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**Sok Central**

**Till:** Wändel-Liminga Ulla

**Ämne:** VB: UK/H/0636/001,003; Post-licensing commitment to assess sexual maturation in children; final UK Assessment Report

**Bifogade filer:** AR 19 July 2007.doc

1994-0112, Fontex®, 4 mg/ml, Oral lösning, UK/H/636/03

AR of Commitment IVB -> 0 /rs

**Från:** MR-DCprocedures, [mailto:MR-DCprocedures@mhra.gsi.gov.uk]
**Skickat:** den 19 juli 2007 16:38
**Till:** List-H-MRVE (EUDRA); List-H-MRNA (EUDRA)
**Kopia:** Riegl, Martina; Dunne, Dr Julia
**Ämne:** UK/H/0636/001,003; Post-licensing commitment to assess sexual maturation in children; final UK Assessment Report

Dear Colleagues,
Please find attached the final assessment report for the above mentioned procedure.
Thank you
kind regards,

**Katherine Haros**
**Mutual Recognition and Decentralised Project Co-ordinator**
**Medicines and Healthcare products Regulatory Agency**
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# RMS

## FINAL Assessment Report

# Post-licensing commitment to assess sexual maturation in children

# CLINICAL

# Prozac

# (fluoxetine)

UK/H/0636/001,003

# Applicant: Eli Lilly

| | |
|---|---|
| **Start of the procedure:** | 12 October 2006 |
| **Date of this report:** | 19 July 2007 |
| **Deadline for comments:** | 27 July 2007 |

## 1 RECOMMENDATIONS

Based on the review of the MAH's response the RMS considers that the Draft Protocol Addendum B1Y-MC-HCLU(1) *A Study of Sexual Maturation in Children Enrolled in the Treatment of Children with Depression (TADS Jr.)* dated 6 July 2007 is acceptable and the present procedure can be concluded.

## 2 ASSESSMENT OF RESPONSES

**Question**

**Please provide an amended draft protocol 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.**

Summary of MAH's response

The MAH has submitted an amended Draft Protocol. Assessments are outlined in the table below.

| Assessment | Timing |
|---|---|
| *Tanner staging | Last baseline visit<br>End of 12-week double-blind treatment period<br>End of 12-week double-blind treatment period + 6 months , + 12 months, + 18 months, + 24 months |
| LH and FSH | Serial measurement at approximately 20-minute intervals for 120 minutes, between 7:00 a.m. and 9:00 a.m. (+/- 2 hrs)<br>Last baseline visit<br>End of 12-week double-blind treatment period<br>End of 12-week double-blind treatment period + 6 months , + 12 months, + 18 months, + 24 months |
| Testosterone (boys) and Estradiol (girls) | Single measurement using the blood draw nearest the final draw at 9:00 am<br>Last baseline visit<br>End of 12-week double-blind treatment period<br>End of 12-week double-blind treatment period + 6 months , + 12 months, + 18 months, + 24 months |
| LHRH | LHRH infusion test occurs at end of 120 minute LH/FSH serial measurements. Stimulated LH/FSH measumrements occur approximately 30 minutes after infusion<br>Last baseline visit<br>End of 12-week double-blind treatment period + 12 months, + 24 months |
| Prolactin | Single measurement at approximately 30-minutes into LH/FSH serial measurements<br>Last baseline visit<br>End of 12-week double-blind treatment period + 12 months, + 24 months |
| Height, weight, BMI | Each visit |

* To be assessed by a nurse practitioner, physician assistant, or physician.

Abbreviations: FSH = follicle-stimulating hormone; LH = luteinizing hormone; LHRH = luteinizing-hormone releasing hormone; BMI = body mass index.

Assessment of MAH's response, conclusions

The amended draft protocol is considered satisfactory. All requested amendments have been incorporated. Stadiometers will be provided to all research sites to promote accuracy in height measurement. The training training and testing of medical professionals performing the TANNER staging is considered satisfactory. ***Issue resolved.***

## 3 CONCLUSION AND RECOMMENDATION

The amended draft protocol is considered satisfactory. The procedure to assess the draft protocol for the assessment sexual maturation in children as addendum to the TADS Jr study can be concluded.