

[REDACTED]

**From:** Raine, Dr June  
**Sent:** 05 February 2019 16:45  
**To:** [REDACTED]  
**Cc:** Woolley, Dr Jane; [REDACTED] Morgan, Sarah  
**Subject:** RE: Regulatory Update: France's FDA-Equivalent Agency Reissues Finasteride Warning

Dear [REDACTED]

Thank you for this information on reporting for finasteride which is very helpful indeed. I agree that there is nothing further which would change our previous communication.

I'm sure you are keeping an eye on the PSURs for finasteride - I seem to recall that SE as lead MS took quite some convincing that the product information especially the PIL for the lower strength product needed to be improved.

Kind regards  
June

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**From:** [REDACTED]  
**Sent:** 05 February 2019 16:26  
**To:** Raine, Dr June <June.Raine@mhra.gov.uk>; Woolley, Dr Jane <Jane.Woolley@mhra.gov.uk>; [REDACTED]  
[REDACTED] Morgan, Sarah <Sarah.Morgan@mhra.gov.uk>  
**Subject:** RE: Regulatory Update: France's FDA-Equivalent Agency Reissues Finasteride Warning

Dear June

The article from the Post Finasteride Syndrome Foundation has been prompted by the release of a DHPC from the French NCA. I can confirm that the information is broadly in line with the DSU article. We did not send a DHPC but proactively alerted Hair Loss Clinics to the DSU article. PRAC did not consider a DHPC was necessary.

I had a quick look in the UK Database to see if we have seen an increased number of reports (the DSU dates from May 2017 and an increase in reporting may have been expected after that). In the UK there may have been a slight increase but last year the number of reports have generally dropped off.

UK Database reports for finasteride (note this is for the drug substance so also includes the 5 mg dose) appear to be stable with less reports for 2018 than in 2017:

Sexual function and depression PT terms with raised EGBM (total number of reports- data extracted 05-02-2019)

Drug Ingredient	PT		N	EGBM
FINASTERIDE	Organic erectile dysfunction		6	77.262
FINASTERIDE	Sexual dysfunction		32	20.611
FINASTERIDE	Testicular disorder		10	19.267
FINASTERIDE	Libido decreased		65	18.765
FINASTERIDE	Infertility		5	14.95
FINASTERIDE	Ejaculation failure		30	12.023
FINASTERIDE	Erectile dysfunction		208	10.68
FINASTERIDE	Ejaculation disorder		21	8.358
FINASTERIDE	Decreased interest		6	5.045

FINASTERIDE	Depression suicidal		6	4.605
FINASTERIDE	Depression		79	3.33

Sexual function and depression PT terms reported 2017-2019 (based on data extracted 05-02-2019)

		Number of reports UK database for 2016	Number of reports UK database for 2017	Number of reports UK database for 2018	Number of reports in UK database for 2019
FINASTERIDE	Depression	2	10	4	
FINASTERIDE	Depression suicidal	0	1	2	
FINASTERIDE	Erectile dysfunction	12	16	10	
FINASTERIDE	Ejaculation failure	1	2*	5**	
FINASTERIDE	Sexual dysfunction	0	1	2	
FINASTERIDE	Organic erectile dysfunction	0	0	0	
FINASTERIDE	Ejaculation disorder	0	0	1	
FINASTERIDE	Libido decreased	0	4	3	
	Total	15	32	22	

\*includes one recovered outcome; \*\* includes outcome unknown in one case.

The increased reporting comment may originate from wording for the PI which rather than point to a causal relationship instead states that there are an increased number of reports of depression and suicidal ideation. I don't think that there is anything in the article which is not already in the public domain for our patients.

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**From:** Raine, Dr June <[June.Raine@mhra.gov.uk](mailto:June.Raine@mhra.gov.uk)>

**Sent:** 04 February 2019 18:23

**To:** [REDACTED] Woolley, Dr Jane <[Jane.Woolley@mhra.gov.uk](mailto:Jane.Woolley@mhra.gov.uk)>; [REDACTED] Morgan, Sarah <[Sarah.Morgan@mhra.gov.uk](mailto:Sarah.Morgan@mhra.gov.uk)>

**Subject:** FW: Regulatory Update: France's FDA-Equivalent Agency Reissues Finasteride Warning

Dear All

FYI Interesting that ANSM has sent a DHPC letter on finasteride and the risk of psychiatric disorders and persistent sexual dysfunction.

I assume that the messages are equivalent to our DSU article?

June