

## New Braille Tools Emerge

**T**wo new Braille technologies help packagers comply with impending European Union legislation. One creates code, while the other makes sure it meets quality standards. According to European Directive 2001/83/EC Article 56a, drugs will be required to repeat label information in Braille for sight-impaired customers.

Cortegra (Parsippany, NJ) has met customer demand for Braille labeling compliance by creating embossed cartons. "Inquiries have been driven by the increasing awareness in the EU and the standards and regulations developed for Braille requiring packaging products to have product names in Braille in October 2010," says Narendra Srivatsa, business development manager. These questions spurred Cortegra to begin manufacturing cartons with an uncontracted Braille system, which refers to Braille printed or embossed individually, instead of in a chain.

"Because the EU requires drug names to be spelled out, the uncontracted system becomes a natural fit," Srivatsa explains. In an uncontracted system the word "and," for example, would be spelled out using three sets of characters, but in a contracted system,

one character.

Cortegra uses special tooling to emboss the cartons. "It is a high-prec-



Photo By Hector Torres

**Cortegra offers cartons embossed using an uncontracted Braille system.**

sion operation because without the precise application, you could end up either ripping the cartons, creating unwanted rejects, or end up with the Braille characters being ineffective—creating a product that the customer has no value for," says Srivatsa. "Carton positioning, pressure, and other factors play an important role here."

Mandated labeling laws have led

another company to create a quality control solution specifically designed for measuring Braille dot height. Global Vision (Montreal) will soon introduce BraillePoint, a measurement tool to accurately measure Braille dot height and ensure readability.

Braille height is a concern, but there is no consensus on a target height. According to standardization body Euro Braille Standard of the European Computer Manufacturers Association (ECMA; Geneva): "The Braille dot height was, is, and will be one of the key issues in the discussions about the Braille standard."

Because Braille heights are typically under one millimeter, they are difficult to manually inspect for accuracy.

Says Global Vision COO David Perlis: "It is difficult to ensure the complete accuracy of all Braille on packaging." BraillePoint will provide a correct, consistent measurement of tactility, Perlis says.

The Global Vision system facilitates proper compliance by detecting expected dot heights and tolerance levels based on specific quality standards set by users. BraillePoint can alert

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## Progress of Compliance Designs Discussed at HCPC Event

**H**ard-to-open packages as well as the cost of the formats can be hurdles to adopting compliance systems. However, compliance packaging is gaining momentum, participants said at the Healthcare Compliance Packaging Council's 16th Annual Symposium on Patient Compliance in New Brunswick, NJ. Consensus at the event seemed to be that unit-of-use is the wave of the future.

Schering-Plough has put a process in place for developing "patient-centric" packaging. Packaging for new products in development for each drug class will

be evaluated, reported Jennifer Johns, a manager in Schering-Plough's package development group.

"Compliance is a big issue for us. [The group will examine] compliance and how to minimize patient confusion in using the drug. We are looking at blisters and bottles, with supporting global professional research." The process will also encompass brand identity issues in some cases, Johns said.

Eli Lilly has "a broad program" in place for addressing "not just packaging, but patient needs in general," said David

Furusho, manager of quality assurance, PSR&D, Eli Lilly & Co.

John Bitner, director of packaging development, Watson Pharmaceuticals, said that generic packaging has improved to support patient use issues, but generic pricing can't support high packaging costs. "We say 'differentiated' rather than 'innovative' to indicate that we are differentiating with a purpose, and not running up the cost," said Bitner. "Our clients demand that we control our costs. We have a profit margin to work with. Packaging has to be a shared expense."

## Industry Briefs

Folding carton manufacturer **Rondo-Pak** (Norristown, PA) showcased its new expansion during an open house on June 12. The company has added a new KBA Rapida 105 printing press with hybrid technology that handles both conventional and UV inks. It also features a Dri-vetronic plate mounting system, an Anilox coating unit, and a Densotronic scanner. Rondo-Pak also has a Man Roland 700 printing press. Another recent addition was a Bobst Media 45 Gluer that can operate at speeds of up to 90 thousand cartons per hour.

Custom injection molder and contract manufacturer **Plastics Engineering and Development Inc.** (PEDI; Carlsbad, CA) announced the manufacture of a pharmaceutical diagnostic tray produced through a customized film insert

molding process. Using a 120-ton Sumitomo injection-molding machine outfitted with a Yushin robot, PEDI is molding a 384-well tray for biological testing. Human cells and pharmaceutical drugs are placed in the wells of the tray for research and development. To manufacture the tray, plastic is molded onto the film in a Class-100,000 clean room. The critical requirements for this application include flatness of the molded well tray and maintaining the clarity of the film.

**Menasha Corp.** has broken ground on its Wide Web printing facility in Neenah, WI. The expansion will add about 44,000 sq ft to the printing facility. It will include the addition of a press that will increase Menasha Packaging's growth opportunities for product provided directly to customers as well as for its internal use. The press is manufactured by Fischer & Krecke.

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users, via a computer interface, to any dots outside this range and guarantee accurate Braille readability. The system also meets EMEA and FDA 21 CFR Part 11 requirements.

Braille wording for the medicine name, formulation, and strength must be included in addition to printed words. After drug approval, a three- to six-month period is all that stands before the text must be added on the package. Medicine created prior to the rule, and all imports have until October 30, 2010, to comply with the Braille law.

Braille cannot interfere with any mechanism that would read the packaging. The code must be on the secondary packaging, but is not required on primary packages.



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