[redacted]

From: [redacted]@moh.govt.nz
Sent: Friday, 25 August 2017 10:38 AM
Subject: Re: RELEASE UNDER s61(5) - ARTG 174123Australasian Medical & Scientific Ltd - ESSURE System - Contraceptive, tubal occlusion, Insert [SEC=UNCLASSIFIED]
Attachments: Signed Copy of the Medical Device Recall Letter 24 August 2017.pdf

Hi [redacted]
Thanks for that and for your time on the phone. I really appreciate the open communication we are able to have.

We were sent a very similar recall letter, but required a number of changes including removal of 'voluntary', removal of the text around recall not related to safety concerns and removal of the references supporting use of the device. Attached is a copy of the almost agreed letter for NZ. The only changes we still required at this stage were removal of the references supporting use of the device from the bottom of the letter.

1.

Thanks
[redacted]

[redacted]
Compliance Management
Medsafe
Clinical Leadership, Protection & Regulation
Ministry of Health
DDI: [redacted]

http://www.medsafe.govt.nz
mailto:[redacted]@moh.govt.nz

From: [redacted]@health.gov.au>
To: [redacted]@moh.govt.nz'" <[redacted]@moh.govt.nz>,
Date: 25/08/2017 12:24 p.m.
Subject: RELEASE UNDER s61(5) - ARTG 174123Australasian Medical & Scientific Ltd - ESSURE System - Contraceptive, tubal occlusion, Insert [SEC=UNCLASSIFIED]

To Medsafe New Zealand,

Approval under subsection 61(5) of the Therapeutic Goods Act 1989
Under subsection 61(5) of the Therapeutic Goods Act 1989**:-**

The Secretary may release to a national regulatory authority of another country, or an international organisation, being another country or an organisation with which the Commonwealth has co-operative arrangements relating to the assessment or regulation of therapeutic goods, therapeutic goods information the release of which is consistent with those arrangements.

In relation to issues with **ARTG 174123 - Australasian Medical & Scientific Ltd - ESSURE System - Contraceptive, tubal occlusion, Insert**, I, as delegate of the Secretary for the purposes of section 61 of the Act, approve under section 61(5) of the Act the release to Medsafe New Zealand of the therapeutic goods information relating to these actions as set out below.

Please note the information given below and/or attached is being released by the TGA in accordance with the collaborative arrangements between the TGA and Medsafe. The content includes non-public information and in accordance with these arrangements, it should be treated in confidence by Medsafe and not be disclosed to any other party except as provided for in those arrangements.

[redacted] as discussed this is a Draft only as an FYI – I've not considered it fully yet and the content may change.

Regards

[redacted]
Recalls & Case Management Section
Manufacturing Quality Branch

Phone: [redacted]
Direct eFax: [redacted] Office Fax: [redacted]
Email: [redacted]@tga.gov.au

Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: [redacted]@amsl.com.au]
Sent: Tuesday, 22 August 2017 9:55 AM
To: [redacted]
Cc: [redacted]@bayer.com)'
Subject: ACTION: proposed voluntary recall letter for TGA submission - RE: Follow-up from the TGA call. [SEC=No Protective Marking]
Importance: High

Dear [redacted] dear [redacted] dear [redacted]

I am following up on this communication from Friday. Do you have any update regarding our proposed voluntary recall letter?

Kind regards,

[redacted]

amsl diabetes amsl medical

[redacted]
Email: [redacted]@amsl.com.au
Web: www.amsl.com.au

2 McCabe Place, Chatswood NSW 2067
PO Box 5197 Chatswood West NSW 1515

Dear [redacted] dear [redacted] dear [redacted]

As agreed, please find attached the proposed letter AMSL and Bayer drafted regarding the voluntary recall of Essure.

Please let me know if you have any questions or if there is any change you want to be made.

Kind regards,

[redacted]

amsl diabetes amsl medical

[redacted]
Email: [redacted]@amsl.com.au
Web: www.amsl.com.au

2 McCabe Place, Chatswood NSW 2067
PO Box 5197 Chatswood West NSW 1515

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Medical device recall

ESSURE® Permanent Birth Control

Catalogue Number/Order code: ESS305

Batch Numbers: All

23 August 2017

ISSUE

New Zealand Medical & Scientific Ltd (NZMS), following consultation with Medsafe, is undertaking a recall of all unimplanted ESSURE in New Zealand due to a temporary suspension of the European EC certificate for Unimplanted ESSURE which has occurred during the European certificate renewal process.

ACTION

1. Please inspect your stocks and quarantine all unimplanted ESSURE kits.
2. Email us so we may arrange for your stock to be recovered. We require this information to reconcile this process.
3. If any of the recalled stock could have been transferred from your hospital to another, please immediately let that hospital know of the recall. Please then telephone us so that we can make contact with the hospital supplied from your hospital.
4. This notice should be forwarded to all those who need to be aware of this information within your organisation.
5. Please complete the Attachment A Response Letter included in this notice.

NZMS sincerely regrets any inconvenience caused to your hospital and is fully committed to supporting you in this matter. If you have any questions regarding this recall, please contact:

[redacted] / New Zealand Medical & Scientific Ltd (NZMS)
[redacted]

Phone: [redacted]
Mobile:
Email: [redacted]@nzms.co.nz

[redacted]

Date: 24 August 2017

References:

1. NICE Interventional Procedures Guidance: Hysteroscopic sterilisation by tubal cannulation and placement of intrafallopian implants [IPG587]; July 2017. Available at: https://www.nice.org.uk/guidance/ipg587

2. FDA Essure Benefits and Risks. November 2016. Available at: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProstheticcs/EssurePermanentBirthControl/ucm452250.htm

3. Bouquet et al. Rapport bénéfice risque du dispositif de stérilisation définitive Essure® 30 May 2017. Available at: www.ansm.sante.fr