

Hedgecock Isabelle

Från: AktCirk
Skickat: den 21 september 2009 12:19
Till: KLAS
Ämne: FUM SKA LÄGGAS UPP_ Prozac_UK/H/0636/001,003_follow up f referral
Bifogade filer: AR 24 August 2009.doc

Uppföljningsflagga: Följ upp
Flagga: Har meddelandeflagga

Från: Daniels Jenny
Skickat: den 21 september 2009 09:23
Till: AktCirk
Kopia: Wändel-Liminga Ulla
Ämne: VB: Prozac_UK/H/0636/001,003_follow up f referral

Dnr 211: 2009/58507

FUM efter referral.

Hej AktCirk!

AR - Sättis in i

IVB → Q
 1994-0112
 1995-0254

Jenna FUM bör letas fram och läggas upp i LVIS.

Vänliga hälsningar
 Jenny
 4291

Från: Wändel-Liminga Ulla
Skickat: den 18 september 2009 16:34
Till: Daniels Jenny
Ämne: VB: Prozac_UK/H/0636/001,003_follow up f referral

Hej Jenny,

Detta kan vara ett ärende som inte är upplagt (jag hittade den inte i LVIS för några dagar sedan). Det är ett psot authorisation commitment for Prozac (Fontex), som vi fick AR för ett litet tag sedan (bifogar AR). Detta är en kommentar vi vill skicka ut.

Hoppas du kan hitta på vart den ska skicaks.... TACK Ulla

Dear All,

Regarding the clinical post licensing commitment to assess sexual maturation in children, the MAH has identified several problems with fulfilling the commitment agreed when the referral was finalized. We acknowledge these problems, however, we do to some extent question the unfeasibility of the company setting up a registry /observational study themselves.

Nevertheless, we think that the non-clinical FUMs should be finally assessed before it is finally decided whether further clinical work is necessary. In such case, the MAH should provide stronger argumentation why setting up a registry / observational study themselves is not feasible.

Hans Melander, Ulla Wändel Liminga

Palestro Cristian

Från: Daniels Jenny
Skickat: den 21 september 2009 09:20
Till: 'uk-h.mrve@uk-h.eudra.org'; 'at-ages-h.mrve@at-ages-h.eudra.org'; 'be-h.mrve@be-h.eudra.org'; 'de-pei.mrve@de-pei.eudra.org'; 'de-h.mrve@de-h.eudra.org'; 'gr-h.mrve@gr-h.eudra.org'; 'es-h.mrve@es-h.eudra.org'; 'fr-h.mrve@fr-h.eudra.org'; 'ie-h.mrve@ie-h.eudra.org'; 'it-h.mrve@it-h.eudra.org'; 'lu-h.mrve@lu-h.eudra.org'; 'nl-h.mrve@nl-h.eudra.org'; 'pt-h.mrve@pt-h.eudra.org'
Kopia: Wändel-Liminga Ulla
Ämne: UK/H/0636/1,3 - Prozac/Fontex - SE Comments
Bifogade filer: AR 24 August 2009.doc

UK/H/0636/001
UK/H/0636/003

Dear Colleagues,

Regarding the clinical post licensing commitment to assess sexual maturation in children, the MAH has identified several problems with fulfilling the commitment agreed when the referral was finalized. We acknowledge these problems, however, we do to some extent question the unfeasibility of the company setting up a registry /observational study themselves.

Nevertheless, we think that the non-clinical FUMs should be finally assessed before it is finally decided whether further clinical work is necessary. In such case, the MAH should provide stronger argumentation why setting up a registry / observational study themselves is not feasible.

On behalf of Hans Melander and Ulla Wändel Liminga for the Medical Products Agency,
Kind regards

Jenny Daniels
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Email to Part IVB/Mskin