



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

[REDACTED]
Legal Director Asia / Pacific
Specsavers Pty Ltd
520 Graham Street
PORT MELBOURNE VIC 3207

Dear [REDACTED]

**Application for Approval for the use of 'restricted representation' under section 42DE
of the *Therapeutic Goods Act 1989***

I refer to your letter dated 12 December 2011, in which you seek approval under Section 42DF(1) of the *Therapeutic Goods Act 1989* ("the Act") for Digital Retinal Photography sponsored by Specsavers Pty Ltd to be marketed to consumers with "restricted representations".

As set out in subsection 42DF(4)(c) of the *Therapeutic Goods Act 1989*, prior to making a decision, the decision maker must take into consideration the public interest criteria mentioned in the part of the *Therapeutic Goods Advertising Code* dealing with restricted representations. The public interest criteria are set out at the Attachment to this letter.

Your submissions on the application of the public interest criteria to the proposed use of the restricted representation would assist the decision maker in making a decision on this matter.

As you are aware, your application will be referred to the *Therapeutic Goods Advertising Code Council (TGACC)* for consideration at its next meeting, which is scheduled to be held on 1 February 2012. I would therefore appreciate your submission on the application of the public interest criteria before 25 January, in order to ensure that your submission can be considered by the TGACC. Should you have difficulties meeting this deadline please do not hesitate to contact me or the TGA Advertising Unit.

Yours sincerely

Marlene Keese
Manager – Advertising Unit
Recalls and Advertising Section
Office of Product Review
Telephone: (02) 6232 8398

13 January 2012

R12/12211

Attachment – Extract from Appendix 6 to the Therapeutic Goods Advertising Code

Public interest criteria to be applied by TGACC

In considering an application for approval to include in an advertisement a reference to a disease, condition, ailment or defect specified in Part 2 of **Appendix 6**, the Secretary must consult the TGACC. In making a recommendation to the Secretary, the TGACC must take into account:

1. Consumers', or certain groups of consumers', vulnerability when faced with the disease, condition, ailment or defect;
2. Whether the reference would be likely to result in consumers not seeking timely professional advice where appropriate (such as where timely professional advice is important to prevent negative health consequences or irrevocable deterioration or progression of disease);
3. Whether the reference would be likely (alone or through repetition or together with other references) to have a negative impact on public health (or to have an effect on persons other than those to whom the advertisement is directed); and
4. Such other aspects of the public interest as may appear to be appropriate.
5. The World Health Organization notes that responsible self-medication can:
 - Help prevent and treat symptoms and ailments that do not require medical consultation;
 - Reduce the increasing pressure on medical services for the relief of minor ailments, especially when financial and human resources are limited;
 - Increase the availability of health care to populations living in rural or remote areas where access to medical advice may be difficult; and
 - Enable patients to control their own chronic conditions