FDA Plans to Simplify Formats For Consumer Pharmacy Materials

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With 30 million people on the cusp of receiving health insurance and prescription drug coverage for the first time, thanks to health care reform legislation that Congress may pass, the persistent problems of medication nonadherence and medication errors loom larger than ever. That is the backdrop to the FDA's current effort to revise its dusty and confusing consumer medication information (CMI) program.

CMI refers to the various types of printed materials that pharmacists give patients when they pick up a prescription. Having held a workshop in September, the FDA previewed some potential new CMI formats and then received comments from major drug manufacturers and pharmacy groups. The agency is now on the verge of announcing a new initiative that nearly everyone admits is needed.

Janet Woodcock, MD, Director of the FDA's Center for Drug Evaluation and Research, admits, “We have not made a dent in this epidemic of harm from inappropriate use of drugs or from medication errors.”

She notes that a one-document solution is the logical proposal. Currently, the FDA has three different CMI formats; some are mandatory, and some are not. Each format comes into play under different circumstances.

“I know we have had lots of discussions and workshops about this over the years, but this time we really mean business,” she adds.

The FDA has three types of pharmacy CMI programs. Drug companies voluntarily supply written CMI at the point of purchase for whatever products they choose. The FDA requires patient package inserts (PPIs) to be provided at the pharmacy for only two drug categories: estrogens and oral contraceptives. Paper handouts, called Medication Guides (MedGuides), are required for nearly 90 categories of drugs, all of which have significant risk profiles and could harm a patient if the drug is taken improperly.

All three types of CMI have varying formats even though the FDA has published guidance on what they should look like. CMI pamphlets, consisting of sheets stapled to the vial’s bags that the pharmacist gives patients at checkout, are by far the most numerous. However, according to two surveys conducted for the FDA in 2001 and 2008, the number of patients reporting that they received CMI and the number saying that they found the sheets useful were considerably lower than the number of patients required to answer in the affirmative.

At this point, even pharmaceutical companies think that the FDA’s consumer drug communication program should be simplified. Some of those companies are particularly concerned about the proliferation of MedGuides since 2007, when Congress passed the FDA Amendments Act (FDAAA). That act allowed the FDA to require companies to develop a Risk Evaluation and Mitigation Strategy (REMS) for drugs with certain risk profiles. Between September 2007 (when the FDAAA was enacted) and May 31, 2009, the FDA approved 50 REMSs with MedGuides, including 43 REMSs consisting only of a MedGuide.

Susan Berger, PhD, Senior Director of Risk Management Strategy at Pfizer Inc., claims that the FDA is overusing these guides and that they have become comprehensive-risk communication documents instead of “highly limited information” sheets. More broadly, she argues that any new FDA consumer drug labeling initiative must be carefully limited:

Any patient labeling must include only the directions that the patient requires in order to administer the drug and precautionary information that will enable the patient to use the drug safely, such as a caution against driving or using other substances concomitantly. Comprehensive patient labeling should not be required for any—much less every—prescription drug.

The four prototypes that the FDA previewed at its September workshop would seem to satisfy Pfizer and anyone else concerned about the potential complexity of consumer risk communication. The question is whether a one- or two-page sheet would replace the MedGuides and PPIs. Marcie Bough, Director of Federal Regulatory Affairs at the American Pharmaceutical Association, says:

We support the development of a single, easy-to-read document that could be used to replace, not be added to, the current dispensing of MedGuides, CMI, and PPIs. However, we recognize that there may be some medications that fall outside of the single-document, one- to two-page format generally being discussed.

Although most industry groups seem to agree on the need for a single, short consumer communication format, the American Society of Health-System Pharmacists (ASHP) wants a new CMI format to also include benefits of the medications. Justine Coffey, JD, LLM, ASHP Director of Federal Regulatory Affairs, says:

To date, there has been a greater emphasis on the communication of risk information in CMI. Risk and benefit information should be communicated together in CMI, clearly describing any factors or contributing conditions that should be included in the patient/prescriber decision.

The FDA might not be willing to adjust that balance, though, since the function of CMI, set in law, is to act as a “blinking yellow light” of sorts. The fact that a drug is approved means that it has benefits. But just as motorists slow down and watch for pedestrians or other cars before crossing an intersection with a blinking yellow light, patients are supposed to read the CMI before taking a drug.