between $500 million and $1 billion annually for pharmaceutical manufacturers. With European companies losing two to three per cent of profit due to parallel imports, cost savings delivered by track-and-trace would mitigate losses.

Pharmaceutical firms are incurring significant expenses while maintaining relatively high levels of inventory to meet fluctuating demand due to price volatility. Inventory overstocking is commonplace, as are bottlenecks and stock-outs. The maintenance of excessive safety stock ties up capital and labour that could be more productive in other capacities. The average manufacturer holds 10 per cent of sales in safety stock and pays out up to 10-15 per cent of annual sales to wholesalers in refunds, which accounts for millions in administrative and labour costs as well as lost sales. Reducing inventory management expenses, stock levels, manual checks and product recall costs would streamline drug delivery.

The immediate identification of medication at check points speeds up receiving, processing and replenishment, while facilitating dynamic production and the blocking of defective, counterfeit pharmaceuticals. Real-time monitoring of operations reduces errors and results in precise auditing and inventory forecasting. Clearly, long-term benefits and returns on investment are positive and outweigh the sunk cost of newly-adopted technology.

CURRENT SOLUTIONS

In 2006, the FDA identified RFID as "the most promising technology for implementing electronic track-and-trace in the drug supply chain," recommending that "stakeholders move quickly to implement this technology." With RFID tags, no line of sight is necessary during scanning at the case and pallet level, increasing security and the speed of production and distribution lines. For biologic products, 2D barcode technology is preferred, as scanning does not have the potential to alter the molecular structure of the product. Both RFID and 2D barcodes have their own place in the track-and-trace arena, and their coexistence is essential for the industry.

To test the implementation of RFID tags, an RFID pilot was recently undertaken. The testing of high speed packaging lines (250-300 bottles per minute). Encoding and scanning Ultra-High Frequency (UHF) tags showed accuracy rates of over 99 per cent. With the introduction of generation three and four RFID tags, scanning accuracy will increase radically with the resolution of technical questions pertaining to hardware, software, protocols and integration with existing systems and 2D barcodes. Another pilot was conducted with 2D barcode technology, and demonstrated one hundred per cent print, grade and read accuracy of 2D barcodes at high speed (250-300 cartons per minute).

The industry has been slow in standardising track-and-trace technology. European pharmaceutical manufacturers are already managing several interfaces which are causing interoperability issues and hampering open circulation proliferation. No anti-counterfeiting laws exist specifically for medicines at the EU level. The only piece of legislation is a non-binding resolution adopted in September 2006 calling on the EU 'to take steps to strengthen the regulatory and quality-control capacity for medicinal products.' With already low profit margins for EU pharmaceutical companies, the lack of standardisation is dwarfing real-time transparency and the economic benefits of track-and-trace technology.

HANDLING DATA VOLUME

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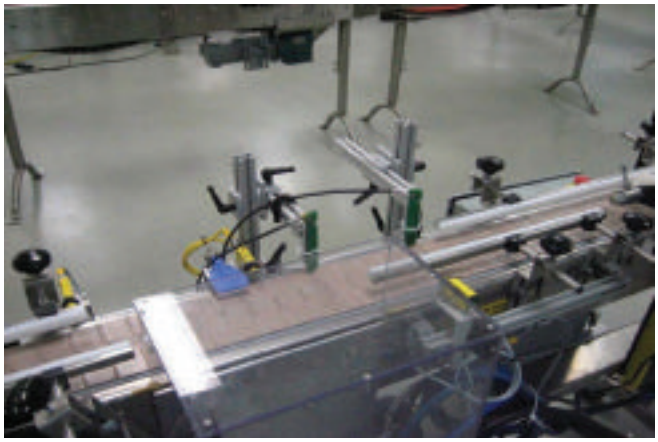
data that are created by track-and-trace. A single package might have as many as 400 attributes. Multiply those by the number of drugs distributed and the number of product transition points in the supply chain, and companies are faced with a significant amount of data that needs proper management. The number of possible endpoints for consuming or creating information increases by several orders of magnitude, generating anywhere from 10 to 100 times the data volume of conventional linear barcode technology. Traditional technology architectures are not prepared to handle this volume, but legislation demands supply chain traceability, regulatory auditing and real-time tracking to protect consumer safety. Data collection, correlation, filtering, cleansing, storage and integration must be efficient if manufacturers wish to comply and maintain a competitive advantage in the market.

There is no doubt that pharmaceutical manufacturers, distributors and pharmacies will need to share data; the only variables are encryption, network security and chip reprogrammability standards which will preserve privacy and data security. By ensuring that all readers on the network are authenticated, data traffic is encrypted and that network architecture and security are adequate, existing methods such as firewalls and access-management technologies will be effective in keeping data safe and available only to authorised parties. By 2009, most challenges should be fully addressed, and business process changes will create opportunities, including real-time decision-making, centralised management and better scalability of operations. Industry-wide deployment will generate efficiencies and positive externalities, depressing costs and increasing the long-term returns on investment. Advances and standardisation in protocol, tags and readers will bring scale and prices to a point where the technology is both consumer- and producer-friendly.

GLOBAL IMPACT

US and EU anti-counterfeiting efforts protect domestic patients, brands, and services. But according to the World Health Organization (WHO), counterfeit medicines comprise up to 10 per cent of globally traded drugs, 30 per cent of the market in some developing countries and over 50 per cent of medicines purchased over the internet from sites that conceal their physical address. Counterfeit medication usually originates in Asia and Latin America where technology makes production cheaper and safety regulations are poorly enforced. The threat is global, and packaging must contain a unique product ID number which consumers can verify via a hotline, regardless of whether they call from suburban America or a street market in Africa.

Counterfeit medication has, in the past, created a global public health crisis; notably after the death of 89 Haitian children in 1995 who took cough syrup containing antifreeze, and the death of more than 2,500 Nigerians in 1996 after receiving a



fake meningitis vaccine. The mounting demand for country-specific and multi-lateral coordinated measures resulted in the launch of the WHO Rapid Alert System (RAS) designed to monitor and warn authorities of pharmaceutical counterfeiting activity. In February 2006, the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) was created, a network comprised of all 193 WHO member states and a consumer verification system. Governments are finally realising that the battle must be fought in developing countries as well in order for anti-counterfeiting measures to achieve their full potential.

In October 2007, the EC announced that it will seek a mandate from European member states to negotiate a new Anti-Counterfeiting Trade Agreement (ACTA) with major trading partners, including the US, Japan, Korea, Mexico and New Zealand. Such an agreement would strengthen efforts to protect intellectual property – including drug manufacturing – around the world. ACTA's goal is to provide an international framework that strengthens global enforcement of intellectual property rights and helps protect consumers from health and safety risks.

CONCLUSION

The complexity of the pharmaceutical supply chain demands that manufacturers and other stakeholders drive towards implementing track-and-trace solutions in order to secure the global supply chain. However, as manufacturers march down the path of implementation, it is critical that they adopt an appropriate technology strategy for their supply chain, local markets and numbers of drugs sold. Manufacturers must also ensure that any technology solution selected is robust, scalable and fully auditable by regulators. Many of these challenges will be addressed in coming years as the industry moves to comply with the requirements set forth in California's 2009 ePedigree legislation. The future integrity of the pharmaceutical supply chain is absolutely dependent on the successful implementation of track-and-trace technology. ◆

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