

Keep everything in focus

Tracking and monitoring pharmaceutical products along global distribution chains has become critical due to the rise of counterfeit medicine. *World Pharmaceutical Frontiers* talks to Keith Cutri, director of business development for **KODAK Brand Protection Solutions**, about managing the threat posed to brand-owners.

How has globalisation changed the management of pharmaceutical distribution chains, and how problematic have diversion and counterfeiting become?

Keith Cutri: Developed countries experience a lower than 1% counterfeiting rate, while developing countries see a much higher one – over 50% in some Asian countries. Overall, it's been estimated that 5% of the global pharmaceutical supply is counterfeited. Diversion is a much harder number to nail down, but some estimate the rate to be close to the counterfeit rate if not higher, worldwide.

What damage can this do to brand-owners and end-users?

The obvious risk to brand-owners is damage to their reputation and brand loyalty, which can mean a lot in the pharmaceutical space given the generic products that compete with traditional brands. More importantly, from a health and safety perspective, consumers are at risk if they are not receiving the proper API (active pharmaceutical ingredient) in their prescription drugs. Diluted formulas and knock-off ingredients can cause health risks, potentially leading a patient down a slippery slope that can lead to serious illness or death.

Are regulatory authorities doing enough to address these issues?

It depends on the country. In the US, the FDA has only issued recommendations on 'e-pedigree' track-and-trace paradigms, but there have been no FDA regulations or US laws passed by Congress that require pharmaceutical manufacturers to implement disparate or universal e-pedigree serialisation systems. The requirements that come closest to a universal track-and-trace system have been proposed by the State of California. The California Board of Pharmacy published its e-pedigree requirements in 2008, and these are scheduled to be phased in between 2015–17. Florida, Texas and New York have also passed their own e-pedigree laws. Any FDA regulations would supersede state regulations.

In Europe, the Falsified Medicines Directive came into effect in January 2013. This law covers all EU countries and requires an authentication feature on the outer packaging of all medicines, a common logo to identify legal online pharmacies, tougher rules on the controls and inspections of producers of active pharmaceutical ingredients, and strengthened record-keeping for wholesale distributors.

Can you tell us about KODAK's Track & Trace System, how it works and how it effectively protects brand-owners?

The KODAK Track & Trace System consists of a software database backbone that drives on-demand printing of visible and invisible serialised codes – in real time – on the packaging line. Dual serialisation allows for visible and invisible codes to be printed on each item, to prevent deliberate removal by diverters or copying by counterfeiters.

Each code can consist of a unique 2D barcode, QR code, alphanumeric or other GS1-compliant mark. The codes are typically printed with commercial continuous inkjet (CIJ) printers with verification and track-and-trace done through the deployment of vision camera systems on the packaging line.

The KODAK TRACELESS AD System is used to print the invisible serialisation code with CIJ printers. Once the packages are serialised, the individual items can be aggregated to cases, cartons and pallets, with print-and-apply labels produced for the corresponding sets of packages. Vision camera systems are used to automate this aggregation process directly on the packaging line, eliminating errors and ensuring proper serialisation for distribution. Standard barcodes are printed on the outer cases and pallets for ease of scanning, with handheld barcode readers used by warehouse operations and distributors.

How does the ubiquitous monitoring solution work and how important is it to engage consumers in brand protection?

The KODAK Track & Trace Incident Monitoring System (IMS) provides a layered approach to the track-and-trace system, using ubiquitous monitoring driven by various smartphone apps, which enable scans in the field by investigators, distributors, retailers, end-users and consumers, each having their own authorised permissions based on user authentication.

As items are scanned around the world, the IMS will generate incident alerts for designated brand protection managers that correspond to various brand protection threats associated with the integrity of the serial code, geographic location of scan and repetitive patterns from previous scans. ■

Further information

Eastman Kodak Company
www.kodak.com/go/brandprotection

