Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

## *THERAPEUTIC GOODS ACT 1989*

## SECTION 14 AND 14A NOTICE

On August 14 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 mannitol (Bronchitol) 40 mg powder for inhalation hard capsule [Aust R 168002] by Pharmaxis Ltd, Frenchs Forest NSW ("the Company"):

That does not conform with paragraph 3(2)(i) of the Therapeutic Goods Order 69, in that the expiry date stamped on the product labels is 25 months from the date of manufacture instead of the approved 24 months.

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 for batch number 12111BAU only.

2. No other changes have been made to the product mannitol (Bronchitol) 40 mg powder for inhalation hard capsule [Aust R 168002].

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