[redacted]

From: [redacted]@health.gov.au>
Sent: Wednesday, 30 August 2017 2:53 PM
Subject: FW: www.tga.gov.au web publishing request - Essure recall web statement [SEC=UNCLASSIFIED]
Attachments: [D17-630573] Web Statement - Essure - August 2017.DOCX; [D17-630573] Web Statement - Essure - August 2017.tr5

Importance: High

To TGA Website,

Approval under subsection 61 (7) of the Therapeutic Goods Act 1989
Under subsection 61(7) of the Therapeutic Goods Act 1989, the delegate of the Secretary may release to the public therapeutic goods information where release is necessary to ensure the safe use of particular therapeutic goods or relating to the reasons for withdrawal of therapeutic goods from supply.
In relation to issues with Essure contraceptive device, I, as delegate of the Secretary for the purposes of section 61 of the Act, approve under section 61(7) of the Act the release to the public of the therapeutic goods information relating to these actions as set out below.

Regards

[redacted]

[redacted]

Health Products Regulation Group
Australian Government Department of Health
T: [redacted] M [redacted] | E: [redacted]@tga.gov.au
Location: Symonston G.G.06

PO Box 100, Woden ACT 2606, Australia

From: Forms and templates [mailto:SharePoint.Admin@health.gov.au]
Sent: Wednesday, 30 August 2017 1:46 PM
To: PSAB Communications
Subject: www.tga.gov.au web publishing request - Essure recall web statement [SEC=UNCLASSIFIED]

Web Publishing Request

Instructions	
	You have been sent this email because [redacted] requested you review it before forwarding it to the approving officer.

Please review the information in the form, add any attachments required and forward this email to the appropriate approving officer. The approving officer must then send the email on to tga.website@tga.gov.au indicating approval

If you have any questions or need to make changes to the request, please email tga.website@health.gov.au.

Section 61 approval required

This request includes a section 61 publishing request. Under section 61 you must give ***explicit authorisation*** for the publication of this information. Please use the standard words below:

I, **[insert name, insert work title]**, am a delegate of the Secretary under section 61 of the *Therapeutic Goods Act 1989* (the Act). As a delegate, I have decided to release the therapeutic goods information contained in the following attached document(s) for Internet publication to the public acting under **[insert subsection, e.g., 61(5A), 61(5C) or 61(7)]** of the Act.

Please ensure your email includes your electronic signature block.

Request details

Website to update:	www.tga.gov.au
Description of job:	Please find attached a web statement regarding Essure contraceptive device to go in the 'Safety information - Alerts' section of the website. Please note the requests for links and hover text in comments.
Existing pages to be updated:	none
Source documents to be approved:	D17-630573
Date to upload:	Standard timeframe
Public consultation:	No
Title length declaration:	I understand that web page titles can be no longer than 70 characters (including spaces) and if any of my titles are longer than this the information will not be published until the title length is reduced.
Style manual declaration:	I accept that minor changes (grammar, spelling, formatting) will be made if the content does not meet the standard requirements.
Review declaration:	I am aware that content must be reviewed in accordance with the web content review requirements.

Add to news on homepage:	Yes
	News text: Hazard alert - labelling update relating to potential risks

Requestor's details

Full name:	[redacted]
Email address:	PSAB.Communications@tga.gov.au
TGA Area:	**Division:** Medicines Regulation Division **Branch:** Pharmacovigilance and Special Access Branch **Section:** Technical and Safety Improvement

Approval

Approver name:	[redacted]
Position:	
Message to approver:	
Section s.61 approval required:	Yes

Essure contraceptive device

Hazard alert – labelling update relating to potential risks

Consumers and health professionals are advised that Australasian Medical and Science Ltd (AMSL), in consultation with the TGA, has issued a hazard alert for Essure. AMSL is also recalling unused stock and withdrawing the device from the Australian market.

Essure is an implanted device that provides permanent contraception for women. A soft, flexible insert is placed into each of the patient's fallopian tubes and, over the following three months, a barrier forms around the inserts, which is intended to prevent pregnancy.

It has been identified that some patients who have received the device may not have been fully informed of the possible device and procedure-related risks before choosing to have Essure implanted.

There have been reports of changes in menstrual bleeding, unintended pregnancy, chronic pain, perforation and migration of the device, allergy/hypersensitivity, or immune-type reactions. Some of these reports were considered serious and resulted in removal of the device, which involved abdominal surgery.

The labelling for the product is being updated. The update includes revised Instructions for Use (IFU) and the introduction of a Patient Information Brochure with a patient-doctor discussion checklist. The updated labelling provides warnings about potential adverse events and situations where device removal may be necessary. The IFU is being updated with additional information, including a new section on patient counselling, as well as changes to sections about safety, clinical studies, directions for use and patient management.

On 31 May 2017, the TGA was informed about the manufacturer's decision to discontinue the distribution of Essure in Australia for business reasons. The Australian Register of Therapeutic Goods entry will be cancelled and there will be no further implantations of Essure in Australia.

Information for consumers

If you have an Essure implant, please be aware of this issue. You may wish to request from your doctor a copy of the Patient Information Brochure, which provides an overview of the procedure, possible side effects and other potential immediate and long-term risks (including pregnancy risk), from your doctor.

If you have any questions or concerns about this issue, or if you have experienced any suspected side effects, talk to your doctor.

Comment [redacted]1]: Please add a link to the 'A [redacted] all actions' webpage http://www.tga.gov.au/safety/recalls-about.htm in a 'Related information' box.

Commen [redacted]2]: Hover text - Information issued to health professionals about issues or deficiencies relating to an implanted medical device or biological product and advice about the ongoing management of patients.

Comment [redacted]: Hover text – The permanent removal of an affected therapeutic good from supply or use in the market.

Information for health professionals

AMSL has written to health professionals who have performed the Essure procedure to provide further information about this issue and to advise them to review the updated IFU and new Patient Information Brochure. The brochure is intended to be reviewed by the patient with their doctor face-to–face, which may assist in identifying any device related issues.

If you have any questions or concerns regarding this issue, contact AMSL on 02 9882 3666.

Reporting problems

Consumers and health professionals are encouraged to report problems with medical devices. Your report will contribute to the TGA's monitoring of these products. For more information, see the TGA Incident Reporting and Investigation Scheme (IRIS).

The TGA cannot give advice about an individual's medical condition. You are strongly encouraged to talk with a health professional if you are concerned about a possible adverse event associated with a medical device.