European Medicines Agency

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QUESTIONS AND ANSWERS ON THE REVIEW OF PROZAC FOR USE IN CHILDREN AND ADOLESCENTS

The Committee for Medicinal Products for Human Use (CHMP) has completed its arbitration review of Prozac (fluoxetine) and associated names[1], and gave a positive opinion to extend its use in the treatment of children suffering from depression, provided that the marketing authorisation holder (MAH), Eli Lilly, carries out additional studies to ensure that the safety profile of Prozac remains acceptable. The new indication is as follows:

Children and adolescents aged 8 years and above: Moderate to severe major depressive episode, if depression is unresponsive to psychological therapy after 4-6 sessions. Antidepressant medication should be offered to a child or young person with moderate to severe depression only in combination with a concurrent psychological therapy.

Why did the CHMP review this medicine?
Prozac is currently authorised for use in adults to treat depression, obsessive-compulsive disorders and bulimia nervosa (an eating disorder) within the European Union.
Following a request from the UK, the MAH for Prozac submitted an application for the extension of the indications to treat depression in children and adolescents, via the mutual recognition procedure[2]. The review was initiated by France on the basis of safety and efficacy concerns on the use of Prozac in this age group.

What data has the CHMP reviewed?
The CHMP reviewed data submitted by the MAH, which included data from experimental models, clinical studies and information published in scientific journals.
Efficacy was supported by three main studies, involving over 750 children and adolescents. All studies compared the efficacy of Prozac in the treatment of depression with that of a placebo (dummy treatment) over 9 to 12 weeks. The CHMP also reviewed safety data from experimental and clinical studies on growth, sexual development and suicide-related behaviour (suicide attempt and suicidal thoughts).

What are the conclusions of the CHMP?
- The studies in children and adolescents showed a positive effect.
- The medicine 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 it 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 experimental 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.

[1] Prozac is marketed also under the names of Fluctin, Fluctine, Fluoxétine Lilly, Fluoxétine RPG Prozac, Fontex, Ladose.
[2] This is a procedure whereby Member States mutually recognise marketing authorisations within the European Union. In case of disagreement during the procedure, the issue is referred to the CHMP for arbitration.

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Overall, the CHMP concluded that the benefits of Prozac are greater than its potential risks for the treatment of moderate to severe major depressive episode in children and adolescents.

For further information, please refer to the Product Information for Prozac as adopted by the CHMP on 1 June 2006. The document is published for information on the EMEA website, pending formal endorsement by the European Commission, and can be found here.