[redacted]

From: Woolley, Dr Jane
Sent: 20 March 2017 12:48
To: [redacted]
Subject: FW: LTT - AlteplaseFrom

Follow Up Flag: Follow up
Flag Status: Completed

H[redacted] – when you reply please can you change the e-mail header? It's really confusing me ☺
Thanks
Jane

From: [redacted]
Sent: 20 March 2017 12:14
To: [redacted]
Cc: Woolley, Dr Jane
Subject: RE: LTT - AlteplaseFrom

Hi[redacted]

Is there any update on finasteride?

Thanks,
[redacted]

From: [redacted]
Sent: 21 February 2017 12:08
To: [redacted]
Cc: Woolley, Dr Jane
Subject: RE: LTT - AlteplaseFrom

Dear[redacted]

The review is specific to finasteride 1 mg (brand name Propecia but also relates to generic finasteride 1 mg for the indication of male pattern baldness).

CMS comments are due on 03/10/2017. The end of procedure is 20/03/2017 so the company have time to comment in between those two dates, if I understand correctly.
I'll put a note in my diary to keep you informed as soon as I know anything.

Best regards
[redacted]

From: [redacted]
Sent: 17 February 2017 11:46
To: [redacted]
Subject: RE: LTT - AlteplaseFrom

Thanks[redacted] That's really helpful.

For the review of depression and related terms, is this a general review of how depression is classified as a side effect? Or is this specific to finasteride?

Also, do you know what the timeframe is for the company to respond to the decision? I assume there is a window for them to request a re-consideration/appeal (sorry, I don't know what the correct terms is)? Jane said it was likely around 30 days but was not sure.

Thanks,
[redacted]

From: [redacted]
Sent: 16 February 2017 16:18
To: [redacted]
Cc: [redacted]; Woolley, Dr Jane
Subject: RE: LTT - AlteplaseFrom

Dear [redacted]

Further to the email below, I just wanted to provide some detail about finasteride 1 mg (brand leader- Propecia) in the event that you receive a press query.

- Finasteride 1 mg (tablet) is used to treat male pattern hair loss. It was authorised in 1999.
- There is also another indication for finasteride - Finasteride 5 mg is used to treat benign prostatic hyperplasia (enlargement of the prostate gland).
- It is difficult to establish how many people use finasteride 1 mg as it is not funded by the NHS. Men either obtain prescriptions privately from their GP; from hair loss clinics or from online private prescriptions (following completion of an online questionnaire).
- Alternative prescription only medicines equivalent to finasteride are not available. Men can buy an over-the counter topical product called minoxidil (Regaine) from pharmacies and supermarkets.
- Recognised adverse reactions of finasteride include sexual dysfunction (erectile dysfunction, ejaculation disorder (including decreased volume of ejaculate). There have been reports post-marketing that in some men these effects persist after stopping treatment. These effects are listed in the product information.
- Reports of severe depression have been received. Depressed mood but not depression is listed in the EU SmPC.
- The possible association between finasteride for hair loss and depression is currently being reviewed within Europe. The MHRA will provide HCPs and patients with an update when the review concludes.

Background – not to be released externally
This issue was discussed at PRAC in February.

The evidence was examined and was considered sufficient to add depression to section 4.8 of the SPC. In addition to company proposals, the PRAC also agreed that, given the therapeutic setting, it would be important for physicians to warn patients of the potential for psychiatric side effects; monitor appropriately and advise cessation of treatment and medical consultation if symptoms occur. The PRAC therefore agreed that this information should be included in section 4.4 of the SPC. The PRAC considered that the need for communications should be considered on a national level.

It is unclear at this stage what the company response will be.

An organisation called PFS foundation (Post Finasteride Syndrome Foundation) hosts an active web forum which aims to fund research into 'post finasteride syndrome' – a term coined to describe persistence of sexual dysfunction and depressive/cognitive symptoms following finasteride use. The syndrome is not been scientifically proven at present. There are also other web fora.

[redacted]

I have had several queries relating to the safety of finasteride and the lines which I have given have included the following:

Within Europe at the Pharmacovigilance Risk Assessment Committee, the EU is conducting our own review of depression and related terms including suicidality. The results of this review will be available later in the year.

In terms of other media interest, there have been documentaries in France, Spain and Belgium which have focused on the harmful effects of finasteride.

Please let me know if you require any more assistance. I can provide a link to the paper which we took to PEAG if you would like some more background to this issue.

Kind regards

[redacted]

Medicines and Healthcare Regulatory Products Agency
[redacted]
151 Buckingham Palace Road
London
SW1W 9SZ

[redacted]

From: Woolley, Dr Jane
Sent: 16 February 2017 11:23
To: [redacted]
Cc: [redacted]
Subject: RE: LTT - Alteplase

Dear [redacted]

Thanks – the line on alteplase looks good.

[redacted] – please can you provide [redacted] with some background information on finasteride (see below)?

Thanks
Jane

From: [redacted]
Sent: 16 February 2017 11:10
To: Woolley, Dr Jane
Cc: [redacted]
Subject: LTT - Alteplase

Hi Jane,

Thanks for meeting me yesterday to talk through the possible upcoming issues with Alteplase and Finasteride.

I've updated the lines we've used previously for Alteplase:

> In 2014, an expert working group of the UK's Commission on Human Medicines began a review of alteplase in the treatment of ischaemic stroke. This was in response to questions raised about the evidence base for treatment. As part of the review, the expert group considered the latest evidence available at the time.
>
> In July 2015, the expert working group published their findings. The group recognised the risks associated with alteplase use, but concluded that these were outweighed by the benefits. They unanimously agreed that alteplase remained safe and effective for use in the treatment of acute ischaemic stroke.
>
> As with all medical products, we will continue to monitor the safety of alteplase. We will consider any new evidence which raises concerns about the safety or effectiveness of alteplase.

Can you please you're happy with these and they're accurate?

Also, for finasteride, are you able to send me a copy of the PRAC decision? Even if it's unlikely that anything will happen for a while, it would be useful to do some background reading to prepare for when we do need to issue some comms.

Thanks,
[redacted]