
DRUG BENEFIT NEWS

Removal of Ranbaxy Generic Rxsls Not Likely to Have Major Impact

The FDA's decision last month to block imports of more than 30 generic drug products from Indian manufacturer Ranbaxy Laboratories Ltd. is not likely to cause Rx shortages or drive up generic drug prices, with the possible exception of a powerful acne drug, say health plans and PBMs. Even though Ranbaxy is one of the largest foreign suppliers of generic drugs, other manufacturers are stepping in to fill the void, they tell *DBN*.

Concerns over drug shortages and price hikes followed the FDA's Sept. 16 decision to slap an "import alert" on dozens of Ranbaxy generic drugs after the manufacturer failed to address repeated warnings regarding "good manufacturing practices" at two facilities.

The import ban affects many widely taken generics, including versions of cholesterol drugs Zocor (simvastatin) and Pravachol (pravastatin), the antibiotic Cipro (ciprofloxacin), the epilepsy drug Neurontin (gabapentin) and the acne treatment Accutane (isotretinoin). The ban does not include the antiviral ganciclovir, as Ranbaxy is the sole U.S. supplier of the HIV drug, the FDA noted.

The FDA said it has no evidence so far that Ranbaxy has shipped any defective products. Nevertheless, a PBM subsidiary of one large health plan decided to take action against the Ranbaxy products this summer after it became clear the FDA had concerns about the firm's manufacturing processes. Prescription Solutions quarantined the identified products in its mail-order pharmacy facility in July, says John Jones, senior vice president of government affairs and pharmacy policy at the PBM unit of UnitedHealth Group.

Generic Accutane Prices May Rise

"When we look at something like that, the first thing you have to ask is, is there something we can do about it if it's a concern?" Jones tells *DBN*. In this case, Prescription Solutions realized that many of the drugs on the FDA's list could be replaced by other manufacturers, Jones explains. "While it might have cost us a little bit more in drug costs, we felt we could basically quarantine those products and replace them with competitors' products and literally dispense practically none of them, except the one that they have a monopoly on." Replace-

ments for the Ranbaxy products were found in less than 48 hours, he says.

Other large players also see little fallout from the FDA's move. Medco Health Solutions, Inc., which is one of the largest U.S. purchasers of generic drugs through its massive mail-order operation, said that the Ranbaxy import alert will not affect the PBM's ability to meet the needs of its members.

"In fact, Medco only dispenses three of the products on the alert list," Keith Bradbury, Medco's executive director of drug information, tells *DBN*. These account for just 660 prescriptions of the more than 2 million that Medco dispenses each week, he adds. "There are alternate suppliers that can provide Medco with its product needs during this interim period," Bradbury says.

There is, however, one Ranbaxy product that could see upward pricing pressure due to the import alert: the severe acne drug Accutane. Ranbaxy had 50% of the U.S. generic market for the product, says **Paul Bogorad**, Ph.D., senior manager at pharmaceutical and biotech consulting firm Putnam Associates.

The drug requires a patient registry because of its safety risk profile, and it is one of the more expensive generic drugs to produce. "There are not a lot of players out there," **Bogorad** tells *DBN*. "That's a product which I'm sure companies are scrambling to replace."

Kevin Gorman, managing partner at Putnam, says that in the short term, drug payers will likely see generic Accutane's price going up. But he also notes that one of the hallmarks of the generic drug industry is its ability to adapt rapidly to marketing opportunities. "Nature abhors a vacuum, so the other people who have supply will quickly bring additional capacity on line," he says. "I'd be surprised if this continues to be a disruption for more than a month to two months."

But will the negative publicity surrounding Ranbaxy troubles play into the hands of skeptics who claim generic drugs are not of the same quality as brands? Most observers say no.

Jones points out that the FDA action relates only to the manufacturing process, and that it did not find any defects in the products themselves. "Because the plants are on foreign soil, the FDA has no direct regulatory control over them," he says. "Its only leverage is to ban importation of products."

Gorman says the FDA's move sends a strong message, particularly as it follows the agency's February 2008 recall of the blood thinner Heparin, which had been linked to several deaths due to allegedly tainted products originating in a Chinese plant.

"The FDA, having been caught short, is effectively shooting a target shot across the bow of Ranbaxy and the generic pharmaceutical industry in general, and saying, 'Hey, we're going to take pre-emptive measures when we think it's appropriate rather than waiting for another Heparin disaster,'" **Gorman** says.

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