



ISSUE BRIEF

Food and Drug Administration (FDA) Risk Communication & Labeling Activities

In 2007, the FDA held several public meetings on issues of interest to pharmacists and provided several important updates on labeling and risk communications. The summaries below relate to: paperless labeling; Medication Guides (MedGuides); Risk Minimization Action Plans (RiskMAPs); and adverse events reporting.

Paperless Labeling

Background

On April 4, 2007, FDA held a public meeting on the electronic distribution of prescription information that is currently found in the package inserts (PIs) attached as paper leaflets for prescription drug products, also known as paperless labeling. APhA supports FDA's initiative to improve prescription labeling information access and usability through electronic distribution of FDA-approved PIs. However, APhA support is contingent upon the new approach being flexible, allowing for ongoing availability of paper information, not creating additional burden on pharmacists, and not creating additional financial burden on pharmacies. APhA is concerned that costs such as printing hardware, paper and ink related to printing PIs would be shifted from the manufacturer to pharmacies. APhA's comments at the public meeting urged the Agency to address how computer infrastructure and technology costs would be addressed.

APhA Position

APhA also recommended that FDA:

- Create a flexible system that allows for both electronic and paper access to PI information given the varying degree of Internet access and electronic capabilities in pharmacies;
- Establish a transition period to phase-in changes to the current distribution system with an educational campaign to pharmacists and other health care providers;
- Develop a central Internet site that is free to access, easy to navigate, and allows for the development of multiple PI formats that provide easy viewing and printing that could be integrated into existing pharmacy computer processing systems and downloaded to hand held devices. Such a system would also allow for improved point-of-care access by prescribes and pharmacists that have limited Internet access; and

- Develop a system that allows pharmacists access to a backup paper system to retrieve PI information in case of emergency or when a computer system is down.
- Establish a system for maintaining and updating a database for PI information to ensure that all health care providers have access to easily accessible, user-friendly and current PI information.

Next Steps

The Agency is analyzing the feedback it received at the public meeting and continues to work internally to make change based on the many recommendations from stakeholders.

Medication Guides (MedGuides)

Background

On June 12-13, 2007, FDA held a public hearing to gather feedback on ways to improve effectiveness and distribution of Medication Guides (MedGuides) through the MedGuide Program. MedGuides are FDA-approved written patient information for certain drugs and biologics that the FDA has determined pose serious and significant public health concerns. Pharmacists are required to distribute MedGuides to every patient every time they receive a medication that requires a MedGuide, both on the first-fill and on refills. Manufactures are responsible for ensuring distribution of MedGuides, either by providing pharmacists with enough MedGuides for every patient for every fill of a prescription that requires a MedGuide, or by providing pharmacists a way to produce enough MedGuides onsite for every patient.

APhA is generally supportive of FDA's initiative to reevaluate and improve the MedGuide Program. However, APhA is concerned with the growing number of MedGuides, the logistics for handling them in the pharmacy and getting them to patients, the impact and disruption to pharmacy workflow, and information overload being experienced by patients taking these medications.

APhA Position

APhA's Recommendations to FDA:

- Explore ways to better enforce current requirement for manufacturers to supply an adequate number of hardcopy MedGuides to pharmacies;
- Streamline the reordering system;
- Streamline the program to allow pharmacy software vendors flexibility to integrate MedGuide information within patient information already being printed automatically with each prescription;
- Consider how to facilitate pharmacy dispensing/printing systems to automatically print the current PDF format of MedGuides;

- Address how changes to the current system would address the cost shift from manufacturers to pharmacies who integrate an electronic printing system;
- Standardize the information that must be included in the patient information, including a consistent format, look and feel to the MedGuides;
- Scientifically evaluate the usefulness and value (including readability) of the current program to see if reach its intended use;
- Remove the requirement to provide MedGuides with every fill and instead limit to first fill, then once a year thereafter; and
- Consider how prescribers could be better informed that certain products require MedGuides, and explore the opportunity for prescribers to provide MedGuides at the point-of-prescribing.

Next Steps

The Agency is analyzing the feedback it received at the public meeting and continues to work internally to make change based on the many recommendations from stakeholders. APhA is working with the Agency to provide assistance as program changes are implemented.

Risk Minimization Action Plans (RiskMAPs)

Background

In 2007, FDA and the Agency for Healthcare Research Quality (AHRQ) held a joint public workshop entitled “Implementation of Risk Minimization Action Plans (RiskMAPs) to Support Quality Use of Pharmaceuticals: Opportunities and Challenges. The intent was to gather feedback from stakeholders to help in the development and implementation of mechanisms to minimize the risks of medications with unusual safety and patient monitoring concerns. Currently, RiskMAPs are required for those medications that FDA has determined have potential risk.

APhA Position

APhA supports efforts by FDA and AHRQ to improve the efficiencies of RiskMAPs and to identify measures that can be utilized to minimize a product’s risk while preserving access to the product’s benefit. However, APhA is concerned with the challenges that pharmacists face with implementing these programs in the practice setting. Specifically, APhA is concerned about the lack of: guidance for FDA and drug manufacturers to follow when deciding if a RiskMAP will be required; criteria to identify what triggers the need for a formal risk management program; standardization, consistency and requirements for RiskMAPs, resulting in increased administrative burden; program evaluation on: effectiveness at minimizing risk; balance of risk versus benefit information; awareness of program by pharmacists, other health care professionals; and

patients impact of the overall program on pharmacy and medical practice. The need for increased communication prior to and after the launch of RiskMAPs.

APhA's Recommendations to FDA:

- Develop specific criteria to guide the determination of when medication will be placed in a risk management program;
- Develop a system-based approach to risk management programs that is both effective in mitigating risk and workable for pharmacists, other health care professionals, and patients to implement and follow;
- Before more RiskMAPs are implemented: identify program systems and tools that have a common infrastructure and make use of available technology; pilot test prior to the launch of a program; ensure that pilot test results indicate that the balance of risk and benefit messages are appropriately communicated and that program participants understand the intent, function and how to implement the program;
- Evaluate the effectiveness of risk management programs at the practice level for pharmacists, physicians, other health care providers and patients so that efforts used to create a RiskMAP is equally matched by efforts to evaluate its effectiveness;
- Create an easy to locate and navigate RiskMAP Web page on the FDA Web site that defines risk management programs, lists all RiskMAPs, summarizes each program with complete implementation instructions; and create quick reference guides or implementation checklists for prescribers, pharmacists and patients;
- Work with stakeholders to develop and support an educational campaign to build awareness and understanding of risk management programs.

Next Steps

The Agency is analyzing the feedback it received at the public meeting and continues to work internally to make change based on the many recommendations from stakeholders. APhA is working with the Agency to provide assistance as program changes are implemented.

Adverse Events Reporting Requirement (1-800 Number)

The Food and Drug Administration Amendments Act of 2007 (Public Law 110-85) directed the Secretary of Health and Human Services (HHS) to implement a 2004 proposed rule regarding adverse event reporting, effective January 1, 2008. However, recognizing implementation challenges with 2008 timeline, FDA published an interim final rule on January 3, 2008, delaying enforcement of the rule until January 1, 2009 to allow pharmacists time for implementation.

The 2004 proposed rule required medication labeling of prescription and non-prescription products include a toll-free number (1-800 number) maintained by HHS for

the purpose of receiving reports of drug-related adverse events. The rule would also require pharmacists and other authorized dispensers to distribute the side effect statement to consumers with prescription medications and over-the-counter products that do not already list the manufacturers contact information. Additionally, the listed the following options for pharmacists and other authorized dispensers to distribute the required labeling, referred to as the “side effects statement,” in one of five ways:

- On a sticker attached to the unit package, vial, or container of the drug product;
- On a preprinted pharmacy prescription vial cap;
- On a separate sheet of paper;
- In consumer medication information; or
- In the appropriate FDA-approved Medication Guide that contains the side effects statement.

Status

FDA will be publishing a final rule before January 1, 2009.

APhA Statements

The following documents are available on the APhA Government Affairs Web site at www.pharmacist.com/GA:

- 6/13/2007 APhA Statement at FDA Hearing on MedGuides
- 6/22/2007 APhA Comments to FDA on Paperless Labeling
- 7/12/2007 APhA Comments to FDA on MedGuides
- 7/31/2007 APhA Comments to FDA on RiskMAPs

Resources

FDA Risk Communication Activities

- Link to the paperless labeling meeting notice at:
<http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/pdf/07-1604.pdf>.
- More information about the MedGuide Public Hearing is available on the FDA Web site at:
http://www.fda.gov/cder/meeting/medication_guides_200706.htm.
- For a list of all MedGuides, go the FDA Web site at:
http://www.fda.gov/cder/Offices/ODS/medication_guides.htm
- For more information about the RiskMAP Public Workshop go to the FDA Web site at: <http://www.fda.gov/cder/meeting/riskMAPs.htm>

FDA Labeling Activities

- Link to the Federal Register notice at:
<http://a257.g.akamaitech.net/7/257/2422/01jan20081800/edocket.access.gpo.gov/2008/pdf/E7-25426.pdf>.
- APhA House of Delegates: www.pharmacist.com/HoD

APhA Government Affairs Resources
www.pharmacist.com/GA