American Latex Allergy Association

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Mandatory Medication Labeling

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The American Society of Health-System Pharmacists (ASHP) has undertaken the issue of potential latex content in medication vial stoppers and pre-filled syringes. The ASHP?s House of Delegates recently approved a mandatory labeling policy, which states, ?Mandatory Labeling of the Presence of Latex: To urge the Food and Drug Administration to mandate that manufacturers of medications and medication-device combination products include labeling information on whether any component of the product, including its packaging, contains natural rubber latex.?

The ASHP describes the events that led to this policy?s creation as follows.

The Executive Committee of the Section of Inpatient Care Practitioners and the Council on Professional Affairs discussed two separate but related issues dealing with allergies to natural rubber latex proteins (hereinafter ?latex?) in June 2004 and September 2004, respectively. The first issue came to the Council on Professional Affairs as a Recommendation from the 2004 ASHP House of Delegates, which suggested that ASHP should develop a policy that all medication containers and devices be required to indicate on their labels whether they contain latex. The second issue came from the Section of Inpatient Care Practitioners, which suggested that natural rubber latex be eliminated from drug products.

The presence of latex in drug product containers presents a significant challenge to health care workers. Hospital policies for preventing latex allergy reactions vary, as often discussed on ASHP?s e-discussion groups. For patients with a documented latex allergy, much time is spent to minimize potential risk through avoidance. These practices include using latex-free products, ?popping the top,? and a ?one-stick policy.? Information regarding the composition of the closure is often difficult to obtain, even from the manufacturer. Databases exist but are not available or accessible in every pharmacy, and they may not be regularly updated with all products. Determining the latex status of a product can be time consuming and laborious, and may ultimately result in a treatment delay.

In determining what ASHP?s policy on latex content should be, the Section considered what the current FDA labeling requirements are and the feasibility of a ban on latex.

In 1997, FDA issued a rule requiring labeling statements on medical devices, including device packaging containing natural rubber that contacts humans. This rule by the Center for Devices and Radiological Health

requires that medical devices containing natural rubber latex state, ?Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.? Syringes are considered medical devices and therefore are subject to the FDA labeling requirement. However, medication-device combination products, such as prefilled syringes, are not subject to the FDA labeling requirement (Federal Register 21 CFR Part 801). The Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) of FDA, which have jurisdiction over medication-device combination products such as prefilled syringes, did not adopt the natural rubber latex labeling rule.

Questions have remained as to whether the dry natural rubber used in pharmaceutical vial closures and syringe plungers releases allergenic proteins, creating an allergen exposure risk for individuals receiving injectable medications. When synthetic butyl and isoprene rubber stoppers became available in 1996, the United States Pharmacopeia considered a proposal to exclude natural rubber from pharmaceutical vial closures. The proposal was not adopted, however, because there was insufficient peer-reviewed literature to show that natural rubber vial closures contribute to a significant risk for reactions in latex-allergic individuals, and CDER and CBER did not enact a ban on use of latex. The Section and the Board of Directors concluded that it is more realistic to advocate that FDA require pharmaceutical manufacturers to indicate the natural rubber latex status on all medication and medication-device combination product containers than to advocate a ban at this time. The Section and the Board of Directors believe that this labeling requirement would relieve substantial strain on pharmacy department staffs and ultimately result in a safer practice for patients.

The American Society of Health-System Pharmacists (ASHP) is the 30,000-member national professional association comprised of pharmacists who work with doctors and other health professionals in hospitals, ambulatory care clinics, and long-term care and home care facilities. ASHP?s mission is to support pharmacists in helping people use medications safely and effectively.

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