European Medicines Agency

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QUESTIONS AND ANSWERS ON THE RECALL OF VIRACEPT

On the evening of 5 June 2007, the European Medicines Agency (EMEA) was made aware by Roche Registration Limited of a contamination with a harmful substance affecting the production of Viracept. As a consequence, the medicine is being recalled from the European Union market, with immediate effect.

What is Viracept?

Viracept is an antiviral medicine, available as tablets or as a powder to make up an oral suspension. It is used in combination with other antiviral medicines to treat adults, adolescents and children over 3 years of age who are infected with human immunodeficiency virus (HIV-1), the virus that causes acquired immune deficiency syndrome (AIDS).
The active substance in Viracept, nelfinavir, is a protease inhibitor. It blocks an enzyme (protease) that is involved in the reproduction of HIV. When the enzyme is blocked, the virus does not reproduce normally, slowing down the spread of infection.

What is a recall?

A recall is a procedure through which a medicine may be removed from the market. Recalls may happen for many reasons, such as a problem with the manufacturing of a batch of medicine, and result in the affected packs of the medicine being returned to the manufacturer, generally through the wholesalers and the pharmacists.

Why is Viracept being recalled?

The company that makes Viracept, Roche, received some complaints from patients that the Viracept tablets they were taking had an unusual smell. The company, as part of the investigation into the complaints, carried out some analyses on the tablets. They found that they contained an unexpected substance (a contaminant) called ethyl mesylate. Ethyl mesylate, also known as methane sulfonic acid ethylester, is a known genotoxic substance (harmful to DNA, the genetic material in cells). Genotoxic substances may cause cancer or, if used during pregnancy, harm to the child in the womb.

The contamination is related to the way the active substance nelfinavir is made, so it may have affected all presentations and strengths of Viracept. The company decided to organise an immediate recall of all packs in the European Union.

What are the consequences for patients?

Patients who are currently receiving Viracept should contact their doctor immediately as they will have to change their antiretroviral medication. Changing from Viracept to another antiretroviral medicine is likely to be based on individual resistance patterns, and on the other anti-HIV medicines the patient is also taking, and may vary from patient to patient.

Patients who have been taking Viracept may have been exposed to ethyl mesylate. The level of risk to patients of having taken the substance is difficult to measure. There can be a particular concern when the medicine has been taken by pregnant women, as genotoxic substances can harm the unborn child. Pregnant women who have taken Viracept should carefully discuss with their doctor what further action to take.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 71 29
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

Patients should also follow the instructions given in their country to return their partly used and unused packs of Viracept, usually to their local pharmacy, so that they can be sent back to the manufacturer.

What are the consequences of the recall for prescribers?
While Viracept is not available, doctors will have to use alternative medications for the treatment of their HIV-patients. When switching patients, they will have to take into account the potential for interaction between various antiretroviral agents.

What will happen next?
The company is doing some further investigation into the production process for Viracept to identify the exact reason for the contamination.
The EMEA will update this document as new information becomes available.