

Delivering Traceability in the Pharmaceutical Supply Chain

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The distribution of counterfeit medicine is one of the pharmaceutical industry's biggest threats. It is believed that 7% of all medicines world-wide are counterfeit. The figures become even more shocking on a regional basis, with 40% in South America and nearly 70% in West Africa. This is rapidly becoming far more of a health problem than it is an economical problem. Fortunately, companies like IBS are helping pharmaceutical companies tackle the problem and turn around a situation that could, left un-checked, end up being a global disaster.

There are a number of key trends in the pharmaceutical market that are compounding the counterfeit problem. Massive growth of Internet sales and also unlicensed markets, as well as the huge potential for producing copy medicines in India or China, all help to flood the market with counterfeits.

Increased acceptance by patients of generic medicines has forced the major manufacturers into purchasing many of the generics manufacturers. The aging population of Europe, China and the US are driving demand for more and more medicines for a lower price. For many countries, governments have to shoulder the burden of much of these costs because of their healthcare systems.

At last, technology is coming to the industry's aid to help better control of medicines, with a range of packaging and labeling products becoming available to tackle the problem. However, making sure this technology is fully integrated into the pharmaceutical supply chain is the only way to ensure companies can gain a full track and tracing solution that will effectively deal with counterfeiting.

These solutions are also essential for dealing with potential future threats to the pharmaceutical industry. People expect instant availability of their medicines, yet with potential massive requirements for products such as a vaccine for the avian flu virus, which is expected to return more strongly - how well can the industry actually cope? Information is out there, in recall scenarios, government stocks and in national/regional trends surveys, which will help, but this information needs to be consolidated. Pharmaceutical companies need a complete tracing solution using IT

systems that can handle the flow of data through the various databases, as well as integrate them with any of the electronic labeling technologies.

The industry needs IT systems that can handle and store more items and execute more and more smaller transactions. To increase their own profitability, they need to offer more value added services and be better able to control and secure products in the supply chain. They also need to reduce errors and improve the process of handling returns. Suppliers in particular also need to gather sales information and generate better control of products' movement.

As part of its security processes, companies need to have systems in place that can help identify counterfeit products as well as delivering better lot and expiry date control.

Regulations

Before these systems can be truly effective, responsibility falls upon governments and pharmaceutical authorities to regulate labeling requirements. Every product needs to have, as a minimum legislative requirement, a National Pharma Code (eg. Global Trade Item Number GTIN), Lot Number, Expiry Date and Serial Number. Then suppliers, wholesalers and pharmacies need to deliver reports according to the new regulations, such as who entered the information, where the shipment was sent from or to, date and time information, and the transaction code, which covers whether the items were delivered, received or destroyed. These processes are being put in place and IBS is one company that is developing its IT systems to help companies meet these regulations.

The basic data for all medicines is already available and is being put onto electronic labeling. This information includes the pharma code, the supplier or importer, the size of the unit, the pharma product group and any special controls required. These labels are essential for logistics practices and, effectively integrated into a supply chain management system, enable accurate, automatic processes for reception and preparation, putaway and storage, order picking, checking, packaging, pricing, sortation, dispatch, shipping and delivery.

Automatic Identification Technology

The most common form of auto ID is the bar code, which has been around for years and is a well accepted and standard technology. Its main limitation is in the amount of information that can be held in a traditional bar code. However, the latest Data Matrix codes allow labels to hold entire ASCII character sets and use multiple encoding modes that allow up to 2335 characters. The technical conference at GIRP in January 2006 recommended the use of these Data Matrix labels and EFPIS has also delivered a statement recommending their use.

The other main auto ID technology is RFID. This technology is growing in acceptance and now has considerable potential for the pharmaceutical industry. By 2010, RFID is planned to be an available and viable solution for item tagging, on cases and pallets of all products. As soon as 2007 RFID will be available for case and pallets of products with a high counterfeit rate. Timing depends on the availability of secure technology, which should not do any harm to the product and provides a reader accuracy rate of more than 99.9%.

The simple truth is that any electronic label will improve supply chain processes, increasing efficiency and profitability as well as reducing the threat of counterfeiting and theft. It will lead to improved service and stock control, reduce returns and deliver better call-back control.

Most large pharmaceutical companies are now testing a variety of labeling technologies and are in advanced pilot projects. They are recognizing that once labels are implemented throughout the supply chain it will deliver major cost savings, improved accuracy and increased speed. The real winners will be those companies that also invest in well-designed, integrated supply chain systems that exploit the true benefits of the labeling technology. Through this control, companies can help to increase worldwide availability of safe licensed medicines and help fight back in the battle against the counterfeiters.

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