Tab 6

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Minute

File No. 2010/012670

Larry Kelly
Coordinator
Monitoring and Compliance Group

Purpose:

To approve a request by DVM that the Recalls Section coordinate and record action taken under s41KA for a medical device that has been cancelled from the ARTG.

Issue:

A medical device – camera thermographic – was cancelled from the ARTG by the sponsor Meditherm, in September 2010. Based on the clinical review of available information on the device it is recommended that the sponsor be required to undertake action for those devices in the market.

Background:

- The device was identified in the paper, *Testing for Breast Cancer: Will the real breast screening test please stand up?*" published by [redacted] in April 2010. **(folio 2-7)**
- A post market product review of the device was initiated.
- The sponsor provided information limited to **(folios 30-47)**:
  - Labels found on the device;
  - Instructions for Use;
  - Clincial information is only what can be found on the website, [redacted]
  - A declaration of conformity for Europe dated 3/3/2008. The sponsor's representative stated that no certificates have been issued because the product is a Class 1 device.
  - IEC 61010-1 test report;
  - EC certificate dated -5/05/2003 which do not seem to apply to this device.
- The sponsor's regulatory affairs consultant informed TGA the sponsor would be cancelling the device from the ARTG "on the basis that the sales in Australia were trivial compared with USA, Europe and other regulatory regions, he considered it best to stop further sales in the TGA regulatory region." **(folio 48)**
- The device was cancelled from the ARTG in September 2010.**(folio 49)**
- Due to the concern that these devices would still be available for use and were being advertised as being safe to use for breast cancer diagnosis it was decided to continue to investigate whether there was information that would assist TGA in determining whether this type of device is safe and effective for breast cancer diagnosis. Information on the device's technology and clinical evidence was gathered by TGA and reviewed by Office Device Authorisation, Clinical Section.
- The review concluded that;

- The available clinical evidence is insufficient and does not support the use of this device for the purpose of breast cancer diagnosis. In fact the majority of information on the sponsor's website concludes that thermography has no role to play in breast screening, diagnosis, prognosis assessment and detection/early prediction of intramammary breast cancer, and
- There was a degree of foreseeable misuse of the device should it be used by untrained staff and that it could lead patients to believe they had been adequately screened for serious conditions which may lead to them not seeking further screening by other modalities.

- TGA believes there are at least 32 devices in use in Australia.**(folio 46)**
- As the device may be misused, may not be safe and may lead patients to a false sense of having been adequately scanned for serious conditions, it is recommended that the sponsor be required to notify its customers that the device has been removed from the register because they decided not to provide evidence of the device's effectiveness in breast cancer diagnosis.

Comment:

Scientific Evidence

- No scientific evidence was officially provided by the sponsor or manufacturer to support the intended purpose of the device. There is however, information on the sponsor and manufacturer's website that was used in the review. Review by Clinical section of the available literature on thermographic imaging concluded that:
  - The available clinical evidence is insufficient and does not support the use of this device for the purpose of breast cancer diagnosis. In fact the majority of information on the sponsor's website concludes that thermography has no role to play in breast screening, diagnosis, prognosis assessment and detection/early prediction of intramammary breast cancer, and
  - There was a degree of foreseeable misuse of the device should it be used by untrained staff and that it could lead patients to believe they had been adequately screened for serious conditions which may lead to them not seeking further screening by other modalities. **(folio 108-115)**

Correspondence with sponsor

- S41JA letter **(folios 12-15)**
- Emails at folios **17,20, 28, 48**
- Note for file at folios **29**
- Letter from TGA dated 1 October cancelling inclusion from the ARTG. **(folio 116)**

Legislative Requirements

- Sections 41KA(1) Item 7
- S41KA(2)(b)
- S41KB

Options:

Approve DVM's request for the recall section to coordinate the action of notification of customers about the cancellation of the ARTG entry.

Recommendation:

1. That you sign the letter to the sponsor requiring them under s41KA to notify customers of the cancellation from the ARTG on the basis that:
   - The sponsor has not provided information in response to a S41JA letter and has instead cancelled the inclusion. Also, review of available information questions whether this device can be safely used.

2. Request that the recall section coordinate this action as they have the SOPs and IT infrastructure for this type of process already in place. Also this type of notification is included under s41 KA which includes recall provisions.

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Has this been discussed with Recalls

R1. **SIGN** the letter to the sponsor requesting that they undertake the required action.

R2. **APPROVE** DVM's request for the recall section to coordinate the proposed action under S41KA

Yes agreed.

R3. **SIGN** the Minute to Recalls Section

Pamela Carter

Pam Carter
Director

23 November 2010

R1. AGREED / NOT AGREED

R2. SIGN / NOT SIGNED

Larry Kelly
Group Coordinator
Monitoring and Compliance Group
26 November 2010