

From: [REDACTED]
To: [REDACTED]
Subject: RE: ACSMD paper [SEC=UNCLASSIFIED]
Date: Wednesday, 5 August 2015 8:06:56 PM
Attachments: [Item 5.1 - Essure contraceptive device - cover page.tr5](#)

Hi [REDACTED]

I have reviewed all changes comments in regards to the ACSMD paper. I have added some additional words and agree with all other changes.

In regards to the issues raised by [REDACTED]

1. For Attachment 1 – IFU: I feel that it would be useful for the committee to see both the United States and “outside USA” (currently used in Australia) IFU versions. I have now deleted all other IFU pages and updated both the cover sheet and the copy of the IFU in the TRIM folder (TRIM number R15/588643).
2. Attachment 4 has been placed in the TRIM folder, see TRIM R15/625421.

As always, happy to discuss further or make additional amendments,
Warm Regards,

[REDACTED]

[REDACTED]
Medical Officer
Medical Devices Branch

[REDACTED]
Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: [REDACTED]
Sent: Wednesday, 5 August 2015 5:59 PM
To: [REDACTED]
Subject: FW: ACSMD paper [SEC=UNCLASSIFIED]

Hi [REDACTED]

[REDACTED] has come back with a few changes and comments in this paper. I have made some changes in response however; there is one question regarding risk management that I would like you to have a look at and add/alter accordingly if you don't mind. Change other things too if you see that it is incorrect.

Thanks

[REDACTED]

[REDACTED]
Director, Device Vigilance and Monitoring Section (DVM)
Medical Devices Branch (MDB)
Therapeutic Goods Administration

PO Box 100
Woden
ACT 2606

[REDACTED]

From: [REDACTED]
Sent: Tuesday, 4 August 2015 1:27 PM
To: [REDACTED]
Cc: [REDACTED]
Subject: FW: ACSMD paper [SEC=UNCLASSIFIED]

Hi [REDACTED]

We've now reviewed the paper and have tracked a number of minor editorials and added a few queries for your response please. Can you have another look and respond to the queries before I update and send to Cheryl for approval. Also -

- Attachment 1 is the IFU and it's in twelve languages. Do you want us to delete the non-English pages? We also noted there are two versions in English, for inside and outside USA. Which is approved by TGA, presumably the 'outside USA' version, so delete the US version also?
- Attachment 4 is not available in the TRIM container yet.

Thanks

[REDACTED]

[REDACTED]
Director
Secretariat Section
Pharmacovigilance and Special Product Access Branch

[REDACTED]

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: [REDACTED]
Sent: Friday, 24 July 2015 11:31 AM
Subject: RE: ACSMD paper [SEC=UNCLASSIFIED]

Great, thanks [REDACTED]

We'll get it finalised and approved by [REDACTED] next week, then out to members. It won't hurt letting them have it earlier.

[REDACTED]

[REDACTED]

Director
Secretariat Section
Pharmacovigilance and Special Product Access Branch

[REDACTED]

Therapeutic Goods Administration

Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: [REDACTED]
Sent: Thursday, 23 July 2015 5:45 PM
To: [REDACTED]
Subject: ACSMD paper [SEC=UNCLASSIFIED]

Hi [REDACTED]

The one and only paper for the next ACSMD is ready for you to cast your eyes over. It has been saved in the working documents file for the meeting.

Kind regards

[REDACTED]

[REDACTED]

Director, Device Vigilance and Monitoring Section (DVM)
Medical Devices Branch (MDB)
Therapeutic Goods Administration

PO Box 100
Woden
ACT 2606

[REDACTED]