Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

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[redacted]

DECISION TO IMPOSE REQUIREMENTS
Under section 41KA of the *Therapeutic Goods Act 1989* in relation to the cancelled entry of 'electrical impedance scanner' from the Australian Register of Therapeutic Goods

1. As a delegate of the Secretary to the Department of Health and Ageing for the purpose of section 41KA(1) of the *Therapeutic Goods Act 1989* (the Act), I am writing to inform you of the requirements that I am imposing on you under section 41KA(2)(b) of the Act arising out of the cancellation of 'electrical impedance scanner' (the Device) from the Australian Register of Therapeutic Goods (the Register, ARTG).

Background

2. As you are aware, the Therapeutic Goods Administration (TGA) has undertaken a review of the Device as part of its post-market review of medical devices included in the Register in relation to which therapeutic claims have been made about breast imaging, breast scanning and/or breast screening. The Device was included on the Register under number 152697.

Correspondence

3. On 23 March 2010, a delegate of the Secretary by letter addressed to [redacted] (as Managing Director of) [redacted] requested under section 41JA of the Act that the following information and documents be provided within 20 days:

1. an original or correctly notarised copy of the manufacturer's Australian Declaration of Conformity*, as required under Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations)
   * *The declaration of conformity must conform to Australian requirements. A European declaration of conformity is not acceptable.*
2. the total number of adverse events reported for each device in Australia, and worldwide;
3. the details of any regulatory action taken against the Sponsor or manufacturer in relation to each device in Australia, and worldwide;
4. the labelling, instructions for use and advertising material for the device;
5. copies of all certificates from Notified Bodies that support the inclusion of the device on the ARTG;
6. the total number of each device distributed in Australia, and worldwide;
7. copies of the clinical evidence used to establish conformity with Australian Essential Principle 14, and as described in Guidance Document Number 4: Clinical Evidence Requirements for Inclusion of Medical Devices in the Australian Register of Therapeutic Goods, and as required by Part 8 of Schedule 3 of the Regulations, including evidence to support the clinical competence of its author (eg a short curriculum vitae);

8. risk management reports for the product;
9. electrical safety test reports/ certificates for electromedical equipment.

4. On 21 April 2010, TGA received an email from [redacted] that included a letter signed by you, appointing [redacted] as the delegate for [redacted] regarding the matter of the post market review of the Device.

5. On 24 April 2010, [redacted] during a telephone conversation with TGA indicated that your company would commence procedures to remove the Device from the Register because you realised that the conditions of inclusion could not be met.

6. On 27 April 2010, the TGA requested by email to [redacted] further information in relation to the Device noting that you were considering cancelling the Register entry.

7. On 14 May 2010, by email [redacted] responded to the request stating that the information had been prepared and was waiting to be reviewed by you. [redacted] stated that he would send the package of information followed by the cancellation of the Device from the Register.

8. On 28 May 2010, TGA sent a letter signed by the delegate of the Secretary proposing to cancel the device from the Register because you failed to provide the information requested on 23 March 2010 under section 41JA of the Act.

9. On 3 June 2010, [redacted] provided via email to TGA a copy of the completed Authorisation to cancel a product from the Register dated 29 April 2010.

Legislative overview

10. The Secretary, or her delegate, may impose requirements on a person in relation to whom a kind of device was included in the Register when that entry has been cancelled (see section 41KA(1) of the Act, Attachment A). These requirements include requiring that person to inform a specified class of persons, in the specified manner and within such reasonable period as is specified, to the effect that the kind of device has been cancelled from the Register (see section 41KA(2) of the Act).

Information Considered

11. I have considered the following relevant material in coming to my decision:
    (a) the Act (relevant extracts at Attachment A);
    (b) the *Therapeutic Goods Regulations 2002* (the Regulations);
    (c) the Register entry submission information for ARTG number 152697;
    (d) letter from the TGA to [redacted] dated 23 March 2010;
    (e) correspondence to the TGA dated 21 April 2010 and TGA file note dated 24 April 2010 recording a conversation with [redacted] who acknowledged that the conditions of inclusion of the Device on the Register by [redacted] could not be met and the intention to consult with Board of Directors [of [redacted] and then to fax a copy of the form to the TGA requesting removal of the Device from the ARTG;
    (f) email from TGA to [redacted] dated 27 April 2010;
    (g) email from [redacted] to TGA, dated 29 April 2010;
    (h) email from the TGA to [redacted] dated 11 May 2010;
    (i) email from [redacted] to TGA dated 14 May 2010;

(j) letter from the TGA to [redacted] dated 28 May 2010 proposing to cancel the Register entry.
(k) an email to TGA from [redacted] dated 3 June 2010 providing information about the cancellation of the Device from the Register dated 29 April 2010;
(l) Department of Health and Ageing "National Horizon Scanning Unit Emerging Technology Bulletin. New and emerging technologies for breast cancer detection", dated February 2009; and
(m) TGA Clinical assessment of available information dated 6 August 2010.

Decision

12. The Device supplied by [redacted] in Australia remains in circulation when it has not been shown by you (as the person recorded in the Register as the sponsor) that it complies with the essential principles under the Regulations; specifically, you have not produced clinical evidence to demonstrate that the Device performs in the way intended by the manufacturer (see essential principles 3 and 14). I consider in those circumstances that it would be appropriate that those who were so supplied are advised that the Device has been cancelled from the Register and the circumstances in which that cancellation occurred.

13. For that purpose I have decided under section 41KA(2) of the Act that you are required to:

(a) notify all customers to whom you have supplied the Device in Australia stating:
  (i) the Australian Register of Therapeutic Goods entry for the Device (ARTG number 152697) was cancelled from the Register on 4 June 2010;
  (ii) [redacted] requested the Secretary cancel the entry following a request for information and documents from the TGA which included evidence that the Device complied with essential principle 14 set out in the *Therapeutic Goods (Medical Devices) Regulations (2002)*. Essential Principle 14 requires every medical device to have clinical evidence appropriate for the use and classification of the Device; and
  (iii) that there are advertising requirements under the Act, the *Therapeutic Goods Advertising Code 2007* (the Code) and the *Trade Practices Act 1974* (TP Act). These requirements include:
    - a person must not publish or broadcast an advertisement about therapeutic goods: if that good is not entered on the Register (refer to section 42DL (1)(g)of the Act);
    - that a therapeutic good cannot be advertised in a manner that is likely to be misleading or likely to lead to consumers inappropriately treating potentially serious diseases (see section 4(2) of the Code); and
    - that goods generally cannot be advertised in a manner that is likely to mislead or deceive (see section 53 of the TP Act).
(b) provide the proposed text of the notification referred to in paragraph (a) to this Office for approval within 10 working days from the date of this letter and prior to its distribution to your customers together with a list of all the customers to whom it is proposed to provide the notification.
(c) send the notification to those customers using the approved text within 10 working days from the date of the TGA approval.
(d) provide evidence to this Office within 2 working days after the notification of the customers with evidence of that notification (including the text sent),
(e) comply with the requirements in paragraphs (b) to (d) even if the time periods set out in those paragraphs are not met.

14. The TGA is required, under section 41KB of the Act, to place a notice setting out the above requirements in the Commonwealth Gazette as soon as practicable after imposing any requirements under section 41KA of the Act. This notice will be published (in the Commonwealth Gazette and on TGA's website) 5 working days after TGA has approved the text of the letter. If the requirement at paragraph 13(b) is not complied with, this notice will be published within 10 working days from the date of this letter.

Important
Failure to comply with any of the requirements set out in paragraph 13 above (including the time within which they must be complied with) may result in a criminal offence under 41KC of the Act or a civil penalty under section 41KCA of the Act.

You are reminded that under section 41MI of the Act it is an offence for a sponsor to import or supply in Australia medical devices for use in humans that are not, unless otherwise authorised or exempt, included in the Register in relation to that person.

The relevant contact officer is the Recalls Coordinator, Trevor Byrne on (02) 6232 8636 or email at trevor.byrne[redacted]

Should you wish to appeal against my decision to impose requirements under section 41KA in relation to the cancelled entry of 'electrical impedance scanner' from the register, information about your appeal rights are outlined in Attachment B.

Yours sincerely,

Larry Kelly
Delegate of the Secretary
Coordinator
Monitoring and Compliance Group

7 December 2010

ATTACHMENT A

Legislative extracts

Therapeutic Goods Act 1989

41GL Immediate cancellation of entries of kinds of medical devices from the Register

The Secretary may, by written notice given to the person in relation to whom a kind of medical device is included in the Register, cancel the entry of the kind of device from the Register if:

...

(d) the person requests in writing the cancellation of the entry of the kind of device from the Register;

...

Part 4-9—Public notification and recovery of medical devices

41K What this Part is about

The Secretary can require action to recover medical devices, or to inform the public about medical devices, that do not comply with requirements or cannot lawfully be supplied.

41KA Public notification and recovery of medical devices

(1) The Secretary may, in writing, impose requirements, relating to a kind of medical device, on a person if:

(a) any of the circumstances referred to in the second column of an item in the following table occur in relation to the kind of device; and

(b) the person is referred to in the third column of that item of the table.

Circumstances in which requirements may be imposed

...

Item	Circumstance relating to a kind of medical device	Person subject to requirements
7	Its entry has been cancelled from the Register	The person in relation to whom it was included in the Register

(2) The requirements may be one or both of the following:

(a) to take specified steps, in the specified manner and within such reasonable period as is specified, to recover medical devices of that kind that have been distributed;

(b) to inform the public or a specified class of persons, in the specified manner and within such reasonable period as is specified, to the effect that the circumstances referred to in paragraph (1)(a) have occurred in relation to medical devices of that kind.

(3) If the circumstances referred to in paragraph (1)(a) apply only to some medical devices of that kind, the Secretary may limit the imposition of the requirements to the medical devices of that kind to which those circumstances apply.

(4) A requirement to recover medical devices under this section does not apply to a medical device that cannot be recovered because it has been administered to, or applied in the treatment of, a person.

41KB Publication of requirements

The Secretary must cause to be published in the *Gazette*, as soon as practicable after imposing a requirement under section 41KA, a notice setting out particulars of the requirement.

41KC Criminal offences for failing to comply with requirements relating to a kind of medical device

(1) A person commits an offence if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches a requirement imposed on the person under section 41KA; and

(c) the act or omission has resulted in, or will result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

(2) A person commits an offence if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches a requirement imposed on the person under section 41KA; and

(c) the act or omission is likely to result in harm or injury to any person.

Penalty: 2,000 penalty units.

(3) Subsection (2) is an offence of strict liability.
Note: For strict liability, see section 6.1 of the *Criminal Code*.

(4) A person commits an offence if:
(a) the person does an act or omits to do an act; and
(b) the act or omission breaches a requirement imposed on the person under section 41KA.
Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

41KCA Civil penalty for failing to comply with requirements relating to a kind of medical device
A person contravenes this section if:
(a) the person does an act or omits to do an act; and
(b) the act or omission contravenes a requirement imposed on the person under section 41KA.
Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.
...

ATTACHMENT B

Appeal Provisions

Reconsideration by the Minister

The decision under section 41KA is an "initial decision" within the meaning of Section 60 of the Act. This means that if you are a person whose interests are affected by this decision, and you wish to appeal against this decision, you may do so in writing to the Minister under Section 60 of the Act. Any appeal 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:

Parliamentary Secretary to
the Minister for Health and Ageing
Parliament House
CANBERRA ACT 2600

The letter should be headed:

"APPEAL UNDER SECTION 60 OF THE THERAPEUTIC GOODS ACT 1989"

In accordance with the Act the Minister may delegate the power to consider an appeal. Should you be dissatisfied with the result of your appeal then, subject to the *Administrative Appeals Tribunal Act 1975*, you may apply to the Administrative Appeals Tribunal for a review of the Minister's/Delegate's decision.