RECALL COPY 23

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

File Reference: 2010/012670
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[redacted]
Managing Director
[redacted]

DECISION TO IMPOSE REQUIREMENTS
Under section 41KA of the *Therapeutic Goods Act 1989* in relation to the cancelled entry of 'Camera Thermographic' 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 'Camera Thermographic' (the Device) from the Australian Register of Therapeutic Goods (the Register).

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 143474.

Correspondence

3. On 10 August 2010, a delegate of the Secretary by letter addressed to [you 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. clear, legible copies of all information that accompanies the product when supplied to users (including packaging and labelling and any instructions for use);
3. copies of any brochures, flyers, leaflets, published advertisements and website URL's which advertise the product in Australia;
4. the total number of each device distributed in Australia, and worldwide;
5. the total number of adverse events reported for each device in Australia, and worldwide;
6. the details of any regulatory action taken against the Sponsor or manufacturer in relation to each device in Australia, and worldwide;
7. a summary 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. copies of all certificates from Notified Bodies that support the inclusion of the device on the ARTG;
9. risk management reports for the product;
10. electrical safety test reports/ certificates for electromedical equipment.

4. On 21 September 2010, [redacted] (your regulatory affairs consultant) provided material described at paragraph 9(j) below. He also advised that further material would be provided.

5. On 21 September 2010, the TGA provided [redacted] with the link to "National Horizon Scanning Unit Emerging Technology Bulletin New and emerging technologies for breast cancer detection, February 2009".

6. On 22 September 2010, [redacted] by email to the TGA, requested (on your behalf) that the Device be cancelled from the Register. [redacted] advised the reason for the cancellation was "on the basis that sales in Australia are trivial compared with USA, Europe and other regulatory regions, he (referring to you) considered it best to stop further sales in the TGA regulatory region".

7. On 24 September 2010, as a result of the request from [redacted], a delegate of the Secretary cancelled with immediate effect the inclusion of the Device in the Register under section 41GL(d) of the Act. Notice of the cancellation was advised to [redacted] on 1 October 2010.

Legislative overview

8. 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). 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

9. I have considered the following relevant material in coming to my decision:
   (a) the Act (relevant extracts at Attachment A);
   (b) the Regulations;
   (c) the Register entry submission information for ARTG number 143474;
   (d) letter from the TGA to [redacted] dated 10 August 2010;
   (e) correspondence to the TGA dated 16 August 2010 and TGA file note dated 16 August 2010 recording that the letter sent to [redacted] was sent to the incorrect address (noting that this was the address previously provided to the TGA as [redacted] address);
   (f) email from TGA to [redacted] dated 16 August 2010;
   (g) letter from TGA to [redacted] dated 15 September 2010 and email to [redacted] dated 15 September 2010;
   (h) email from [redacted] on behalf of [redacted] dated 15 September 2010;
   (i) email from TGA to [redacted] on behalf of [redacted] dated 16 September 2010;
   (j) TGA file notes dated 16 and 17 September 2010;
   (k) email from [redacted] acting as Regulatory Affairs Consultant for [redacted] providing:
      (i) Pamphlet entitled "Breast Health", copyright 2003, otherwise undated;

(ii) Test report for the Device from Compix Incorporated (the Manufacturer) dated 7 March 2008;
(iii) Meditherm Thermal Imaging System Installation and Operating Instructions, version 2.0, dated 3 March 2008;
(iv) Links to two case studies (as purported evidence of compliance with essential principle 14) – I have reviewed both case studies;
(v) Certificate from Ault Incorporated dated 5 May 2003;

(l) email from [redacted] dated 22 September 2010 and the 'Authorisation to cancel a product from the Australian Register of Therapeutic Goods';
(m) Department of Health and Ageing "Statement on use of thermography to detect breast cancer' dated 17 July 2008;
(n) TGA Clinical evidence assessment dated 23 September 2010; and
(o) letter from TGA to [redacted] advising that the Device has been cancelled from the Register dated 1 October 2010 effective from 24 September 2010.

Decision

10. 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. 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.

11. 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 143474) was cancelled from the Register on 24 September 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 (which requires every medical device to have clinical evidence appropriate for the use and classification of the device) set out in the Regulations; and
(iii) that they note the advertising requirements under the Act, the *Therapeutic Goods Advertising Code 2007* (the Code) and the *Trade Practices Act 1974* (TP Act). That is, a person must not publish or broadcast an advertisement about therapeutic goods: if that good is not entered on the Register (refer to section 41DL 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 inappropriate by 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.

12. 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 11(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 11 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]

Yours sincerely,

Larry Kelly
Delegate of the Secretary
Coordinator
Monitoring and Compliance Group
26 November 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.
...