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Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Minute

File No. 2010/004802

Larry Kelly
Office Head Office of Devices Blood and Tissues

Request for MVMS to continue to review a product which has been cancelled from the register by the sponsor, because they could not provide the requested information, with a view to recalling product already supplied if the product already supplied does not meet the essential principles for safety and performance.

Issue:

The MVMS is reviewing products identified in a National Horizon Scanning Unit Emerging Technology Bulletin on breast cancer detection technologies. One product identified in the bulletin has recently been cancelled from the register by the sponsor. The sponsor has stated that they were unable to provide the information requested under S41JA to substantiate the intended purpose and other requirements when the product was included in the register. This device was not assessed for safety and performance prior to entry on the ARTG therefore a review of information to determine whether it meets the essential principles and is safe to use is necessary given that this device appears to have been widely distributed and promoted as a safe form of breast cancer screening. The issues raised by [redacted] are that these products will be used and promoted to detect and diagnose cancer which is contrary to the currently accepted research. The reporters raise the issue that if these devices are being promoted as safe and effective and there is no research to support this stance then the health of patients is at risk.

Background:

- The MVMS received a complaint from [redacted] on 9 March 2010 **(folio 172-176).**
- [redacted] provided the National Horizon Scanning Unit Emerging Technology Bulletin which discusses new and emerging technology in breast cancer screening. **(folio 4-54)** The bulletin also names devices that are on the register that [redacted] believes are making claims that are not proven which could lead women to access these devices and not receive appropriate advice and treatment.
- The Horizon bulletin names [redacted] as the sponsor of a device on the register under ARTG entry 152697 that uses electrical impedance to detect differences in capacitance and resistance between neoplastic and surrounding normal tissue. The [electrical] ~~safety~~ diagnostic ability of the device is not questioned however, the effectiveness of the device to detect breast cancer (high number of false negatives 62 and 74%) is. **(folio 33-35)**
- The MVMS has requested under S41JA information from the sponsor **(folio 179-182)**. Information requested included labelling, instructions for use, Australian DoC and clinical evidence. This letter is dated 23 March 2010.

- The sponsor initially replied that they have a representative that would provide the information however, after 3 months of not supplying the information a proposal to cancel letter was sent, dated 28 May 2010.
- The MVMS has had a response from the sponsor to the effect that they are cancelling the device. The documentation has been sent to eBs, dated 29 April 2010. **(folio 201)**
- The TGA has the power to request under S41JA information from sponsors for products that have been included on the register during the notice period specified in the Regulations. Regulation 8.1 states that the notice period if it relates to manufacturing records and distribution records is five years. Therefore the MVMS has requested the sponsor provide the information requested in the letter dated 23 March 2010. The sponsor has not replied. **(folio 202)**
- The MVMS has also gathered information about this device from:
    - Information provided by the sponsor to include the device **(folio 154-165)**,
    - Sponsor's website **(folio 56-64 and 110-153)**
    - Manufacturer's website **(folio 65-109)**
- The information gathered from the application reveals that the sponsor supplied an EC certificate which covers one product with the serial number MEM CZ 2007 001. A Declaration of Conformity has not been provided. However, information on the sponsor's website suggests that these products are in approximately 50 clinics or beauty therapy salons around Australia.

Recommendation:

- That you approve of a review continuing and in particular a clinical evaluation being conducted on the information provided at the time of inclusion, gathered from the sponsor and manufacturer's websites and any other information that is publicly available. And;
- That, if the evaluation reveals that the device does not meet the essential principles for safety and performance further regulatory action is recommended to remove this product from use.

Branch Head's Response to recommendation:

I Agree [✓] Mallen 16/6/2010 **Do not agree to the recommendation [ ]**

Pamela Carter
Name
date 15 June 2010

Pam - has there been a response yet to TGA's advertising title at ff ?? (Susan Coates 7 June) ? Lara.