Regenstrief study finds that generic drugs often have incorrect safety labeling

13 December 2012

Despite U.S. Food and Drug Administration regulations requiring generic medications to carry identical warnings to those on corresponding brand-name products, a study by Regenstrief Institute researchers has found that more than two-thirds of generic drugs have safety-warning labels that differ from the equivalent brand-name drug.

The investigators reviewed 9,105 product labels for over 1,500 drugs available on DailyMed, an online repository of labeling information maintained by the FDA and the National Library of Medicine. Of the 1,040 drugs with more than one manufacturer's label, 68 percent showed some discrepancies within their safety information.

The majority of generics showed relatively small differences across their labels, but nine percent showed differences of more than 10 side effects. Errors included out-of-date information, incomplete data and, in one case, information for the wrong drug altogether.

"Physicians frequently use labeling information, either directly or indirectly, to make prescribing decisions. They need to know about side effects, drug interactions and other safety issues," said Regenstrief Institute investigator Jon Duke, M.D., M.S., assistant professor of medicine at the Indiana University School of Medicine, who led the study. "We found that generic drug labels may contain incomplete or incorrect safety information. Until this problem is resolved, physicians and patients should rely on brand drug labeling only, even when the patient is getting a generic version of a drug."

Information on medication side effects are often conveyed to patients by their doctors or by pharmacists through information sheets accompanying a pharmacy purchase. These information sheets are based on the medication labels.

Safety studies are conducted by the brand name manufacturer before the medication goes on the market. The FDA does not require that the generic manufacturer duplicate these studies.

The researchers extracted drug safety data from medication labels using the Structured Product Label Information Coder and Extractor, or SPLICER, a software application created by Dr. Duke and colleagues. In a previous study, SPLICER was shown to have an accuracy of 94 percent.

"The solution to the problem of labeling inconsistency may be a centralized listing of drug side-effects, maintained independently of individual manufacturer labels. Drug labels would simply reference this common repository rather than attempting to maintain all the information within a single document. Clinicians could refer to this resource for the most up-to-date safety information regardless of generic manufacturer," Dr. Duke said.

Provided by Indiana University