Information Exchange System

Alert No. 121

Marketing authorization of efalizumab in the European Union to be suspended due to safety concerns

The European Medicines Agency (EMEA) has recommended the suspension of the marketing authorization for efalizumab (Raptiva from Serono)\(^1\). The Agency has based this recommendation on the advice of its Committee for Medicinal Products for Human Use (CHMP) that the benefits of efalizumab no longer outweigh its risks. Efalizumab was authorized in the European Union in September 2004, for treating moderate to severe chronic plaque psoriasis in adult patients who did not respond to, or had a contraindication to, or were intolerant to other systemic therapies.

The CHMP has reviewed reports of serious side effects with efalizumab, including three confirmed cases of progressive multifocal leukoencephalopathy (PML) (with two deaths) in patients who had taken this medicine for more than three years. Having considered all available data, the CHMP has concluded that efalizumab's benefits are modest, that it is associated with serious side effects such as Guillain-Barré and Miller-Fisher syndromes, encephalitis, sepsis, opportunistic infections etc, and that there is a lack of effectiveness and safety data to support its use in patients who have no other treatment options.

The EMEA advises that patients who have been treated with efalizumab should be monitored for neurological symptoms and symptoms of infection; those who are currently taking efalizumab should not stop treatment abruptly but should consult their physician to discuss other treatment options.

(Efalizumab is marketed in Australia, Austria, Canada, Germany, Greece, Ireland, Kuwait, Mexico, Netherlands, Norway, Poland, Spain, Sweden, Switzerland, United Kingdom and the United States of America\(^2\).)

References: