

Genzyme Drug Rationed More in Europe in Shortage
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(Adds rationing breakdown in the second paragraph.)

By Lisa Rapaport

Aug. 14 (Bloomberg) -- The European Medicines Agency has increased restrictions on use of Genzyme Corp.'s drug Cerezyme for Gaucher disease because a shortage of the therapy has become more severe than previously expected.

All children and certain adults with life-threatening disease should receive the drug at a reduced dose, while less severe patients should forego treatment altogether, the agency said today in a statement on its Web site.

Genzyme said in June it would ration two drugs, Cerezyme, its biggest-selling product, and Fabrazyme, a treatment for Fabry disease, after shutting its Allston Landing plant in Boston to decontaminate after detecting a virus called Vesivirus 2117. Earlier this week Genzyme said it would discard at least 80 percent of a batch of Cerezyme that was in the process of being developed.

"Although the manufacture of both medicines is resuming according to plan, Genzyme has now informed the European Medicines Agency that the existing stocks of Cerezyme are lower than previously communicated," the EMEA said in its statement.

In a letter to Genzyme on July 30, the U.S. Food and Drug Administration ordered a re-inspection of Genzyme's plant because the company didn't "fully or adequately" make necessary changes and "all promised actions" hadn't been completed during a May inspection of the facility, the Cambridge, Massachusetts, company said in a July 31 statement.

Sanitization is finished and production of Fabrazyme and Cerezyme resumed the last week of July, the company said on July

31. During a re-inspection, the FDA will review Genzyme's effort to decontaminate the plant.

Most of Genzyme's medicines treat rare hereditary disorders caused by lack of enzymes needed for critical bodily functions.

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