

[REDACTED]

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**From:** Woolley, Dr Jane  
**Sent:** 16 January 2015 15:23  
**To:** [REDACTED]  
**Subject:** RE: comments for finasteride PSURs

Hi [REDACTED]

For the sake of international relations I have modified it a bit so that it doesn't mention the lack of any information in their AR (but still making it clear that we had to go to the PSUR to find the information).

I have also included a little bit more about the information that is out there, including mention of the Post Finasteride Syndrome Foundation – might convince someone to take it a bit more seriously you never know!

Any way see what you think and change anything you don't like.

Thanks  
Jane

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**From:** [REDACTED]  
**Sent:** 16 January 2015 14:18  
**To:** Woolley, Dr Jane  
**Subject:** comments for finasteride PSURs

Dear Jane

The ARs sent by the RMS don't go into any detail on the areas that we had suggested that we review. Looking at the original PSUR on Sentinel the company have provided reviews on the relevant areas but in all instances have concluded that the cases are too sparse to draw any conclusions from. They have suggested that they are all monitored under routine Pharmacovigilance.

It is hard to comment when the report we are supposed to be commenting doesn't mention the proposed areas we have provided comments for. The company have a point that many of the cases lack detail but this should perhaps be followed by a proposal of how they intend to follow up future cases to complete areas of missing information.

Would be ok to comment something like:

As a conclusion of the previous PSUR it was agreed that points to be addressed in the next PSUR would include

- cognitive impairment; mental impairment and memory impairment.
- Muscle atrophy including any evidence from published literature and clinical trials and a discussion of biological plausibility and potential causality for both indications and doses.
- Testicular atrophy including a breakdown of reports concerning the SOC of Reproductive system and provide a discussion of biological plausibility and potential causality for both indications and doses.

From the brand leader PSUR it would appear that most cases are excluded on the basis of too little information or confounding by other conditions [such as depression for cognitive disorder and memory impairment].

Many of the cases have multiple terms (including both sexual and cognitive effects) which, in some publications, are loosely termed 'post finasteride syndrome'. The MHRA has received many queries about this possible syndrome from patients, based on their own experiences and their reading; many have referred to the Post Finasteride Syndrome Foundation (<http://www.pfsfoundation.org/>), who are currently conducting studies to further evaluate the potential mechanism. In light of this the MAH should add this group of events as a potential risk in the RMP and

provide a review of the data (including any evidence for a possible mechanism) regarding these proposed associations in the next PSUR? The MAH should also suggest ways of better collecting relevant information on these adverse effects from spontaneous reports.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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