

PROLAC - GERMANY

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CONFIDENTIAL

Re: Additional Feedback Regarding the Fluoxetine Review by the Commission A

Through additional contacts I have been able to find out the following information:

1. Only the 20 mg pack will be registered and the 30 mg, 40 mg and 50 mg packs will be denied registration on the ground that we have demonstrated the 20 mg is the right dose.
2. The proposal of the Commission A for the indication would be: for the treatment of depressive illness when no sedation is necessary. This is very very close to the English package insert.
3. The counterindication because of acute suicidality should become a warning whereby the physicians should be advised that in the absence of sedation, the risk of higher suicidality should be taken into account.
4. The counterindication for agitated patients and for patients with pronounced sleep disturbances should not be an absolute counter-indication but rather a relative counterindication (this in Germany is very similar to a precaution) whereby physicians would be particularly careful with those patients. An exact wording has not been proposed by the Commission A.
5. In the event of combination therapy with Lithium, a follow-up of blood levels would be necessary which is anyway standard for Lithium therapy in Germany.

At the moment, we do not have information on the other counter-indications for epilepsy, renal impairment, hepatic insufficiency, acute intoxication, but Nick will try to speak to Prof. [REDACTED] the rapporteur, to find out more. In the meantime, we have learned that Dr. Karkos will come back on September 15 and we know that a meeting is planned on that day at the BGA to discuss the wording. Straeter suggests that we make a proposal for the wording of these issues after having taken into account the advice of the Commission A and Nick will work with Allan on this. I hope we can agree on this in the coming week and that we will have a chance to present our proposal and influence the wording that will be decided in this September meeting.

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So far so good. Let's keep our fingers crossed for another couple
of weeks.

Regards,

Claude

BOUCHY CLAUDE

IVMI