

Malta, 19 February 2009
Circular No. P03/2009

Re: The EMEA recommends suspension of the marketing authorisation of Raptiva (efalizumab)

The European Medicines Agency (EMA) has recommended the suspension of the marketing authorisation for Raptiva (efalizumab), from Serono. The EMA's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Raptiva no longer outweigh its risks, because of safety concerns, including the occurrence of progressive multifocal leukoencephalopathy (PML) in patients taking the medicine.

Raptiva has been authorised in the European Union (EU) since September 2004 to treat adult patients with moderate to severe chronic plaque psoriasis (a disease causing red, scaly patches on the skin), who have failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate and PUVA (psoralen ultraviolet-A).

The CHMP reviewed the medicine at the request of the European Commission, following reports of serious side effects, including three confirmed cases of PML in patients who had taken Raptiva for more than three years. PML is a rare brain infection that usually leads to severe disability or death. Two of the three confirmed cases of PML reported to the CHMP resulted in the patient's death. The CHMP also received an additional report of a suspected case of PML, which could not be confirmed.

Following review of all available data on the medicine's safety and effectiveness, the CHMP concluded that:

- Raptiva's benefits are modest;
- in addition to PML, Raptiva is associated with other serious side effects, including Guillain-Barré and Miller-Fisher syndromes, encephalitis, encephalopathy, meningitis, sepsis and opportunistic infections (infections occurring in people with compromised immune systems);
- there is not enough evidence to identify a group of patients in which the benefits of Raptiva outweigh its risks, in particular there is a lack of data on effectiveness and safety in patients who have no other treatment options and who may already have a weakened immune system as result of previous treatments.

The CHMP was therefore of the opinion that the risks of Raptiva outweigh its benefits and that the marketing authorisation for this medicine should be suspended in the EU.

Prescribers should not issue any new prescriptions for Raptiva and should review the treatment of patients currently receiving the medicine to assess the most appropriate alternatives. They should make sure that patients who have been treated with Raptiva are closely monitored for neurological symptoms and symptoms of infection. Patients who are currently taking Raptiva should not stop treatment abruptly, but should make an appointment with their doctor to discuss the most appropriate replacement treatment.

The EMA's recommendation has been sent to the European Commission for the adoption of a legally binding decision.

The Medicines Authority has participated in these discussions held at the EMA and is in agreement with the full [press release](#) and [Q&A document](#) issued by the EMA, attached here for your perusal.