BlueCross BlueShield of Illinois

Ranbaxy Pharmaceuticals atorvastatin Recall

On Nov. 9, 2012, Ranbaxy Pharmaceuticals announced that it was initiating a voluntary recall of its popular cholesterol lowering medication atorvastatin, which is the generic version of Pfizer's Lipitor. The reason for Ranbaxy's recall was due to the possibility of small (less than 1 mm) glass particles in its product. It also reported that the probability of an adverse event is low, but that it could not be ruled out.[1] Presently, Ranbaxy has not received any reports of adverse events.[1]

Interestingly enough, the recall only affects the 10, 20 and 40 mg strengths of atorvastatin calcium (i.e. it does NOT include the 80 mg strength).[2] In addition, Ranbaxy reported that the recall includes 41 specific lots of atorvastatin. A list of the recalled lot numbers can be found at: http://www.ranbaxyusa.com/newsdisp281112.aspx. Ranbaxy has notified its distributors and retailers of the recall and affected lots are no longer being distributed.[2]

Patients that are experiencing adverse effects from taking the affected medication should contact their health care provider immediately. Patients with atorvastatin prescriptions from Ranbaxy should contact their pharmacist or Ranbaxy's Customer Coordinator at 866-266-7623 to find out if their prescription is affected.

Generic Lipitor is currently manufactured by five pharmaceutical companies: Apotex Inc., Dr. Reddys Labs, Mylan Pharmaceuticals, Sandoz Inc. and Teva Pharmaceuticals.[3] There is no anticipated drug shortage for the 10, 20, 40 mg strengths of atorvastatin. Patients taking affected Ranbaxy atorvastatin should have their medication substituted seamlessly by their pharmacist. The substituted medication may look different. Patients with questions about product identification should contact their pharmacist for clarification.

The FDA recall process

Drugs may be recalled from the market by three methods; (a) the manufacturer can perform a voluntary recall, (b) the FDA can request the manufacturer to perform a recall, or (c) the FDA can mandate a recall.[4] Each recalled drug has an individual classification of Class I-III, which are explained below:[1]

- **Class I recall:** a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.
- **Class II recall:** a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- **Class III recall:** a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

As an example, the recall of Ranbaxy's atorvastatin 10, 20 and 40 mg is a voluntary recall with a classification of Class II.[5] The recalled medication should be sequestered by the pharmacy and the distributor and sent back to the manufacturer for destruction. The FDA may monitor and audit any step of the process. Recalls protect public health by removing potentially harmful products from the market.

References

1. Food and Drug Administration. Ranbaxy Issues Voluntary Nationwide Recall of 41 Lots of Atorvastatin Calcium Tablets 10 Mg, 20 Mg and 40 Mg Due to Potential Presence of Foreign Substance. Available at http://www.fda.gov/Safety/Recalls/ucm329866.htm. Accessed Nov. 29, 2012.
2. Ranbaxy Pharmaceuticals. Ranbaxy Issues Voluntary Nationwide Recall of 41 lots of Atorvastatin Calcium Tablets 10 mg, 20 mg and 40 mg Due to Potential Presence of Foreign Substance. Available at: http://www.ranbaxyusa.com/newsdisp281112.aspx. Accessed Nov. 28, 2012.
3. Food and Drug Administration. Approved Drug Products with Therapeutic Equivalence Evaluations 32nd Edition. Cumulative Supplement 10 October 2012. Available from: Food and Drug Administration. Accessed Dec. 7, 2012.
4. Food and Drug Administration. Drug Recalls Available at: http://www.fda.gov/drugs/drugsafety/DrugRecalls/default.htm. Accessed Nov. 29, 2012.
5. Food and Drug Administration. Enforcement Report - Week of Nov. 28, 2012 Available at: http://www.accessdata.fda.gov/scripts/enforcement/enforce_rpt-Product-Tabs.cfm?action=select&recall_number=D-060-2013&w=11282012&lang=eng. Accessed Nov. 29, 2012.