

## **Strategies for Reducing Cost and Boosting Efficiency When Complying with E-Pedigree and Braille Legislation**

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In 2007, legislation for the Federal Food, Drug, and Cosmetic Act stipulated that the Secretary of Health and Human Services will develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, adulterated, misbranded, or expired drugs.

On January 1, 2011, the state of California's pharmaceutical traceability law will go into effect, impacting every pharmaceutical package sold in the state. Dozens of other states are now in various stages of adopting or defining their own anti-counterfeiting regulations for pharmaceuticals. Meanwhile in Europe, pharmaceutical packaging now conforms to legislation mandating Braille identification on secondary packaging.

Compliance issues are not new for consumer packaged goods companies and their converter partners. What is new is the increased level of traceability of pharmaceuticals — down to the individual primary and secondary package and then linking those to shipping containers and pallet loads. In effect, legislation is creating a system where the lineage — pedigree of a product — will be verifiable from source to destination. This new process is called “e-pedigree” — the ability to electronically trace the origin of pharmaceutical products back through the

supply chain to the manufacturer. Counterfeiting products is a global issue and not limited to pharmaceuticals. The lessons learned by converters now will be vital to success later over a range of packaging.

The mandate in Europe to emboss Braille identification on pharmaceutical packaging will likely be adopted in North America sometime in the not too distant future. The production issue for Braille on cartons is more about set up and throughput than it is about determining pedigree. For example, during a fact-finding trip to Europe, I visited a plant where a converter spent 12 hours on set up for a four-hour run. The same story of time consuming set up for Braille is being repeated in plants throughout Europe.

### **The e-pedigree process for cartons**

A unique identifier for every pharmaceutical carton can either be accomplished through a 2D barcode — a class of barcode containing a significant amount of data — or Radio Frequency Identification (RFID) tags, which also have significant data storage capacity.

The choice of one identifier over the other for a converter depends on cost and the e-pedigree strategy selected for linking primary and secondary packages, shipping containers, and pallets into a traceable chain. RFID and 2D barcode are not mutually exclusive. Barcodes can be used cost effectively, for example, on the primary, secondary, and shipping packaging, while an RFID tag is applied to pallets. As the cost of RFID technology falls, these tags may be a solution for primary and secondary packaging as well. E-pedigree software captures and stores all the relevant production and shipping data.

Applying a 2D barcode or RFID tag to a carton while it is on the folder gluer seems to make sense because this is the point in production just prior to when the primary and secondary packaging join. The e-pedigree software will then link the primary and secondary package identifiers into a unique and traceable chain. Roberts PolyPro has observed a number of practical issues that make folder gluer application sub-optimal. Most folder gluers utilize belts above and below the carton, which severely limit 2D and RFID placement options. If there is a misprinted code or incorrectly placed tag, there is no cost effective means of ejecting the blank. On high throughput folder gluers, ink from a 2D print head will not have time to dry and smearing is likely.

Adding Braille to a carton involves embossing. Currently in Europe the strategy is to emboss at the die cutter. One of the problems the Europeans are having is that the ratio of set-up to run time is out of proportion. It takes technicians too long to accurately align the embossing elements. The second production issue involves the Braille “bumps,” which have a tendency to lock cartons together when blanks are stacked.

### **Solve e-pedigree identification and Braille embossing at infeed to the folder gluer**

Rather than on the folder gluer, Roberts PolyPro recommends locating the 2D print head, the RFID applicator, or Braille embosser on the machine’s infeed system. This strategic location offers the most cost effective and flexible solution. For example, if it takes one second for the ink of 2D print to dry, simply add length to the infeed vacuum conveyor.

Similarly, adding the Braille embosser on the infeed system where the blanks are running through individually drastically reduces set-up time because technicians are essentially working with the parameters of one blank, not a sheet of multiple blanks. With this solution, the converter retains the integrity of the Braille bumps because there is no surface wear from stacked blanks rubbing against one another. The converter also eliminates the issue of stacked blanks sticking to one another.

Infeed systems that convey blanks via vacuum, not belts, present the entire outer surface of the package for printing, tagging, or embossing — tuck flap, main panel, or end panel. This option gives the converter maximum flexibility in locating the e-pedigree identifier or Braille embosser. In the case of Braille this can even be over a score line, which is impossible when embossing at the die cutter.

Integrating a 2D, RFID, or Braille system to an existing infeed system or specifying a new one is faster and more cost effective than specifying and installing a new folder gluer. State-of-the-art infeed systems optimized for e-pedigree and Braille cost from \$50,000 to \$200,000 on average. Most systems come in at the lower end of the range. The rule of thumb is the tighter the registration requirement, the higher the cost of the machine. Focusing on the infeed is also a fast option. In a matter of two or three months, the hardware for the e-pedigree or Braille can be in the plant.

## **What to look for in today's state-of-the-art infeed solution for e-pedigree and Braille**

Vacuum-based conveyor systems are essential for infeed systems used for e-pedigree or Braille. A vacuum conveyor eliminates the need for top or bottom belts. And, as mentioned above, conveyors without belts present the entire outer surface of the carton for e-pedigree and Braille application and provide maximum flexibility for placement. The most advanced vacuum systems rely on a fan that pulls high-velocity, negative air flow over a large surface area. These systems are reliable, quiet, eliminate the need for pumps and filters, and are easy to maintain.

All successful e-pedigree and Braille applications require control and accuracy in terms of registration. Check to see that the infeed supplier offers placement accuracy of at least +/- .03 inches (.762 mm). Placing lugs at the leading edge of the blank rather than the rear edge is one method to ensure high registration accuracy. Another contributor to accuracy is timed sequencing through computer control. Optimum systems also incorporate a cam to gently and accurately feed blanks without scuffing or hanging up.

Fast, efficient set up is essential. Ask the supplier to provide details on set-up procedures — the simpler the better. Maintenance and safety features go hand-in-hand with set up. Negative-pressure vacuum-bed technology removes the need for hundreds of top belt bearings and nip points that tend to require frequent and time consuming adjustment. Fewer moving parts reduce maintenance costs and help to ensure a safer environment for workers.

Converters should work with a supplier that has the ability, willingness, and expertise to integrate any third party 2D, RFID, or embossing hardware. This gives the converter maximum flexibility to choose the optimum hardware for the e-pedigree or Braille application.

With the carton infeed strategy, converters will find that the hardware component of systems designed to prevent counterfeiting and to provide more helpful packaging for the blind are not as costly, time consuming, or difficult to implement as it may initially appear.

**For More information:**

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