



June 22, 2007

Docket Officer
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20857

**RE: Electronic Distribution of Prescribing Information for Prescription Drug Products
Docket No. 2007N-0114 (72 Fed Reg. 15701 (April 2, 2007))**

Dear Docket Officer:

The Healthcare Distribution Management Association (HDMA) appreciates this opportunity to respond to the request by the Food and Drug Administration (FDA) for comments regarding Electronic Distribution of Prescribing Information for Prescription Drug Products, Docket No. 2007N-0114 (72 Fed Reg. 15701 (April 2, 2007)).

HDMA represents the nation's primary, full-service healthcare distributors. Our members are large national companies and regional, family-owned businesses. Each and every day, HDMA member companies safely and efficiently deliver nine million healthcare products to more than 144,000 pharmacies, hospitals, nursing homes, physician offices, and clinics across the United States. This essential function is provided with little public recognition or visibility, and at great savings to the healthcare system. HDMA members serve as the central link in a sophisticated national supply chain. As such, we have a responsibility to work closely with our supply chain partners to safeguard patient health. We take this mission very seriously, and we support manufacturers, pharmacies, and the government in ongoing efforts to ensure the U.S. medicine supply remains secure, efficient, and highly regulated.

HDMA supports and appreciates FDA's effort to explore how to best electronically distribute FDA-approved prescribing information or package inserts (PIs) for prescription medicines and biological products. HDMA previously offered testimony to FDA on this issue at the public hearing on April 27, 2007. We supplement that oral testimony with these written comments. Specifically, we address:

- How distributors use the current, paper PIs,
- Benefits distributors believe will be possible with electronic PIs,
- Logistical issues in continuing the availability of paper PIs in an electronic system,
- Recommendations for an electronic PI system,
- Additional issues for consideration in a paperless PI regime.

HOW DISTRIBUTORS USE THE CURRENT PAPER PIs

Wholesale distributors recognize that a prescription drug's PI is critical to the regulatory status of the product. The PI, of course, sets out the basis for the drug's approval and provides all the information necessary for healthcare professionals to safely prescribe and dispense the drug. Further, wholesale distributors understand the importance of the many ongoing initiatives to improve the content and format of the PI, such as the final rule on prescription drug labeling (71 Fed. Reg. 3921 (Jan. 24, 2006)), implementation of Structured Product Labeling (SPL), and the inclusion of PIs in online databases, such as DailyMed. Nevertheless, for the wholesale distributor, the PI has no functional purpose at all.

The distribution of prescription drugs involves a product flow and an information flow. The information that accompanies the lawful distribution of that product – the PI – is very significant to the manufacturer, the prescriber and the dispenser. The wholesale distributor, however, is wholly concerned with product flow. The information within the PI is not relevant in any way to the wholesale distributor's operations to assure the timely and safe delivery of pharmaceutical products.

Theoretically, the Storage and Handling section of the PI is useful to a wholesale distributor. Appropriate storage and handling is, of course, an important component of a distributor's operations. However, distributors would not disturb the paper PI attached to a drug package to learn, for instance, at what temperature a refrigerated product should be kept. Rather, distributors typically receive storage, handling and other product information directly from the manufacturer before the distributor receives the products and their attached PIs. Distributors request storage information from manufacturers by using the HDMA Standard Product Information form¹, by contacting the manufacturer directly, or by visiting the manufacturer's Web site. Distributors can also find product information from other sources, including:

- The package label or case container,
- The product's Material Safety Data Sheet (MSDS),
- Internet sources, including DailyMed, the FDA Web site, and the manufacturer's Web site, and
- A medical information service.

Distributors do not use the PI, generally do not reach the prescriber, do not interact with patients, and do not provide counseling services. There is, thus, little to no value in having them serve as a conduit for this information, in paper or electronic form. Our members include a paper PI with the products they distribute because the Food, Drug, and Cosmetic Act requires it. A paper PI has no other utility to the wholesale distributor and as discussed in the next section, its absence would not be missed.

¹ Available at: http://www.healthcaredistribution.org/resources/new_product_form.asp

BENEFITS DISTRIBUTORS BELIEVE WILL BE POSSIBLE WITH ELECTRONIC PIs

Our members believe that there are means for delivering the PI to those who need and use it that are superior to simply gluing the paper on to a drug's container or package. HDMA agrees with stakeholders who testified at the public hearing that an electronic system represents a better approach to ensuring the delivery of PI information to the prescribers, dispensers, and others that serve patients. An electronic system would enhance patient safety by speeding the availability of critical new risk information to prescribers and dispensers. An electronic PI will help ensure that those who need the PI to counsel their patients know where to obtain the most current information quickly.

There would be other operational benefits for distributors if paper PIs no longer accompanied drug products. Many distributors use automated systems for picking drug products to fill customer orders, which can be clogged or jammed by paper PIs. An electronic system could enhance operational efficiencies and reduce manual handling efforts needed for paper PIs.

Further, at the hearing, stakeholders offered testimony that lengthy printed PIs were increasing package, product, and storage costs, especially for products that require refrigeration. Maintaining cold storage is costly and the space is limited. HDMA members strongly agree with the viewpoint presented that changing to an electronic PI would, for many products, substantially decrease packaging, shipping, and storage costs.

We understand that pilot programs have been tested that involve different mechanisms by which pharmacies and prescribers receive PIs electronically from manufacturers and/or are able to access PIs from a central repository such as DailyMed. As distributors did not participate in these pilots, we are not in a position to discuss the relative benefits of different approaches. We can say that for wholesale distributors, any operational benefits that might arise from electronic PIs depend upon direct transfers of information from manufacturers to those who need the PI. Wholesale distributors do not need to be, and should not be, part of the chain of distribution of electronic PIs.

LOGISTICAL ISSUES IN CONTINUING THE AVAILABILITY OF PAPER PIs IN AN ELECTRONIC SYSTEM

Although several witnesses at the April 27th public meeting recommended that paper PIs be available even after an electronic system is in place, few gave specific suggestions as to how the paper PIs would be provided under this system. HDMA would be adamantly opposed to a paper-electronic hybrid system where it is expected that the same drug product would be available either with a paper PI or without one.

Such a system would be very confusing, particularly if it were expected to be administered within the current distribution system. The complexity would erode many of the efficiency gains that

make electronic PIs attractive and feasible, and substantially increase costs for wholesale distributors, and consequently, for their customers. To implement such a system:

- Distributors and manufacturers would have to perform major reconfigurations of their warehouse storage set-ups to segregate the products with paper PIs included from those without the PI included,
- Distributors and manufacturers would also have to substantially revise product ordering computer software; inventory management systems; and their pick, pack, and ship procedures,
- They would also have to retrain staff, and
- Since the NDC number is the best (and only) reliable identifier suitable for product ordering systems, FDA would also have to require two sets of product NDCs for the same product, one NDC for those with the paper PI affixed, and a separate, distinct NDC for those without the paper PI. Customers ordering the product with the paper PI would have to specify an NDC different from those ordering the product without the PI. HDMA does not know of an alternative means available to distinguish product packages with, and those without, paper PIs without creating separate NDCs.

Given how disruptive administering a dual system would be, distributors generally would prefer retention of the current paper PI system rather than trying to retool their operations to accommodate customer preferences for either an electronic or a paper PI, or both.

RECOMMENDATIONS FOR AN ELECTRONIC PI SYSTEM

While there is no need for the distributor to be part of an electronic PI system, based on our own experience with electronic systems development, HDMA offers the following suggestions for an electronic PI system.

- We recommend creation of one, uniform system offering information in a single format, managed by a single entity. An electronic system that runs on multiple systems and formats would waste human, technology and capital resources, and would be too complex for the fast throughput, high volume healthcare product delivery system. If a single system is not feasible, HDMA recommends a system of compatible, networked sites.
- HDMA strongly urges rejection of a combined system that requires both paper and electronic PIs. The ultimate goal should be to have all PIs available electronically, with a back-up system available to assure that the information contained within the PI is always available to healthcare professionals.
- If it is determined that in some limited cases, for example, due to limited workspace at the dispensing site, other restrictions where the drug is prepared or administered, or for a defined pe-

riod of time for newly approved prescription drugs (when, presumably, pharmacists and practitioners would most need access to the PI), certain drugs should have paper PIs available, HDMA recommends against allowing the same product to be packaged with and without a paper PI. If a paper PI is required or otherwise going to be available on or in the package for an individual product, *all* of those products' packages should include the paper PI.

- Drug packages should be modified to include information on where to obtain the electronic PI, such as a Web site and/or an 800 number. As discussed, when a distributor might need storage or other information in the paper PI, it is able to obtain that information from several easily available sources. Adding information to the drug package about where to obtain the electronic PI would help everyone in the supply chain, including distributors, find the PI quickly and efficiently should they need to do so.
- The manufacturer currently assumes the costs associated with creating and providing the paper PI. HDMA sees no need to significantly alter the current cost structure if and when the PIs are provided electronically.
- PIs should be transmitted directly from the manufacturers to the Web site(s) where they will reside and/or to the prescribers and dispensers. Making the distributor a gatekeeper between the manufacturer and those who counsel patients and dispense medications is not appropriate or efficient.
- Electronic transmission of PIs must be independent of any other electronic product identification and tracking systems that are used or under development in the supply chain.

ADDITIONAL ISSUES FOR CONSIDERATION IN A PAPERLESS PI REGIME

At this juncture, an electronic PI system is still in the preliminary stages. As the *Federal Register* notice sets out, FDA is gathering information about who within the healthcare system uses paper PIs, how they use them, and what logistical challenges would arise with electronic distribution. HDMA has identified three additional issues not yet addressed.

First, it appears FDA has not yet focused upon how electronic PIs might alter repackaging operations. FDA did not specifically seek comment on repackaging, yet, repackaging is a very common activity throughout healthcare that encompasses contract packaging undertaken at the request of the original drug manufacturer, unit dose and unit of use repackaging undertaken at the request of hospital and pharmacy dispensers, and general repackaging undertaken at the request of a customer whereby larger drug packages (e.g., 1,000 count) are repacked into smaller quantities (e.g., 100 count). FDA has regulations and guidances governing repackager operations, including establishment registration, drug listing, good manufacturing practices, labeling, and stability testing. The agency will need to address what, if anything, repackagers would need to do if PIs were converted from print to electronic formats.

HDMA posits that it would become very confusing and burdensome if every repackaged drug product triggered dissemination of a new, electronic PI. As an alternative, HDMA members propose that only one PI – the one generated by the manufacturer – would be linked to the repackaged drug. At the public meeting, stakeholders described an electronic system that linked a drug's bar code and embedded National Drug Code (NDC) to the applicable PI for that product. A user would scan the drug's bar code and then immediately be brought to the PI, which would be residing in a database.

Second, there will also need to be a reliable and visible means of alerting the healthcare community when a manufacturer updates a PI. Currently, dispensers and prescribers know when a PI changes by, among other things, the date identified on the PI. A similar alert mechanism would need to be in place for updates to electronic PIs.

Third, as FDA noted in the *Federal Register* notice announcing the public hearing and call for comments, the agency interprets 21 C.F.R. § 201.100(c)(1) as requiring that "adequate directions for use," that is, the PI, be "*Labeling on or within the package from which the drug is to be dispensed.*" 72 Fed. Reg. at 15702. At this stage, FDA has not yet identified what regulations and guidelines would need to be amended to accommodate distribution of an electronic PI in lieu of a paper one.

HDMA believes that § 201.100(c)(1) of the regulation and potentially other regulations will need to be amended if FDA proceeds with implementation of an alternative, electronic system for dissemination of the PI. We suggest modifying the beginning of this section as follows:

"Electronically available labeling ~~on or within the package from which~~ applicable to the drug ~~is~~ to be dispensed..."

Further guidance will probably also be needed.

CONCLUSION

HDMA appreciates this opportunity to share its views with FDA and to provide our perspectives on replacing paper PIs with a system of electronic distribution. Should you have any questions, please feel free to contact me at 703-885-0240 or at aducca@hdmanet.org.

Sincerely,



Anita T. Ducca
Senior Director, Regulatory Affairs and Healthcare Policy