

6th June 2007

Dear Colleague

Recall of Viracept (nelfinavir) due to contamination

We have today been alerted to the recall of Viracept (nelfinavir) by the manufacturer Roche due to a contaminant, ethyl mesylate, a genotoxic/carcinogenic agent. Viracept is authorised for the treatment of HIV-1 infected adults, adolescents and children of 3 years of age and older.

All Viracept products (tablet and oral powder formulations) are being recalled from the European Union market with immediate effect and a Class 1 Medicines Recall has been issued by the MHRA today. The contaminant, ethyl mesylate, has been identified in some recent batches of Viracept; the level of contamination may vary between products and we believe patients' safety is best protected by recalling all remaining stock.

The level of risk to patients resulting from this contamination is difficult to quantify but will depend on individual circumstances. There may be a particular concern when the medicine has been taken by pregnant women or children.

The advice to patients taking Viracept is to contact their physician or clinic immediately to discuss changing to another appropriate medicinal product. Patients currently receiving Viracept will need to be switched to an alternative treatment based on their individual resistance profile and this is likely to vary from patient to patient. We have also recommended that they take their Viracept product(s) back to their clinic or pharmacist in order that it may be returned to the company.

Along with the European Medicines Evaluation Agency and other European regulators, we are in discussions with the company about further investigations into the production process for Viracept to identify the exact reason for the contamination. In the meantime, they are also putting in place an alternative manufacturing method in order to be able to supply Viracept again in about two months time.

Please report suspected adverse drug reactions to the MHRA and CHM using the Yellow Card Scheme (website at www.yellowcard.gov.uk).

Further information is available on the EMEA or MHRA website (www.emea.europa.eu or www.mhra.gov.uk).

Yours sincerely



Professor Kent Woods
CEO