

[REDACTED]

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**From:** Woolley, Dr Jane  
**Sent:** 14 August 2014 09:29  
**To:** [REDACTED]  
**Subject:** RE: finasteride

Hi [REDACTED]

I think your idea of re-wording it along the lines you suggest is a good one. Happy for you to go ahead and do this.

Thanks very much  
Jane

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**From:** [REDACTED]  
**Sent:** 14 August 2014 09:10  
**To:** Woolley, Dr Jane  
**Subject:** RE: finasteride

Hi Jane,  
Thanks for letting me know. I think the concern around this was with the fact that the PSUR always lacks the information needed to review properly, that's why SMRM wanted to specifically ask for more detailed information to be included next time. Perhaps we can re-word it to say, we are aware cognitive impairment will be reviewed in the next PSUR however would be grateful if the MAH is asked to provide further detailed information as we've requested. How do you think we should proceed with this?

Thanks,  
[REDACTED]

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**From:** Woolley, Dr Jane  
**Sent:** 13 August 2014 16:26  
**To:** [REDACTED]  
**Subject:** FW: finasteride

Hi [REDACTED]

I was just talking to [REDACTED] about the PSUR and she mentioned that she had already raised cognitive impairment in the last PSUR....!

Thanks  
Jane

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**From:** [REDACTED]  
**Sent:** 13 August 2014 15:43  
**To:** Woolley, Dr Jane  
**Subject:** RE: finasteride

Dear Jane,  
I asked the RMS to raise cognitive impairment already during the last PSUR procedure so I don't think that we will need to raise this again: it should already be one of the areas to be addressed in the new reporting period. Depression is being followed up also but it would probably be worth mentioning suicidal ideation specifically. [REDACTED] certainly sent the PSUR to me the last time it came in so I can always ask her to make sure that remains allocated to me.

Best  
[REDACTED]