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Europe's medicines regulator calls for recall of Biogen, AbbVie multiple sclerosis drug

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(Reuters) - Europe’s medicines regulator recommended the immediate suspension and recall of Biogen Inc and AbbVie Inc’s multiple sclerosis drug Zinbryta, following 12 reports of inflammation of the brain, three of which cases were fatal.

A sign marks a Biogen facility in Cambridge, Massachusetts, U.S.

January 26, 2017. REUTERS/Brian Snyder

Biogen and AbbVie withdrew the drug last week, after the European Medicines Agency (EMA) started an urgent review. bit.ly/2CUHj8k

"A preliminary review of the available evidence indicates that immune reactions observed in the reported cases may be linked to the use of Zinbryta. Zinbryta may also be linked to severe immune reactions affecting several other organs," the EMA said on Wednesday. bit.ly/2oWAUEF

The regulator added that it was recommending the immediate suspension of the medicine's marketing authorization in the European Union and a recall of batches from pharmacies and hospitals.

"EMA's recommendation to suspend Zinbryta and recall the product is being sent to the European Commission for a legally binding decision," it said.

Zinbryta was approved by U.S. regulators in 2016 with a warning on the packaging due to risks of liver damage, with Biogen selling the self-administered drug in Switzerland, Canada and the EU and AbbVie in the United States.

In November, the European regulator flagged safety concerns about the drug, restricting its usage to reduce the risk of serious liver damage.

The drug, which has been used to treat over 8,000 patients so far, brought in worldwide sales of $107 million last year, with Biogen's share being $53 million.

Zinbryta became part of the U.S. political debate over high drug costs in September, when Democratic Congressman Elijah

Cummings asked the government to take action on the drug's $87,000 price tag.

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