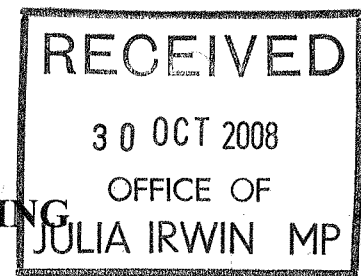
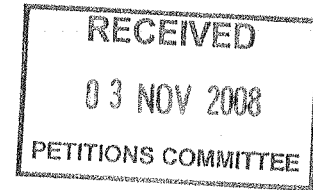




THE HON NICOLA ROXON MP
MINISTER FOR HEALTH AND AGEING



Mrs Julia Irwin MP
Chair
Standing Committee on Petitions
House of Representatives
PO Box 6021
Parliament House
CANBERRA ACT 2600



Dear Mrs Irwin

Julia

Thank you for your letter of 4 September 2008 referring the petition recently received by the Standing Committee on Petitions, regarding access to treatment with BOTOX® (botulinum toxin type A purified neurotoxin complex) through Medicare and the Pharmaceutical Benefits Scheme (PBS).

I am sympathetic to the circumstances faced by people with hyperhidrosis.

Over 3,000 medicines are currently subsidised by the Australian Government through the PBS. Medicines are listed on the PBS on the advice of an independent, expert advisory body known as the Pharmaceutical Benefits Advisory Committee (PBAC) which is made up of doctors, other health professionals and a consumer representative. The PBAC considers applications from companies for PBS listing having regard to the medicine's clinical effectiveness and cost-effectiveness (value-for-money) compared with other available treatments. Companies cannot be compelled to apply for PBS listing.

The Therapeutic Goods Administration (TGA) evaluates submitted data to establish the quality, safety and effectiveness of pharmaceuticals when used as intended. BOTOX has been registered for a number of medical uses by the TGA.

BOTOX is presently PBS-listed through the Botulinum Toxin Program for the following uses:

- treatment of blepharospasm (involuntary contraction of the eyelid muscles) associated with dystonia (a movement disorder), including benign blepharospasm and VIIth nerve disorders (hemifacial spasm) in patients 12 years of age and older;
- treatment of dynamic equinus foot deformity due to spasticity in ambulant paediatric cerebral palsy patients two years of age or older; and
- treatment of spasmodic torticollis (wry neck), either as monotherapy or as adjunctive therapy to current standard care.

The TGA has also registered BOTOX for the treatment of severe primary hyperhidrosis of the axillae (excessive sweatiness of the armpits). However, the PBAC has not yet considered a submission for the listing of BOTOX for this condition, and therefore is not able to recommend that the medicine be listed for this use.

Signatories to the petition may wish to contact the manufacturer of this product, Allergan Australia Pty Ltd, to establish its intentions in respect of seeking an extension of the current PBS listings of BOTOX to include the treatment of individuals with severe primary hyperhidrosis of the armpits. The contact details are as follows:

Allergan Australia Pty Ltd
77 Ridge Street
GORDON NSW 2072

Telephone: 1800 252 224 (free call)
Facsimile: (02) 9498 0290

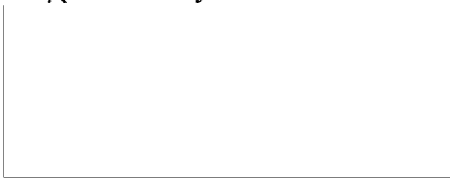
Private prescriptions can be very costly for some patients and I understand that this is a real concern. I must advise, however, that the PBS cannot provide subsidies for medicines which are not listed in the *Schedule of Pharmaceutical Benefits* or when the conditions for which a medicine is subsidised through the PBS are different to the patient's condition. Exceptions cannot be made on an individual basis.

I am pleased to confirm that the Medicare Benefits Schedule (MBS) currently provides for the treatment of severe primary hyperhidrosis of the axillae through the surgical excision of axillary sweat glands or sympathectomy (removal or blockage of the nerve trunk), and injection of BOTOX. The MBS item numbers involved are 30180 and 30183 (for surgical excision), 35003 and 35006 (for sympathectomy) and 18362 (for injection).

People suffering from hyperhidrosis may be interested to know that the Government offers a 20% tax rebate on some out-of-pocket medical expenses above \$1,500 in a financial year. More information on this medical expenses tax offset can be obtained by contacting the Australian Taxation Office's Personal Tax Enquiries Line on 13 28 61 or from its website at www.ato.gov.au

I trust that the above information is of use.

Yours sincerely



NICOLA ROXON

24 OCT 2008