

WRITTEN QUESTION E-3007/06
by Anne Ferreira (PSE)
to the Commission

Subject: EMA's approval of the use of Prozac (fluoxetine) for children aged eight or over

On 6 June 2006, the EMA (European Medicines Agency) approved the use of Prozac (fluoxetine) for children aged eight or older. This approval is surprising given that in April 2005 the EMA advised against the use of this drug for youngsters under 18 years.

What action will the Commission take in response to this approval and the reservations voiced by the Member States?

What measures will the Commission introduce as regards pharmacovigilance?