Malta, 25 September 2007

Circular No. P12/2007

Dear Healthcare Professional,

Re: Lifting of Suspension of the Marketing Authorisation for Viracept® (nelfinavir)

As you were informed in MA Circular No. P07/2007, dated 26.06.2007, a recommendation was given by the European Medicines Agency (EMEA) to suspend the marketing authorisation for Viracept® following contamination of certain batches with ethyl mesilate, a known genotoxic substance. In the interim, the Marketing Authorisation Holder (MAH) of Viracept® (Roche) has implemented corrective and preventive measures as recommended by the Committee for Medicinal Products for Human Use (CHMP). Following assessment of these measures as well as an inspection of the manufacturing site, the CHMP recommended the lifting of the suspension of the marketing authorisation for Viracept®. The Medicines Authority has participated in these discussions held at the EMEA and is in agreement with the attached **press release** and **Q & A document** on Viracept® issued by the EMEA. The Medicines Authority will notify healthcare providers and patients in a timely fashion once the Commission Decision is issued and supply of Viracept® can be resumed.

Medicines Authority
198, Rue D'Argens, Gzira, GZR 03 – Malta.
Tel. (+356) 23439000 Fax. (+356) 23439161 email: info.mru@gov.mt