Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

SECTION 14 AND 14A NOTICE

On August 30 2012, the delegate of the Secretary of the Department of Health and Ageing for the purposes of subsection 14 and 14A of the *Therapeutic Goods Act 1989* ("the Act") gave his consent to:

(a) the supply of the product paroxetine (as hydrochloride hemihydrate) (Paroxetine-GA) 20 mg tablet blister pack [Aust R 199080] by Ascent Pharma Pty Ltd, South Melbourne, VIC ("the Company"):

That does not conform with paragraph 3(2)(c) of Therapeutic Goods Order 69, in that the name of the active ingredient is expressed differently to the approved version on the labels on the cartons.

Pursuant to subsection 15(1) of the Act, the consent given by the delegate of the Secretary as described above is subject to the following conditions:

1. The consent applies only to batches 600 and 601 of the above product and to a third batch, the batch number for which should be provided to the TGA prior to its release.

2. No other changes have been made to the product paroxetine (as hydrochloride hemihydrate) (Paroxetine-GA) 20 mg tablet blister pack [Aust R 199080].

3. The carton label to be used for the above batches is identical to that provided in correspondence from the Company dated August 14 2012. It includes the over-sticker as specified by the TGA.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8444 Fax: 02 6232 8605 Email: info@tga.gov.au
www.tga.gov.au