Viracept Impurity Was Not at Cancer-Causing Levels

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Roche has conducted animal studies showing that batches of Viracept (nelfinavir) found to be contaminated with ethyl methanesulfonate (EMS) in the spring of 2007 did not contain high enough levels of the impurity to cause cancer, according to a report by AIDSmap.

In June 2007, Roche—the manufacturer of Viracept in all countries outside of the United States, Canada and Japan—had to recall supplies of Viracept. This was because batches of the drug manufactured between March and May of that year were accidentally contaminated with EMS, a potentially cancer-causing impurity.

A similar problem with North American supplies of Viracept, manufactured by Pfizer, led to temporary restrictions on the use of the drug in the U.S. and Canada in the fall of 2007. Pfizer has since worked with the FDA to determine an acceptable level of EMS in Viracept to be sold in the U.S.

Meanwhile, Roche has consulted with an independent panel of toxicology experts, about a series of animal studies that Roche conducted with EMS. The levels of EMS found in Viracept last spring, the studies concluded, were not high enough to cause cancer.

Roche is consulting with community groups and leading HIV specialists worldwide about these findings. These results have also been provided to European drug regulators who will review the information at a June meeting.

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