

EU regulators push Shire drug over Genzyme

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In a blow to Cambridge-based Genzyme Corp., the European Union's chief drug regulator said Tuesday that doctors should not prescribe a Genzyme drug to new patients because of continuing shortages. The European Medicines Agency said that physicians should instead prescribe a competing drug made by Shire plc, a U.K.-based drug company whose Human Genetics Therapies division is headquartered in Lexington and Cambridge, England.

EU regulators said Genzyme told them that supplies of Fabrazyme, to treat the rare Fabry disease, would not return to normal until the end of the year. In a supply update dated June 29, Genzyme also said that shortages would worsen this summer, resulting in some patients not receiving scheduled doses at all. The company has been producing 30 percent of the needed supply over the past several months and had previously said that the introduction of a new cell bank in June would help to ease the shortage.

Inventories of the drug have been a casualty of persistent manufacturing problems at the Genzyme plant in Allston. The [plant was temporarily closed](#) [1] for six weeks last summer, and continuing issues prompted a serious enforcement action by the U.S. Food and Drug Administration, called a [consent decree](#) [2], earlier this year.

The company wrote in the supply update that the new cell bank is not yet producing the targeted levels of cells, and that the supply will be further disrupted by additional manufacturing steps put into place as part of the FDA consent decree. Genzyme officials also said that previously disclosed water system problems in April have also impacted Fabrazyme inventories.

European regulators said no new patients should be started on Fabrazyme unless there is no other option and even suggested that patients taking small doses of Fabrazyme consider switching to Shire's drug. But EU regulators made it clear that these recommendations are temporary and do not affect the approval of Genzyme's drug. Shire's alternative, Replagal, has not yet been approved in the United States. However, the drug has been [fast-tracked by the FDA](#) [3], and the regulator has given Shire permission to provide the drug, on a limited basis, prior to approval.

Genzyme's (Nasdaq:GENZ) shares dropped on the news, to \$50.95, from \$52.80 at the previous close, in midday trading Tuesday. Meanwhile, Shire's (Nasdaq:SHPGY) stock rose in midday trading, to \$63.56 from \$62.31 at the previous close.

[SOURCE](#) [4]

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