

# Stakes Are High for Mexican Pharma RFID Mandate

To participate in Mexico's federal Seguro Popular health-insurance program, which currently serves 4 million families, drug manufacturers and distributors will use UHF and HF RFID tags to track pallets, cases and individual containers of pharmaceuticals.

By Beth Bachelordor

Sept. 26, 2006—Mexico may be forging ahead of the United States when it comes to using RFID to secure the pharmaceutical supply chain. The country has issued a mandate requiring manufacturers and distributors to affix RFID tags on drugs sold to individuals covered under Seguro Popular, a governmental health-care institution that operates similarly to an insurance company. Created in 2002, Seguro Popular expects to assist more than 5 million families by year's end.

The RFID requirement, part of Seguro Popular's Supply Chain Model, was first presented to the pharma industry in March, and is designed to help trace and authenticate drugs to improve drug safety, fight drug counterfeiting and help the Mexican government determine payments for the drugs, according to Jorge Morales, director of operations for ISCEA-Mexico. The International Supply Chain Education Alliance (ISCEA) provides supply-chain training and certification worldwide, with the Mexican branch of the ISCEA serving as RFID technical advisor to Seguro Popular.

The U.S. Food and Drug Administration (FDA) has been investigating the use of RFID to protect the U.S. pharmaceutical supply chain against counterfeit drugs, but currently does not require the technology's use. Instead, the FDA has urged drug manufacturers, wholesalers, distributors and retailers to begin testing RFID as a way to comply with the Prescription Drug Marketing Act of 1987. That act requires drug distributors to document (via a pedigree, though not necessarily in electronic form) the chain of custody for drug products as they move through the distribution system (see FDA Issues New 'Counterfeit Drug Task Force' Report).

Under the Seguro Popular Supply Chain Model, the Mexican government will require manufacturers and distributors to affix UHF RFID tags on cases and pallets, and HF RFID tags on item-level containers of pharmaceuticals. The government has not specified a required air interface for UHF tags, though EPCglobal Gen 2-compliant tags are recommended. As for the HF tags, the model calls for ISO14443B-compliant tags, but more air-interface protocols may be added later.

The government has not set a specific date for compliance, but manufacturers and distributors will be expected to comply as the government rolls out the supply chain and RFID capability on its end. The HF RFID tags will be encoded with a serial number and the drug's name, as well as its manufacturer, distributor and expiration date; the UHF tags used on cases and pallets will include a serial number, drug's name, and manufacturer. Although HF tags are being used for items, 96-bit EPC data standards will be followed, with a special variation of the EPC serial number specially designed by EPCglobal Mexico and ISCEA Mexico, according to Morales. The GTIN information (header, filter, partition, company prefix and item reference) remains the same, but Morales says what has changed is the usage of the 38-bit serial number to accommodate

the expiration date and distributor ID number. "A standard of usage for these memory locations was needed so that the whole industry would use them in the same way," he says.

Depending on agreements reached between manufacturers and distributors, the tags can be encoded either by the manufacturer just before the drugs are shipped to a distributor, or by the distributor after a manufacturer. The tags are scanned at various points along the supply chain, and the data is collected to document the drug's movement.

Individuals covered under Seguro Popular will receive contact smart cards (not RFID-enabled) containing their identification numbers; these cards are used to obtain treatment from authorized Seguro Popular doctors. The doctors program into the cards their identification numbers, as well as any prescriptions. The individuals can then go to participating pharmacies, where the smart cards are read at point-of-sale systems to find out the drug prescriptions. The point-of-sale systems will also be equipped with RFID readers, so that when the pharmacist pulls the drugs from the shelves, the POS RFID reader will scan the drug's RFID tag. That information will then be married with the information culled from the individual's smart card.

"More than an RFID/e-pedigree mandate, it is a supply-chain model that benefits from RFID technology for its operation," says Morales. Not only does the model trace and authenticate the drug's lineage to ensure it isn't counterfeit, it also traces each organization that has handled the drug—including the manufacturer, distributor, pharmacy and doctor—so the government can assign appropriate payments for the drug. "The information of all the parts involved is sent via the POS terminal to Seguro Popular," Morales says, "and fund transfers are made to the parts involved."

Mexico's RFID mandate won't apply to all drug manufacturers and distributors, only to those that wish to participate in the Seguro Popular program. However, the incentive is high: By year's end, 20 million individuals—nearly 20 percent of the nation's estimated total population of 103 million people—will be participating in the health-insurance program. The government expects Seguro Popular to cover as many as 50 million individuals in the future, according to Morales. "If manufacturers and distributors are interested in participating in that future market, they must comply," he says.

No date has yet been set for nationwide compliance with the Seguro Popular Supply Chain Model. Morales says compliance will occur independently in Mexico's 32 states as RFID-enabled POS terminals are installed in Seguro Popular-affiliated pharmacies. Purchase orders can be sent to manufacturers and distributors that include the RFID requirement.

Thus far, two pharmaceutical companies are testing RFID in their operations: Farmacéuticos MAYPO, a nationwide distributor of specialized pharmaceutical products, and Específicos Stendhal, a specialty pharmaceutical lab. MAYPO is already capable of tagging drugs for Seguro Popular, according to Morales. The company is now gearing up to test the pharmacies' POS infrastructure. "Case and pallet tagging is not a priority at the moment, but UHF tagging and programming for authentication and traceability is also offered by MAYPO to some costumers like Stendhal," Morales says. "MAYPO's case is very valuable, because it is the first distributor to comply, and through them more that 30 manufacturers are ready to comply too."

Stendhal is complying with the HF tag requirements of Seguro Popular through MAYPO, and is also testing UHF tags for authentication. Stendhal can either place and program UHF tags in their facility, or just place the tags and let MAYPO do the programming without modifying their production line, according to Morales.