

QSM/MC/IEA.114

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Information Exchange System**Alert No. 114****All batches of Viracept (nelfinavir) recalled from the
European Market due to possible contamination with
a genotoxic substance**

The European Medicines Agency (EMA) has issued a Press Release announcing the Europe-wide recall of Viracept (nelfinavir), an antiretroviral medicine used to treat HIV-1 infected adults, adolescents and children of three years of age and older. This recall was initiated after Roche, the manufacturer, identified the presence of ethyl mesylate in some batches of Viracept. Ethyl mesylate is a genotoxic substance that is harmful to DNA.

As the contamination may have affected all strengths and presentations of Viracept, the company is undertaking a worldwide recall of this medicinal product. All packs of Viracept currently available on the market are being recalled. Packs of the product that patients may have at home are to be returned to the pharmacy.

Patients receiving Viracept are directed to contact their doctor immediately for advice on appropriate treatment alternatives. The EMA advises that the level of risk to patients resulting from this contamination is difficult to measure and that this is currently under further investigation.

The public will be updated with conclusions from the assessment of additional information from the marketing authorization holder and from other relevant ongoing investigations as soon as they are available.

References:

1. European Medicines Agency announces recall of Viracept. Press Release, EMA/251283/2007, 6 June 2007 (www.emea.europa.eu).
2. WHO Statement on Roche's Viracept recall. Latest News, WHO Prequalification Programme, 8 June 2007 (<http://mednet3.who.int/prequal/>).