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FALLOUT OF NEW US LABELLING NORMS

Lawsuits From Across Atlantic Loom

Trouble may hit Indian pharma firms if USFDA okays safety warning upgrades on labels

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NEW DELHI

Indian pharmaceutical companies may have to brace themselves for a possible surge in lawsuits from patients and consumer groups in the United States if the regulator there goes ahead with its plan to grant generic drugmakers the freedom to update "newly acquired" safety warnings on their product labels.

The US Food & Drug Administration (USFDA) is currently inviting public comments on a proposal to allow generic drugmakers to independently update safety warnings on product labels, which it says can speed up dissemination of safety information to doctors and patients in the country.

Additionally, generic drugmakers will have to inform the innovator drug firm making the branded drug about the change in label.

Manufacturers and analysts said this move could mean that generic drugmakers would have to assume greater responsibility over their product labels and face greater liability for failing to warn patients in the US on side effects.

"This move, if implemented, will increase the scope of liability for generic drug firms in the US as they will have to assume shared responsibility with innovator drug firms for failing to update safety warnings on their products," said Praful Bohra, analyst at brokerage firm Nirmal Bang Securities.

Under the current norms, generic drugmakers are not meant to change their product labels until the innovator drug firm updates safety warnings on the label of its corresponding brand name product.

In effect, generic companies have no control over the labelling of their products and therefore cannot be held accountable for alleged inadequacies in those labels, a position that has been upheld in the US courts.

"Generic manufacturers had been largely protected from lawsuits pertaining to failure-to-warn claims. But if this rule is put into effect, they will no longer be able to assert that they lacked unilateral ability to alter the information contained in their product labels. This will permit injured customers to pursue claims," said Girish Bakhru, analyst at HSBC Securities and Capital Markets, in a recent research note. It might be too early to quantify the impact of the proposed rule, Bakhru said but added that in the longer run the entire industry would face a material impact.

Generic drugmakers including Indian pharma firms account for 80% of prescriptions generated in the US.

Generic Pharma Association (GPhA), an industry body which counts among its members US subsidiaries of top India-based drugmakers such as Ranbaxy Labs, Dr Reddy's, Sun Pharma and Cadila Healthcare said that it was "very concerned that multiple versions of critical safety information would lead to unnecessary confusion and uncertainty for prescribers and other healthcare professionals, with harmful consequences for patients".

Currently, generic manufacturers are required by law to have the identical label as the reference brand.

Uniform safety information avoids confusion among patients, doctors, pharmacists and nurses, and assures all healthcare practitioners that they can rely on consistent information to inform their decisions and patient conversations, Ralph G Neas, president, GPhA said in a statement.

A GPhA spokesperson told ET that the body was still assessing the potential legal impact of the move on generic drugmakers.

Senior executives of leading Indian drug firms ET spoke to said on the condition of anonymity that they expected litigation costs for generic drugmakers to go up substantially in the US if the proposal was implemented. "This will expose generic firms to a completely different set of litigation, from which they have stayed protected till now. This will definitely translate into more lawsuits for generic drug firms on inadequate safety warnings and higher costs," said an executive.

Regulatory