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## **FURTHER QUESTIONS AND ANSWERS ON THE FOLLOW-UP TO THE VIRACEPT RECALL<sup>1</sup>**

The European Medicines Agency (EMA) is continuing to work on the steps following the recall of Viracept by Roche Registration Limited, because of contamination with a harmful substance. A review by all the health authorities involved in the recall has taken place, and more information can now be made available. The EMA's recommendation to the European Commission that Viracept's marketing authorisation be suspended still applies.

### **What has been happening with Viracept?**

Recent batches of nelfinavir mesilate, the active substance in Viracept, have been contaminated with high levels of ethyl mesilate, a known genotoxic substance (harmful to DNA, the genetic material in cells). The medicine has been recalled by the manufacturer, Roche, and all packs are being returned to the manufacturer. By now, all patients in the European Union who were taking Viracept should have been switched to alternative treatments.

Detailed information on the actions taken since the recall can be found in the previous question-and-answer documents.

### **What has been happening since the June 2007 CHMP meeting?**

At its June meeting, the Committee for Medicinal Products for Human Use (CHMP) recommended that the marketing authorisation for Viracept be suspended<sup>2</sup>, and the European Commission is now preparing the Decision.

Since then, the following has been happening:

- On 6 July 2007, a meeting, called by the EMA, took place between Roche, the EMA, the European Commission, the World Health Organization (WHO) and the Spanish and Swiss regulatory authorities. The company reported on the progress made with their action plan to address the reasons why the contamination occurred, and to prevent it from happening again. The company plans to have a full report available by mid-August for assessment by the CHMP.
- On 18 July 2007, the Pharmacovigilance Working Party, the CHMP's group of experts on the safety of medicines, reviewed the proposal from Roche for patient registries. More information on these can be found below.
- The EMA's toxicology experts have reviewed the proposed toxicity studies from Roche, which are designed to identify more precisely what level of exposure to the contaminant is harmful. The company has planned three studies, two of which are expected to start by the end of July.

The CHMP was updated during its July 2007 meeting on all actions taken, and will discuss the matter again at its September meeting.

### **What are the consequences for patients?**

Because patients who have been taking Viracept may have been exposed to ethyl mesilate, Roche is putting in place 'patient registries'. All prescribers have been contacted directly in order to set up the registries.

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<sup>1</sup> The previous question and answer documents on the recall of Viracept were published on 6 June 2007 ([here](#)) and 21 June 2007 ([here](#)).

<sup>2</sup> This was carried out as a review procedure under Article 20 of Regulation (EC) 726/2004 initiated by the European Commission.

Two registries are being put in place:

- One registry for patients who were exposed to the medicine made from highly contaminated batches. These were distributed from March 2007 until the time of the recall in France, Germany, Italy, Portugal, Spain and the United Kingdom.
- The other registry will include women who took the medicine during pregnancy and children who have taken Viracept at any time or were exposed to it in the womb. This registry will include patients treated since Viracept was first put on the market in the European Union (EU) in 1998.

The registries, set up on the request of the EMEA, are being established by Roche in co-operation with national authorities in each member state.

All patients included in the registries will be followed up every six months for a minimum of five years. The patients will be seen by their doctors, who will carry out a health status check.

#### **What is the impact of the EMEA's action in Europe on other countries outside the EU?**

The suspension of the marketing authorisation for Viracept has had an impact on the supply of this medicine to other countries outside the EU, which rely on Viracept's EU authorisation to allow it onto their markets. The EMEA has maintained regular contact with the WHO since the initial product recall. The WHO is kept informed of the steps taken by the MAH to address the manufacturing deficiencies and to resume product supply, and will act accordingly for the countries outside of the EU.

The EMEA will update this document as new information becomes available.