IRISH MEDICINES BOARD

Notice Information: Human Medicines - Recall 07 June 2007

Part 1. Product Information

a)	Title:	Viracept
b)	Product Name/Type:	Viracept - oral powder 50 mg/g, 250 mg tablets and 250 mg film-coated tablets
c)	Active Substance:	Nelfinavir
d)	Authorisation Holder:	Roche Registration Limited
e)	Prescription Required:	Yes

Part 2. Problem/Issue

a)	Problem/Issue:	The European Medicines Agency has been made aware in the evening of 5 June 2007 by Roche Registration Limited of a contamination with a harmful substance affecting the production of Viracept (nelfinavir), an antiretroviral medicine used to treat HIV-1 infected adults, adolescents and children of 3 years of age and older. As a consequence, the product is being recalled from the European Union markets, with immediate effect. Roche has identified the presence of an unexpected contaminant ethyl mesylate (also known as methane sulfonic acid ethylester) in some batches of Viracept. Ethyl mesylate is a known genotoxic substance (harmful to DNA). The level of risk to patients resulting from this contamination is difficult to measure, and is currently under further evaluation. As the contamination may have affected all strengths and presentations of Viracept, the company is performing a complete recall of the medicinal product. All packs of Viracept currently available on the market, including packs that patients may have at home, will need to be returned to the pharmacy. Patients receiving Viracept should therefore contact their doctor immediately as they will have to change to another appropriate medicinal product for their condition. Changing from Viracept to another antiretroviral medicine is likely to be based on individual resistance patterns, and may vary from patient to patient. (The above is an extract from the EMEA Press Release)

Part 3. Enquiries

a) All enquiries should be made to:

NOTES 1. The recall affects the 27 EU Member States and Iceland, Liechtenstein and Norway. 2. Viracept is available as an oral powder 50 mg/g, 250 mg tablets and 250 mg film-coated tablets. The marketing authorisation holder is Roche Registration Limited. More information can be found in the European Public Assessment Report for Viracept: http://www.emea.europa.eu/humandocs/Humans/EPAR/viracept/viracept.htm 3. A question and answer document has been prepared and can be found here. 4. This press release, together with other information about the work of the EMEA, can be found on the EMEA website: http://www.emea.europa.eu Media enquiries only to:Martin Harvey Allchurch or Monika BenstetterTel: (44-20) 74 18 84 27, E-mail: press@emea.europa.eu

Part 4. Keywords

a) Keywords: viracept Nelfinavir