Australian Government

Department of Health
Therapeutic Goods Administration

Therapeutic Goods Act 1989
Approval under section 42DF for use of a restricted representation by Endotherapeutics Pty Ltd

I, Jane Cook, Head, Office of Product Review, Therapeutic Goods Administration and delegate of the Secretary to the Department of Health, on receipt of an application from Endotherapeutics Pty Ltd, have approved under section 42DF of the Therapeutic Goods Act 1989 (the Act) the restricted representation described in paragraph (a) below for use in advertisements directed to consumers, for the product identified in paragraph (b), provided the condition identified in paragraph (c) is met:

(a) "erectile dysfunction and/or ED"

(b) 'SomaTherapy Vacuum Erectile Dysfunction Device' ('External Vacuum Erection Device System – Penile rigidity device') – ARTG Number: 123413

(c) The use of the restricted representation identified in (a) is limited to consumer advertisements which contain the advisory statement: "Only to be used on the advice of your doctor." (or words to that effect).

Dated this 10 day of February 2014

Jane Cook
Delegate of the Secretary to the Department of Health;
Head
Office of Product Review

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8444 Fax: 02 6203 1605 Email: info@tga.gov.au
www.tga.gov.au