



Delegate to the Secretary for the
Department of Health and Ageing
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Attention: Mick O'Connor, Director, Recalls & Advertising Section

3 April 2012

Dear Sir/Madam,

Submission for approval for the use of restricted representations

At the meeting of the Therapeutic Goods Advertising Code Council held on 1 February 2012, consideration was given to application that had been received from Specsavers Pty Ltd, in which approval was sought to use "restricted representations" in consumer advertising of the for digital retinalis photography 'Specsavers Pty Ltd – Contact lens, vision corrective, tinted, single use' (ARTG Number 182315). The TGACC noted that the incorrect product had been identified by the applicant. [Note: The correct product is Ophthalmic Camera (ARTG Number 177741) sponsored by Ellex Australia Pty Ltd.]

The approval sought was for the use of proposed wording to the effect that "Digital Retinal Photography is a powerful tool that helps optometrists detect serious eye diseases including glaucoma, macular degeneration and even diabetes."

The reason given for the submission was that "the proposed representation is in line with the TGA public interest criteria, specifically as it will promote the benefit of regular eye examinations using the latest technology."

A news item from the November 2011 copy of "INSIGHT" was attached to the submission as well as a copy of the Notification of Inclusion of a Medical Device, ARTG Identifier: 182315.

In response to a letter from the Manager, Advertising Unit, TGA, seeking a further submission on the application of the public interest criteria in Appendix 6 of the Therapeutic Goods Advertising Code, each of the public interest criteria was addressed by the applicant.

The applicant noted that:

1. the three diseases to which reference is made lead to blindness if untreated and the responsible use of advances in technology to help early detection at low cost is of public benefit;
2. the references to serious diseases is unlikely to lead to consumers not seeking professional advice;
3. this is a superior and positive way for consumers to understand the need for treatment;

4. documentation of the digital images will allow for comparison and identification of deterioration of eye conditions; and
5. routine examinations would promote improved patient education.

Comments made by members in the ensuing discussion included concern that the product is misrepresented as a screening test for glaucoma, macular degeneration and diabetes when it is, in fact, not a screening test but of use only for monitoring eye health for those people that have already been diagnosed with these serious conditions. Promoting its use as a screening test for serious eye diseases and diabetes to the general population through advertising was thought to be inappropriate.

Members noted that other than addressing the public interest criteria, no supporting material or information had been provided with the submission.

Other members' comments included the view that in advertising this product it would be unnecessary to mention serious diseases or conditions and that the use of the word 'detect' is inappropriate. Further, diagnosis and treatment of these serious eye conditions should be provided by an ophthalmologist, not an optometrist.

Members agreed that they do not accept this product as a tool for detection or that references should be made in any advertising of the product to any serious diseases, conditions or disorders.

The TGACC recommends that approval to use the proposed restricted representation NOT be granted.

Yours sincerely,



Judith Brimer
Executive Officer