From: [redacted]
To: [redacted]
Subject: s41JA Request for Information [SEC=UNCLASSIFIED]
Date: Friday, 25 July 2014 5:06:35 PM
Attachments: s41 Gytech Pty Ltd (Essure).DOCX

Dear [redacted]

Attached is a s41JA request for information for the ESSURE System - Contraceptive, tubal occlusion insert medical device. If you have any questions, please don't hesitate to contact me.

Regards

[redacted]
Departmental Officer
Device Vigilance and Monitoring
Office of Product Review

Phone: [redacted] Fax: [redacted]
Email: [redacted]

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

Australian Government
Department of Health
Therapeutic Goods Administration

File Reference: 2014/039228
This document was sent by email on 25 July 2014

[redacted]
Gytech Pty Ltd
PO Box 76
ARMADALE NORTH VIC 3143

[redacted]

Dear [redacted]

Notice requiring information/documents to be provided under section 41JA of the *Therapeutic Goods Act 1989*
ARTG Number: 174123

I refer to the ESSURE System - Contraceptive, tubal occlusion, Insert medical device with the above Australian Register of Therapeutic Goods (ARTG) number.

I have made a decision under subsection 41JA (1) of the *Therapeutic Goods Act 1989* (the Act) to require you to provide information/documents about ESSURE System - Contraceptive, tubal occlusion insert. I am the delegate of the Secretary of the Department of Health for that purposes of section 41JA of the Act.

Reasons for requesting information/documents
Thank you for your letter dated 23 July 2014 regarding the temporary suspension of the NSAI Quality Management System and CE Mark certificates for the Essure system medical device. Your letter states that the reason for the suspension related to procedural regulatory and contractual requirements and that the legal manufacturer BayerHealthcare LLC (USA) has informed you that a recall is not required and that you may continue to supply product manufactured prior to the effective date of suspension. In order to determine whether further action is or isn't necessary, we require further information regarding the reason for the suspension.

Information requested

I require the following information/documents to be provided:

Details of the non-conformities identified by the NSAI audit. This may be provided in the form of a copy of the audit report or any other information/documents that address the issues identified.

Timeframe for compliance

The information/documents must be provided in 10 working days from the date of this letter being no later than 12 August 2014.

Address for sending the requested information

Electronic submission of all information is preferred. The requested information should be sent to [redacted] via:

- email to postmarketdevices@tga.gov.au
- post to
  Device Vigilance Monitoring Section
  Office of Product Review
  Therapeutic Goods Administration
  PO Box 100
  Woden ACT 2606
- courier to
  Device Vigilance Monitoring Section
  Office of Product Review
  Therapeutic Goods Administration
  136 Narrabundah Lane
  Symonston ACT 2609

Please quote the above FILE REFERENCE number on all correspondence relating to this post market review. This information is essential for the TGA to track and identify all pieces of data relevant to the post market review.

Important

- The TGA requires all requested documents to be provided as complete stand-alone documents in the English language (or with certified translations). Cross-referencing to information already provided for other applications or reviews in progress is not acceptable.

- Please refer to the Guidance document available from the 'Medical Devices' area of the TGA website for assistance in compiling the requested documents and particularly the Australian Regulatory Guidelines for Medical Devices (ARGMD) at http://www.tga.gov.au/industry/devices-argmd.htm.

- Information not submitted in the format referenced in the above guidance document may result in submissions not complying with this section 41JA notice.

- Where a device included on the ARTG is no longer being supplied you may choose to cancel the entry by following the instructions on the TGA website at **http://www.tga.gov.au/about/forms-artg-cancel.htm .** If applicable please inform the undersigned when you have been notified that the cancellation has occurred.

- Please note that failure to comply with this request for information may attract a range of sanctions. These are outlined in **Attachment B**.

Should you wish to seek a review of my decision to require you to provide information/documents about ESSURE System - Contraceptive, tubal occlusion, Insert, your rights of review are outlined in **Attachment A**.

Please note that in the event that medical devices are cancelled from the ARTG following a notice under subsection 41JA(1) of the Act requiring information/documents to be provided and a proposal to cancel, the Secretary is required under 41GP of the Act to publish in the Commonwealth Gazette or on the department's website particulars of the

cancellation of the entry from the ARTG as soon as practicable after the cancellation. The TGA's practice is to publish information on its website about that cancellation including the name of the sponsor and product and the grounds on which the goods were cancelled. This information is updated in the event that the cancellation is subject to internal review or review by the Administrative Appeals Tribunal, or other form of legal review. [For more information see http://www.tga.gov.au/about/compliance.htm]

Please contact the undersigned on [redacted] or [redacted] if any aspect of this request for information requires clarification.

Yours sincerely

Signed electronically by

[redacted]
Delegate of the Secretary
Device Vigilance Monitoring
Office of Product Review
Therapeutic Goods Administration

25 July 2014

Signed electronically on: 25 July 2014
Sent by email on: 25 July 2014

ATTACHMENT A

Section 41JA review provisions

Review rights

This decision is an "initial decision" within the meaning of section 60 of the Act. This means that if your interests are affected by the decision, you may seek reconsideration by the Minister. Any request for reconsideration should be made in writing within 90 days after this decision first comes to your notice or to the notice of your company and should be sent to the following address:

The Assistant Minister for Health
Parliament House
CANBERRA ACT 2600

The letter should be headed "REQUEST FOR RECONSIDERATION UNDER SECTION 60 OF THE THERAPEUTIC GOODS ACT 1989".

What you should provide in support of your request for reconsideration

It is important that you include with your request any information in support of the request that you would like the Minister to consider. Under subsection 60(3A) of the Act, the Minister is not able to consider any information that you provide after the making of the request unless the information is provided in response to a request from the Minister or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable. To facilitate the consideration of your request it is also requested that you:

1. include a copy of the decision you want reconsidered;
2. describe with as much specificity as you can, exactly what parts of the decision you believe are incorrect or in relation to which you object, and set out the reasons;
3. identify the parts of the information you provide in support of the request that relate to each of those reasons; and
4. if the decision does not relate to you or your company, describe how your interests are affected by the decision.

The Minister may either personally deal with the request or send it to be dealt with by one of the Minister's delegates within the Department. If you are dissatisfied with the result of the decision on the reconsideration request then, subject to the *Administrative Appeals Tribunal Act 1975*, you may appeal to the Tribunal for review of that decision.

Sanctions in relation to a notice under section 41JA of the Act

Failure to comply with a notice given under subsection 41JA(1) of the Act constitutes an offence under section 41JB(3) of the Act with a maximum penalty of 500 penalty units.

Failure to comply with this notice might also lead to suspension of the medical device/s from the ARTG under section 41GA of the Act or cancellation of the medical device/s from the ARTG under section 41GN of the Act.

Providing information that is false or misleading in a material particular may attract criminal and civil penalties. The criminal penalties are set out in subsections 41JB(4) to 41JB(7) of the Act.

It is a three tiered offence regime:

- subsection 41JB(4) of the Act attracts a maximum penalty of 5 years imprisonment and/or 4,000 penalty units where a person gives information that is false or misleading in a material particular in response to a subsection 41JA(1) notice, and use of the medical device has resulted in, will result in, or would result in harm or injury to any person;
- subsection 41JB(5) of the Act is a strict liability offence that attracts a maximum penalty of 2,000 penalty units where a person gives information that is false or misleading in a misleading particular in response to a subsection 41JA(1) notice, and harm or injury would be likely to occur to any person if that kind of medical device were used; and
- subsection 41JB(7) of the Act attracts a maximum penalty of 12 months imprisonment and/or 1,000 penalty units where a person gives information that is false or misleading in a material particular in purported compliance with a subsection 41JA(1) notice.

The civil penalties for giving information that is false or misleading information in a material particular in purported compliance with a notice are set out in section 41JBA of the Act. The maximum penalties under this section are 5,000 penalty units for an individual and 50,000 penalty units for a body corporate.

A penalty unit is worth $170 (see section 4AA of the *Crimes Act 1914*).