

Sok Central

Till: Wändel-Liminga Ulla; Melander Hans; Ahlström Lena
Ämne: VB: UK/H/0636/001,003; Post-licensing commitment to assess sexual maturation in children; clock stop
Prioritet: Hög
Bifogade filer: RFI 4 2 May 2007.doc

1994-0112, Fontex®, 4 mg/ml, Oral lösning, UK/H/636/03, FUM 02; EMEA/H/A-6(12)/671, 2111:2006/63256

Clock stopp

Sätts in i part IVB till O/pi

Från: MR-DCprocedures, [mailto:MR-DCprocedures@mhra.gsi.gov.uk]
Skickat: den 2 maj 2007 11:26
Till: List-H-MRVE (EUDRA)
Kopia: Riegl, Martina
Ämne: UK/H/0636/001,003; Post-licensing commitment to assess sexual maturation in children; clock stop
Prioritet: Hög

Dear Colleagues,
Please be advised that comments were received from Italy only.
A 4th RSI has been sent to the MAH and the clock has been stopped. A copy of the RSI is attached for your information.

<<RFI 4 2 May 2007.doc>>

kind regards,

Katherine Haros

MHRA

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Dr Carly Anderson
Lilly UK
Erl Wood Manor
Windleham
Surrey
GU20 6PH
UNITED KINGDOM

2 May 2007

Dear Dr Anderson

REQUEST FOR FURTHER INFORMATION

Product: Prozac 20mg capsules (PL 0006/0195) and Prozac Oral Liquid 20mg/5ml (PL 0006/0272)
Type of Procedure: Mutual Recognition
Submission Type: **Follow up Measure no. 2**
EU Procedure Number: UK/H/636/01, 03
Reason: **Post-licensing commitment to assess sexual maturation in children**

With reference to the above submission, further information is needed as follows:

1. Serial measurements of the gonadotrophins LH and FSH should be provided at 6 monthly intervals. Samples should be taken at 20 minute intervals for 120 minutes between 7.00 and 9.00 a.m.
2. Height, weight and BMI should be expressed in standard deviation scores (z-scores) using normative data relevant to the study sites. Change from baseline in height, weight and BMI z-scores should be calculated for the fluoxetine +CBT and placebo + CBT at 12 weeks and be compared using a parametric test. Comparisons between treatment groups for the same parameters should also be undertaken for each visit during the 104 weeks follow-up phase.
3. An amended draft protocol should be submitted taking into consideration all amendments agreed in this procedure. The amended draft protocol should also address procedures for measuring height and weight and for specialized training and assessment of interrater reliability for Tanner rating.

The information should be received within 15 calendar days of the date of this letter.

Please quote our reference in all future correspondence regarding this submission. Do not hesitate to contact me if you wish to discuss any issues further.

Yours sincerely,

Dr Martina Riegl