Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Minute

File Number: 2010/004802

Date: Dec 2010

Section to: Recalls

Issue: Request that Recalls coordinate and document notification requirements taken by TGA under Section 41KA(1) Item 7 for a medical device cancelled from the ARTG.

Sponsor: [redacted]
Device: 152697, Electrical Impendence Scanner
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 June 2010.

Background

The sponsor [redacted] cancelled the device from the ARTG in June 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 indicated to TGA they knew they could not meet the conditions of inclusion of the device and would therefore be cancelling the device from the ARTG.

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.
- 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.

Anecdotal evidence and several individual complaints related to this device indicate that there has been a significant number of these 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 the recall section coordinate the action as they have IT support and SOPs to deal with this type of action. Also the proposed action is being conducted under s41KA of the Act which is used when conducting public notification and recovery of medical devices.

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.

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Dec 2010