



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

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Minute

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Date: 3 April

To: Jodie Varnai
Devices Conformity Authorisation
Office of Devices Authorisation
MAG

From: Rowena Love
Advertising Unit
OPR

Issue: **Application to use a restricted representation in consumer advertising from Specsavers Pty Ltd for the device 'Digital Retinal Scanner' – ophthalmic camera (ARTG number 177741).**

The Advertising Unit has received an application from Specsavers to use of the following restricted representations: "serious eye diseases", "glaucoma", "macular degeneration" and "diabetes" when included in the statement "Digital Retinal Photography is a powerful tool that helps optometrists detect serious eye diseases including glaucoma, macular degenerations and even diabetes". Jane Cook is prepared to approve the representations relating to serious eye disease (glaucoma and macular degeneration) and diabetes only in the context of "retinal changes that may be associated with diabetes." Therefore the representation Jane would be approving is: "Digital Retinal Photography is a powerful tool that helps optometrists detect serious eye diseases including glaucoma, macular degeneration and retinal changes that may be associated with diabetes", in consumer advertising of the above device

I am seeking your input as to whether the approval of the restricted representation when used in the proposed statement above would be likely to be in breach of section 41FN(5) of the Act. The intended purpose for the device as set out in the ARTG is: "The DRS is intended to be used for examining the interior of the eye and for taking colour digital images of a human retina without the use of a mydriatic agent." In your view is the proposed representation (amended so it only refers to "eye diseases" not diabetes per se) consistent with the intended purpose of the device?

As the restricted representation application is due within a statutory timeframe (6 April 2012) your input is urgently required by COB 3 April 2012. If this timeframe is not achievable can you please let me know.

Thank you
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