European Medicines Agency
Press office

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PRESS RELEASE

European Medicines Agency adopts a positive opinion for the use of Prozac in the treatment of children and adolescents suffering from depression

The European Medicines Agency has recommended to extend the indication for Prozac (fluoxetine) and associated names to include the treatment of children of 8 years of age or older who suffer from moderate to severe depression and who do not respond to psychological therapy. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of using Prozac in this indication outweigh its potential risks, but that the marketing authorisation holder (MAH), Eli Lilly, should carry out additional studies to ensure that the safety profile of Prozac remains acceptable.

Prozac and associated names is authorised in most EU Member States for the treatment of major depressive episodes, obsessive-compulsive disorder and bulimia nervosa in adults. Following a request from the UK, the MAH for Prozac submitted an application to extend the indications to include the treatment of major depressive episodes in children and adolescents. The CHMP was requested to begin an arbitration review by France on the basis of unresolved safety and efficacy concerns.

Based on the data reviewed the CHMP concluded:

- The studies in children and adolescents showed a positive effect
- Prozac should only be used together with psychological therapy in patients non-responding to such therapy alone after 4 to 6 sessions
- The starting dose should be 10 mg per day (given as 2.5ml of the oral solution) and may be increased to 20 mg per day after one to two weeks
- If no clinical benefit is seen within 9 weeks, treatment should be reconsidered
- The significance of the observations in animal studies on sexual development, emotional behaviour and testicular toxicity will be further investigated. The MAH will also put in place a system to obtain safety data in treated children, in particular regarding sexual development
- The CHMP confirmed that doctors and parents should carefully monitor children and adolescents for suicidal behaviour, particularly at the beginning of treatment.

--ENDS--

Notes:

1. A question and answer document is available and has been published here.
2. The product information for Prozac as adopted by CHMP on 1 June 2006 is available here.
3. The arbitration was made under Article 6(12) of Commission Regulation (EC) No 1084/2003. This type of procedure is initiated where Member States cannot reach an agreement on an application for a variation of the marketing authorisation in the context of the mutual recognition procedure.
4. The CHMP advised in April 2005 that warnings should be included in the product information of the class of serotonin selective re-uptake inhibitor (SSRI) medicines, including fluoxetine, regarding the increased risk of side-effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) in children and adolescents treated with antidepressants. The April 2005 statement, including advice for prescribers, patients and parents, is available on the EMEA website and can be found here.
5. This press release, together with other information about the work of the EMEA, can be found on the EMEA website: http://www.emea.eu.int

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