

From: [REDACTED]
Sent: Friday, 24 February 2012 12:09 PM
To: [REDACTED]
Subject: Re: TGA Review of SMR Total Conventional Shoulder Prosthesis
[SEC=UNCLASSIFIED]

Yes there's a suggestion on the Minutes of the last OEWG meeting

[REDACTED]

From: [REDACTED]
To: [REDACTED]
Date: 24/02/2012 10:48 AM
Subject: Re: TGA Review of SMR Total Conventional Shoulder Prosthesis [SEC=UNCLASSIFIED]

This is a pity.

We can ask [REDACTED] but would also like to ask someone who uses but does not appear tired to company.

[REDACTED]

[REDACTED]

[REDACTED] Device Vigilance and Monitoring, Office of Product Review, Therapeutic Goods Administration,
PO Box 100, Woden ACT 2606

[REDACTED]
[REDACTED]

www.tga.gov.au

From: [REDACTED]
To: [REDACTED]
Date: 24/02/2012 09:59 AM
Subject: Re: TGA Review of SMR Total Conventional Shoulder Prosthesis [SEC=UNCLASSIFIED]

Dear [REDACTED]

Can I then have a copy of both letters (October and earlier this month) in their final form that they were sent out and the distribution list please?

Regards

[REDACTED]

Biomaterials and Engineering Section
Office of Laboratories and Scientific Services
Therapeutic Goods Administration

 : PO Box 100, Woden, ACT 2606, Australia

✉: [REDACTED] ☎: [REDACTED] ⌂: [REDACTED]

From: [REDACTED]
To: [REDACTED]
Date: 23/02/2012 05:59 PM
Subject: Re: TGA Review of SMR Total Conventional Shoulder Prosthesis [SEC=UNCLASSIFIED]

Dear [REDACTED]

Thank you for your email. We have sent the letter out. I am away at the moment but I will send you a copy of the letter we sent last October when I am back on Tuesday.

Regarding your wish to refer the matter to a shoulder expert, if you have not yet done so, may I suggest [REDACTED] ? He is world renowned, has knowledge of the SMR system and we have sought his opinion on this issue so he is familiar with it.

Kind regards

[REDACTED]

Sent from my iPhone

On 23/02/2012, at 11:41 AM, [REDACTED] wrote:

Dear [REDACTED]

I apologise for the delay in replying to you - I have been away, first on leave and then due to illness.

The Orthopaedics Expert Working Group that advises the TGA met in December last year. They discussed the SMR shoulder - including your submission to the TGA - in some detail, but concluded that the TGA should seek advise from a specialist shoulder surgeon (there are none in the OEWG at present) and to refer the advice back to the OEWG before it makes any final recommendations.

I will need to refer your proposed "Dear Dr" letter to the OEWG for comment. Has the attached letter now been sent? If not, may I suggest that the OEWG has an opportunity to review it before it is sent? The next meeting of the Group is scheduled for 28 March 2012.

The letter states that Lima Australia has already contacted surgeons in October last year about the issue. Can you please provide a copy of that correspondence?

Don't hesitate to contact me if you have any questions of your own

Warm regards

[REDACTED]
Biomaterials and Engineering Section
Office of Laboratories and Scientific Services
Therapeutic Goods Administration

✉ : PO Box 100, Woden, ACT 2606, Australia

✉: [REDACTED] ☎: [REDACTED] ⌂: [REDACTED]

From: [REDACTED]
To: [REDACTED]
Cc: [REDACTED]
Date: 15/02/2012 11:52 AM
Subject: Re: TGA Review of SMR Total Conventional Shoulder Prosthesis

Dear [REDACTED]

Further to my email below dated November 3rd 2011, I have received the additional data that we requested from the AOA National Joint Registry and I can provide you with an update - attached below.

This update is in the form of a letter that we will be sending to all users of the SMR shoulder system in Australia.

Please do not hesitate to contact me if you have any questions.

Kind regards

[REDACTED]

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<SMR Customer Letter Feb 2012.docx>

<image002.gif>

[REDACTED]

Lima Orthopaedics Australia Pty Ltd

T.: [REDACTED]
F.: [REDACTED]

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On 03/11/2011, at 5:50 PM, [REDACTED] wrote:

Dear [REDACTED]

Thank you for your letter to [REDACTED] dated October 6 2011.

Further to our subsequent telephone conversation, please find attached a report covering the information that you requested. As we discussed, we are still awaiting supplementary data from the AOA Joint Registry to complete the report. When we have received the data I will update you.

Please do not hesitate to contact me should you require any further information.

Kind regards

[REDACTED]

<SMR Anatomic Response to TGA V1.pdf>
<AOA Data Request.pdf>
<image002.gif>

[REDACTED]

Lima Orthopaedics Australia Pty Ltd

T.:

F.:

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