



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Minute

To: Rowena Love
Recalls and Advertising Section
Office of Product Review
Monitoring and Compliance Group

From: Pam Whalan
Medical Officer
Office of Product Review
Monitoring and Compliance Group

Re: Application for approval to use a Restricted Representation in advertising – Specsavers Pty Ltd – Ophthalmic Camera (ARTG 177741)

Background

An application for approval to use a restricted representation was received from Specsavers Pty Ltd on 12 December 2011. There has been written correspondence from the TGA (13 January 2012) and the sponsor (25 January 2012).

This application has also been considered by the Therapeutic Goods Advertising Code Council (TGACC) of 1 February 2012. Their advice is noted.

Retinal digital photography is a well recognised effective tool in the diagnosis and management of a number of eye conditions, including glaucoma, macular degeneration, and diabetic and hypertensive retinopathies¹. There have been significant advances in this field over the last decade, with the use of retinal digital imaging for eye disease becoming the gold standard² for this type of assessment.

The debate around digital screening images has been moving from the use of film-based images to the use of digital images³, and more recently to the comparison between standard digital photography and the use of portable, hand held cameras, by minimally trained assistants for digital screening photography in remote locations; this links with the potential for increased use of tele-medicine⁴.

¹ Bernardes, R (et al): Digital Ocular fundus imaging: a review; *Ophthalmologica*; 2011; 226: 161-181

² Constable, IJ (et al): Fred Hollows lecture: digital screening for eye disease; *Clinical and experimental ophthalmology*; 2000; 28; 129-132

³ Bernardes, R (et al): *ibid*

⁴ Constable, IJ (et al): *ibid*

Submission assessment: general comments

Although the intent and rationale of the statement provided by Specsavers in the *Application for approval to use a restricted representation in advertising* is acceptable, the wording for the advertisement is not acceptable.

The wording supplied by Specsavers includes the phrase:

Digital Retinal Photography is a powerful tool that helps optometrists detect serious eye diseases including glaucoma, macular degeneration and even diabetes.

The use of digital retinal photography does not assist in the detection of diabetes, but may assist in the detection and monitoring of diabetic retinopathy.

Recommendation

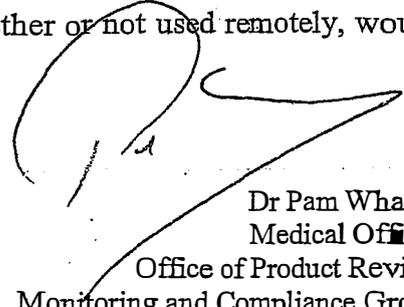
The use of this device is in the public interest to promote the detection and monitoring of those eye diseases apparent on retinal photography.

As discussed with Dr Cook (Head OPR) the wording which is acceptable for approval of this restricted representation is that digital retinal photography:

..... helps optometrists detect serious eye disease including glaucoma, macular degeneration and retinal changes that may be associated with diabetes and hypertension.



The advertising and use of hand-held digital retinal cameras, whether or not used remotely, would require further assessment and is excluded from this advice.



Dr Pam Whalan
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Office of Product Review
Monitoring and Compliance Group
(23 March 2012)

References

Bernardes, R (et al): Digital Ocular fundus imaging: a review; *Ophthalmologica*; 2011; 226: 161-181

Constable, IJ (et al): Fred Hollows lecture: digital screening for eye disease; *Clinical and experimental ophthalmology*; 2000; 28; 129-132