

From the Chief Medical Officer
Dr Michael McBride

URGENT COMMUNICATION

HSS(MD)7/2009

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Dear Colleague

Efalizumab (Raptiva): Suspension of Marketing Authorisation as Risks Outweigh Benefits

I am writing to alert you that the European Medicines Agency (EMA), the European Union (EU) body which is responsible for monitoring the safety of medicines, has recommended that marketing authorisation be suspended for efalizumab (Raptiva) manufactured by Serono and indicated in the management of psoriasis.

This medicine was reviewed after reports of serious side effects, including three confirmed cases of progressive multifocal leukoencephalopathy (PML, a rare but serious disorder of the central nervous system) in patients who had received efalizumab for more than 3 years; two of these patients died.

The EMA's Committee for Medicinal Products for Human Use (CHMP) concluded that, because of safety concerns, the benefits of efalizumab no longer outweigh its risks, notably the occurrence of progressive multifocal leukoencephalopathy (PML) in patients taking the medicine.



Department of
**Health, Social Services
and Public Safety**

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AN ROINN

**Sláinte, Seirbhísí Sóisialta
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MÄNNYSTRIE O

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Your Ref:
Our Ref: HSS(MD)7/2009
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The EMEA has advised that patients who are currently taking efalizumab should consult their doctor or pharmacist at a convenient time to discuss their treatment.

The EMEA has advised patients should not stop efalizumab treatment abruptly as this could lead to the disease coming back or getting worse. Patients should be advised to discuss appropriate replacement treatment with their doctor.

Advice for healthcare professionals:

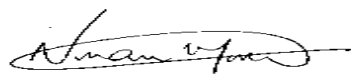
- Prescribers should not issue any prescriptions for efalizumab to patients who are not already taking it.
- Prescribers should review the treatment of all patients who are currently taking efalizumab, with a view to stopping treatment.
- Treatment with efalizumab should not stop abruptly (which could cause psoriasis to return or worsen). Prescribers should consider alternative treatments and continue to monitor the patient's psoriasis.
- Efalizumab's effects on the immune system last for about 8–12 weeks. Healthcare professionals should closely monitor patients for infections and neurological symptoms after stopping treatment.

Further information on the EMEA's decision is available from its website at <http://www.emea.europa.eu/>

Yours sincerely



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Chief Medical Officer



Dr Norman Morrow
Chief Pharmaceutical Officer

This letter is available at www.dhsspsni.gov.uk and also on the DHSSPS Extranet which can be accessed directly at <http://extranet.dhsspsni.gov.uk> or by going through the HPSS Web at <http://www.n-i.nhs.uk> and clicking on DHSSPS.