

[REDACTED]

From: [REDACTED]
Sent: 14 June 2016 10:18
To: [REDACTED]
Cc: Woolley, Dr Jane
Subject: RE: Finasteride

Thanks [REDACTED]

Seems odd that it would be in the CCDS yet they would make a fuss about changing the EU SPC.

I'll get in touch if there's anything else ☺

From: [REDACTED]
Sent: 14 June 2016 10:16
To: [REDACTED]
Cc: Woolley, Dr Jane
Subject: RE: Finasteride

Hi [REDACTED]

We have requested that they review it given that we have had more post-marketing cases of depression (and suicidal depression including two completed suicides). Some of the depression cases have positive de-challenges and it would appear that a sub-population of patients appear to be affected by depression or experience aggravated depression on finasteride.

The MAH are due to submit a cumulative review within the next month or so. Depression is labelled in the USA, Australia, Canada and NZ. and it would seem sensible to align the labelling with this regard.

Let me know if you need any more information.

Best
[REDACTED]

From: [REDACTED]
Sent: 14 June 2016 09:55
To: [REDACTED]
Subject: RE: Finasteride

Hey [REDACTED]

Hope all is ok! I'm on site at [REDACTED] and looking into the depression/depressed mood concern you raised.

They have a variation not yet submitted to amend this to depression in the EU SPC, but has been "depression" in the CCDS from the start.

I wondered if there has been communication between [REDACTED] and MHRA regarding this issue, I'm wondering why they've suddenly decided to change it!

Grateful if you could shed any light!

[REDACTED]

From: [REDACTED]
Sent: 17 May 2016 11:39
To: [REDACTED]
Subject: RE: Finasteride

No problem. I just thought I'd ask but I understand that having too many people could present problems. However, I'm around that week if the opportunity arises.

Glad you are enjoying the job.

Best

[REDACTED]

