Electronic Package Inserts Stir Debate
Pharmacy Groups Worry about Costs of Eliminating Paper

Stephen Barlas

Because the agency is concerned that pharmacists lack the most up-to-date information when they dispense medications to retail customers, the Food and Drug Administration (FDA) is considering how to deliver package inserts (PIs) to pharmacies electronically.

“All of the printed package inserts that we as manufacturers use are out of date the day we print them,” explains D. Bruce Cohen, Technical Director of Unit Operations at GlaxoSmithKline.

Mr. Cohen heads the Paperless Labeling Group of the Pharmaceutical Research and Manufacturers of America (PhRMA). Manufacturers add new indications, new adverse reactions, new testing information, and other data soon after a drug comes to market but before the printed PI can be updated.

PIs are the lengthy, technical papers that are attached to large jugs of tablets that arrive at pharmacies. This literature provides details about the many aspects of each drug, information that pharmacists might not be able to access in databases they customarily use. In addition to sending PIs, manufacturers also send shorter printed patient medication guides (MedGuides) and patient package inserts (PPIs). These materials, which are sometimes given to customers, contain information on a more elementary level than that found in PIs.

At a workshop conducted by the FDA on April 27, 2007, Janet Woodcock, the agency’s Deputy Commissioner, said that the FDA is “committed to facilitating transition to a world of electronic information” and to capitalizing on the efficiencies offered in an electronic environment.

PhRMA has already completed tests of applying bar codes to PIs so that pharmacists can scan the bar code in the pharmacy to bring up the National Library of Medicine’s DailyMed database, which the FDA updates each day. Bar codes were either scanned into a computer or into a stand-alone device. PPIs and MedGuides were also part of the tests. After the pharmacists brought up the latest version of the MedGuide or the PPI on a screen, they printed it out and handed it to the customers.

Pharmacy groups generally consider electronic access to the latest version of a PI, a PPI, or a MedGuide to be a good thing, but the devil is in the details. Although PhRMA is committed to making the changeover to electronic PIs cost-neutral for the pharmacies, John Coster, Vice President of Policy and Programs with the National Association of Chain Drugstores, named some drawbacks:

• a lack of work space for stand-alone terminals.
• the amount of time pharmacists spent waiting for the Internet to work during PhRMA testing
• expenses associated with training staff members
• costs of installing potential Internet lines
• paying for paper and printers
• ancillary computer expenses

Mr. Coster says, “We would like more detail on how this will be accomplished in the short and long term. Moreover, how can FDA guarantee that this cost neutrality will be maintained over the life of the project?”

It is generally agreed that some paper PIs will still need to be distributed. Examples include products that might be on a crash cart, in the emergency department, or in an ambulance.

Douglas Scheckelhoff, MS, RPh, Director of the Section of Pharmacy Practice Managers for the American Society of Health System Pharmacists, has a more expansive view. He foresees that paper PIs will continue to be necessary for drugs that have been on the market for less than two years.

“The paper PIs are important to these products, because prescribing and other information may not yet be available in routine drug information sources or [might not] yet be well known to pharmacists,” he explains.

He also suggests that paper PIs remain available for drugs associated with a high risk of adverse events (e.g., anticoagulants, antineoplastic agents, and opiates) as well as medications with black-box warnings. A third category for which paper PIs would be necessary would include injectable drugs; vaccines; or any medications requiring special compounding, preparation, dilution, or reconstitution.

The Pharmaceutical Printed Literature Association (PPLA) goes even further. This is probably not surprising, because its members print the PIs for the drug manufacturers. Peter Mayberry, Executive Director of the PPLA, says his members have no problem with electronic PIs (e-PIs); in fact, he supports the printing of bar codes on PIs to facilitate the transition to e-PIs. Yet he claims that with an all-electronic system, the FDA would be unable to monitor whether PIs were available for every drug in every pharmacy, as the agency can now do with printed PIs.

“How would the agency guarantee that information similar to that contained in printed PIs is perpetually available to those who dispense Rx [prescription] drugs?” he asks.