

**To:** Kaufman, Keith D.[keith\_kaufman@merck.com]  
**From:** Silber, Cynthia  
**Sent:** Mon 7/20/2009 12:47:36 PM  
**Importance:** Normal  
**Subject:** RE: Are you in office today?  
PROPECIA\_RMP\_Final.pdf

For completeness, here is RMP. See pp. 29-31 and p. 57.

*Cynthia G. Silber, MD*  
*Director, Clinical Risk Management and Safety Surveillance*  
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**From:** Kaufman, Keith D.  
**Sent:** Monday, July 20, 2009 12:16 PM  
**To:** Silber, Cynthia  
**Subject:** RE: Are you in office today?

I don't have last year's PSUR any longer. Is it emailable?

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**From:** Silber, Cynthia  
**Sent:** Monday, July 20, 2009 12:13 PM  
**To:** Kaufman, Keith D.  
**Subject:** RE: Are you in office today?

No. The way we approached it for the RMP (this is just for Propecia) was that we looked at the over 2000 cases of ED that had been reported, and separated out the subset of those with a reported outcome of "not recovered". There were 278 of these, and we reviewed each of them. They were of limited value, as you can imagine, due to lack of information, lack of followup, etc.

There is no MedDRA term for "persistent erectile dysfunction", which complicates the issue of assessing it in a postmarketing environment. There is also no definition of "persistent", either medical or from an agency.

We did not review reports for Proscar.

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**From:** Kaufman, Keith D.  
**Sent:** Monday, July 20, 2009 12:08 PM  
**To:** Silber, Cynthia  
**Subject:** RE: Are you in office today?

Are there that # of persistent erectile dysfunction?

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**From:** Silber, Cynthia  
**Sent:** Monday, July 20, 2009 12:00 PM  
**To:** Kaufman, Keith D.  
**Subject:** RE: Are you in office today?

do you need me to have the 278 reports that we reviewed for the RMP on hand for this discussion? chris is not in today, and I don't keep them on file in my office--

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**From:** Kaufman, Keith D.  
**Sent:** Monday, July 20, 2009 11:26 AM  
**To:** Silber, Cynthia  
**Subject:** RE: Are you in office today?

Need to re-review reports of 'persistent erectile dysfunction' from postmarketing use. I'll ask my admin to set up some time this afternoon if you're available.

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**From:** Silber, Cynthia  
**Sent:** Monday, July 20, 2009 11:24 AM  
**To:** Kaufman, Keith D.  
**Subject:** RE: Are you in office today?

yes


*Cynthia G. Silber, MD*

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**From:** Kaufman, Keith D.  
**Sent:** Monday, July 20, 2009 11:05 AM  
**To:** Silber, Cynthia  
**Subject:** Are you in office today?