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Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Minute

File Number: 2010/012670

Date: Nov 2010

Section to: Recalls

Issue: Request that Recalls undertake recall action under Section 41KA(1) Item 7 for a medical device cancelled from the ARTG.

Sponsor: [redacted]
Device: 143474 – Camera Thermographic
Manufacturer: [redacted]

Recommend that notification of customers is required by the sponsor under s41KA (Public notification and recovery of medical devices) of the Act for a medical device that was cancelled from the ARTG in September 2010.

Background
The sponsor [redacted] cancelled the device from the ARTG in September 2010. The sponsor cancelled this inclusion after receiving a letter from TGA requesting information under S 41JA. The TGA requested the sponsor provide information on how they complied with the essential principles including the provision of clinical evidence to substantiate claims in the intended purpose and advertising.

The sponsor stated in their response to TGA the market for this device in Australia was so small that the manufacturer would not provide the information that was requested.

Information on the device and its technology and clinical evidence was gathered by the TGA and reviewed by the Office of Device Authorisation, Clinical Section. The review concluded that:

- The publicly 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.
- there was foreseeable misuse of the device if it was used to diagnose or screen for breast cancer, and
- scanning with this device may lead the patient to believe they had been adequately screened for serious conditions which may lead them not to seek screening through other modalities.

A former representative of the sponsor has indicated that there have been 32 devices supplied in Australia.

Recommendations

R1 That the sponsor [redacted] be required to undertake action under S41KA(2)(b) of the Act.

R2 The action should include the sponsor writing to their customers stating that the device has been cancelled from the register because they chose this course of action in preference to providing the TGA with information that shows that the device is safe and performs as intended.

R3 The attached letter should be forwarded to the sponsor in relation to the notification action

R4 Request that recalls section coordinate the action as they have the IT system and SOPs to deal with this type of action and also the proposed action is being conducted under s41KA of the Act which is used for conducting recalls.

R5 Request that recall section notify the DVM if the sponsor has not responded to the attached letter and agreed to send out the letter to its customers.

26/11/2010

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