



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Development and Evaluation

Public statement

Viracept (nelfinavir)

Non-renewal of the marketing authorisation in the European Union

On 22 January 1998 the European Commission granted a marketing authorisation for the whole European Union to Roche Registration Limited for Viracept (nelfinavir), an antiretroviral agent of the protease inhibitor class. Viracept was indicated for use in antiretroviral combination treatment of human immunodeficiency virus (HIV-1) infected adults, adolescents and children of 3 years of age and older.

The marketing authorisation was valid for a 5-year period. It subsequently was renewed for additional 5-year periods in 2003 and 2008. Before the expiry of the last 5-year period of validity the Marketing Authorisation Holder did not apply to renew the marketing authorisation.

Consequently, the marketing authorisation for Viracept expired on 23 January 2013. The European Public Assessment Report for Viracept will be updated accordingly to reflect that the marketing authorisation is no longer valid.

