European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency recommends lifting of suspension for Viracept

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) today recommended the lifting of the suspension of the marketing authorisation for Viracept (nelfinavir, as nelfinavir mesilate), from Roche, and the re-introduction of the medicine onto the market in the European Union.

The marketing authorisation for Viracept was suspended on 6 August 2007, following the contamination during the manufacturing process of several batches of the active substance with ethyl mesilate, a known genotoxic substance.

The CHMP has assessed the corrective and preventive measures put in place by Roche, and these have also been verified by an inspection of the manufacturing site. As a result, the CHMP has been reassured that the cause of the contamination has been eliminated and that future production of Viracept would meet the required quality standards.

The CHMP therefore decided to recommend to the European Commission the lifting of the marketing authorisation suspension. Once this decision has been issued, Roche will be able to resume supply of Viracept to patients.

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Notes:

1. A question-and-answer document with more detailed information about the lifting of the suspension for Viracept is available here.
2. Viracept was 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, here.
3. The CHMP recommended suspending the marketing authorisation for Viracept on 21 June 2007. The press release is available here.
4. The suspension of a marketing authorisation is a precautionary measure, during which time a medicinal product is unavailable. The lifting of the suspension is conditional on the marketing authorisation holder resolving the issues identified by the Agency and the subsequent decision of the European Commission.
5. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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