

[REDACTED]

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**From:** [REDACTED]  
**Sent:** 13 January 2021 10:57  
**To:** [REDACTED]  
**Subject:** RE: Finasteride and 'Post-Finasteride Syndrome'

Hi [REDACTED]

Thanks for flagging this. Post finasteride syndrome is not medically recognised which explains why the term isn't entered as an ADR. It was coined by pressure groups in the US {Post Finasteride Syndrome Foundation} who are campaigning to have finasteride removed from the market. It's been a controversial topic for many years given that there have been cases of suicide which are associated with sexual dysfunction and depression. I conducted a review of these serious cases (particularly with regard to depression and suicidality) within the UK and an EU wide review was conducted subsequently. This resulted to additional warnings being added to section 4.4 and 4.8.

I see that there is only one case this year. I have had a look at the case which is retrospective with a notable 84 adverse events. I would suggest that apart from this, other details necessary for assessment are missing which doesn't allow for causality assessment. I wouldn't suggest any further action on the basis of this case and the two received last year.

We can discuss further this afternoon after the vaccine signal meeting or before the signal meeting tomorrow if you prefer.

Best regards

[REDACTED]

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**From:** [REDACTED]  
**Sent:** 13 January 2021 07:57  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** Finasteride and 'Post-Finasteride Syndrome'

Morning [REDACTED]

Hope you are well!

I am just quickly emailing as would really appreciate your opinion on the drug-event combination of 'finasteride' and 'post-finasteride syndrome'. In my signal allocation this week one of the reports I had was concerning this, I don't think it was a particularly helpful case as the report just lists around 80 ADRs stating them to be as a result of post-finasteride syndrome and doesn't indicate dose or duration etc. It just peaked my interest a little bit as I noted there were a number of articles on the topic, although I gather it's not fully understood and there isn't a MedDRA term for it so reporting of it just references the symptoms experienced, most of which are listed in 4.8 in their own right. I did a quick Empirica search and we roughly 17 reports that mention post-finasteride syndrome within their narrative specifically.

The index case:  
[REDACTED]

Have you come across this before?

Many thanks,

[REDACTED]