[redacted]

From: [redacted]
Sent: 17 May 2016 11:22
To: [redacted]
Subject: RE: Finasteride

Hey [redacted]

Thanks for this! I'll pass it onto the team – it's really helpful to have some real insight into the difficulties with products so thought I'd ask the question ☺

[redacted] is the lead inspector, (and is currently on Annual Leave) but I'll make sure I pick this up and discuss with her – it may be very useful to have you on site for review, but that's a decision for [redacted] to make. (There are six inspectors due to be on site already, so that may come into it – I don't know!) The inspection is scheduled on site for 13th – 17th June, with two inspection days in the office the week before.

As soon as I hear anything back (or have any questions) I'll be in touch. I'm assuming you're happy for any of the team to pass any questions they may have onto you?

(and yes – the job is going very well thank you, I am enjoying it immensely!)

[redacted]

From: [redacted]
Sent: 17 May 2016 11:16
To: [redacted]
Subject: RE: Finasteride

Hi [redacted]

I hope you are enjoying your new role. Thank you for emailing me with regard to this.
I am slightly concerned that the cumulative reviews are a bit sparse and cases are dismissed a bit too easily.
There is a difference in labelling between the EU and the USA, Australia, Canada and NZ with regard to depression and Propecia. In the EU 'depressed mood' is labelled rather than 'depression' and we have asked them to look at this again given there appears to be more evidence to suggest that depressive illness may at least be aggravated by Propecia.
The other issue linked to this is the persistence of sexual dysfunction. It is a potential risk on the RMP but again there is an increasing number of cases. There is resistance from the MAH to increase this to an identified risk (it is already labelled as seen post marketing).
I would be keen to establish if these cases are adequately being captured and followed up especially given that this can occur in young patients who then often go on to develop depression/ suicidal depression. Persistent erectile dysfunction or persistent sexual dysfunction or persistent impotence does not exist as PT terms so we are reliant on cases being picked up from the case narrative.
Post finasteride syndrome is a term used by pressure groups who describe a syndrome which involves persistent sexual dysfunction, cognitive impairment, fatigue, low libido. Again the basis of the reports are strongly associated with sexual dysfunction and the consequences of that.
I'm sure that you would routinely look at case follow up procedures and signal detection but it would be good to be reassured that they are rigorous.

When are you doing the inspection? I would be happy to be involved if possible and/or I'm available at the time..

Best
[redacted]

From: [redacted]
Sent: 16 May 2016 11:59
To: [redacted]
Subject: Finasteride

Hey [redacted]

Hope you are well and everything's going ok!

Quick question for you, we're inspecting MSD soon and one of the products we're looking at is Propecia. I understand it's an MRP with SE as lead, but I remember you asking for any information questions we had rec'd for finasteride syndrome, so thought I'd return the question!

Is there anything relevant you'd want us to look at on inspection regarding propecia?

I'm leading the RSI session so anything regarding the SPC or PIL would be helpful, but we're covering everything on the inspection!

[redacted]