

[REDACTED]

From: Woolley, Dr Jane
Sent: 13 August 2014 16:25
To: [REDACTED]
Subject: RE: finasteride

Thanks [REDACTED] – if you wouldn't mind that would be great.
Jane

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]

From: Woolley, Dr Jane
Sent: 13 August 2014 15:03
To: [REDACTED]
Subject: finasteride

Hi [REDACTED]

As I think you know, a couple of signals for finasteride went to SMRM last week – cognitive impairment and suicidal ideation. SMRM agreed to ask Sweden to get the MAH to review them in the PSUR.

Do you know if [REDACTED] knows to send the PSUR our way? If not I can ask her. I'm actually getting even more worried about the b:r balance, given the growing number of reports of this persistent post-finasteride syndrome and its apparent biological plausibility.

Thanks
Jane

Dr Jane Woolley
Unit Manager
Benefit Risk Management Group

MHRA
151 Buckingham Palace Road, London, SW1W 9SZ, UK

[REDACTED]
E-mail: jane.woolley@mhra.gsi.gov.uk
mhra.gov.uk

Stay connected : mhra.gov.uk/stayconnected

MHRA is a centre of the Medicines and Healthcare Products Regulatory Agency