European Medicines Agency
Press office

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PRESS RELEASE

European Medicines Agency agrees on action plan following the recall of Viracept and recommends suspension of the Marketing Authorisation

The European Medicines Agency today agreed on an **action plan to follow-up patients who were exposed to contaminated Viracept** (nelfinavir). Viracept, from Roche Registration Limited, is an antiretroviral medicine used to treat HIV-1 infected adults, adolescents and children of 3 years of age and older. It was recalled from the European market in early June 2007 because during the manufacturing process some batches had become contaminated with ethyl mesilate, a known genotoxic substance (harmful to DNA).

A meeting of toxicology experts held at the EMEA on 13 June 2007 concluded that there are currently insufficient data to establish which doses of ethyl mesilate may be toxic in humans. The CHMP has therefore requested the company to carry out studies in animals in order to calculate toxic levels of ethyl mesilate more precisely. Preliminary results from these studies should be available by the end of this year.

While awaiting the above results, the Agency's Committee for Medicinal Products for Human Use (CHMP) has asked the company to identify the group of patients who have been exposed to contaminated batches of Viracept, with a view to establishing appropriate follow-up and monitoring. The current view of the CHMP is to follow patients exposed to high levels of contaminant in the batches of Viracept released since March 2007, all pregnant women who have ever been exposed to Viracept and all children who have ever been exposed to Viracept, including those exposed *in utero*. The situation will be reviewed as data become available.

Furthermore, the European Medicines Agency today **recommended to the European Commission to suspend the marketing authorisation for Viracept** (nelfinavir), because it had concerns that the quality and therefore the safety of Viracept could not be ensured at this time. As a consequence of the recommended suspension, Viracept will continue to be unavailable for patients until corrective measures have been implemented to resolve the manufacturing issues identified by the CHMP.

Further updates will be provided as more information becomes available.

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NOTES

1. The CHMP reviewed the marketing authorisation of Viracept on the request of the European Commission under Article 20 of Regulation (EC) No 726/2004. This type of procedure is initiated in cases where there are public health concerns with a centrally authorised medicine.
2. The recall was initiated on 6 June 2007. It affected the 27 EU Member States and Iceland, Liechtenstein and Norway. A press release was published and can be found here.
3. Viracept had been authorised 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.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 09
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

4. The suspension of a marketing authorisation is a precautionary measure, during which time a medicinal product is not available. The lifting of the suspension is conditional on the marketing authorisation holder resolving the issues identified by the Agency.
5. A question and answer document has been prepared and can be found here.
6. 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 Benstetter
Tel: (44-20) 74 18 84 27, E-mail: press@emea.europa.eu