

27 November 2008

Proposal to list solifenacin (Vesicare) and mesalazine (Asamax) in the Pharmaceutical Schedule and to remove restrictions on mesalazine

PHARMAC and CSL Biotherapies have entered into a provisional agreement relating to the listing of solifenacin (Vesicare) and mesalazine (Asamax) in the Pharmaceutical Schedule from 1 March 2009. In summary, the proposal is that:

- solifenacin (Vesicare) would be fully funded under Special Authority restriction as a second-line treatment of overactive bladder; and
- the Asamax brand of mesalazine 500 mg long acting tablet would be listed, and the Asacol and Pentasa brands would be referenced price to this. These brands may incur a surcharge if the current suppliers decide not to reduce their price to the level of the reference price.
- mesalazine (tablets and enemas) would no longer be subject to a “Retail pharmacy-Specialist” restriction, meaning that prescriptions written by other types of practitioners would no longer require a specialist endorsement for subsidy.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by 4 pm on **Friday 19 December** 2008 to:

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 PHARMAC

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All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision on this proposal.

Details of the proposal

Solifenacin

- Solifenacin (Vesicare) would be listed in Section B of the Pharmaceutical Schedule at the following prices and subsidies (ex-manufacturer, excluding GST) from 1 March 2009:

Chemical	Formulation	Brand	Pack size	Price and subsidy
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Solifenacin	Tab 5 mg	Vesicare	30	\$59.95
Solifenacin	Tab 10 mg	Vesicare	30	\$78.00

- Solifenacin (Vesicare) would be subject to the following Special Authority restriction:

Special Authority for Subsidy

Initial application from any relevant practitioner. Applications valid without further renewal unless notified where the patient has overactive bladder and a documented intolerance of oxybutynin.

- Solifenacin (Vesicare) would be subject to a rebate arrangement, and would be protected from delisting and subsidy reduction until 1 March 2012.

Mesalazine

- A new brand of mesalazine (Asamax) would be listed in Section B of the Pharmaceutical Schedule at the following price and subsidy from 1 March 2009:

Chemical	Formulation	Brand	Pack size	Price and subsidy
Mesalazine	Tab long-acting 500 mg	Asamax	100	\$39.75

- Asamax would be protected from delisting until 1 March 2012.
- The currently subsidised brand of mesalazine 500 mg long-acting tablets (Pentasa) would be reference priced to Asamax from 1 March 2009 as follows:

Chemical	Formulation	Brand	Pack size	Current price and subsidy	Proposed subsidy
Mesalazine	Tab long-acting 500 mg	Pentasa	100	\$69.06	\$39.75

- The currently subsidised brand of mesalazine 400 mg tablets (Asacol) would be reference priced to Asamax on the basis of the average daily cost, from 1 March 2009 as follows:

Chemical	Formulation	Brand	Pack size	Current price and subsidy	Proposed subsidy
Mesalazine	Tab 400 mg	Asacol	100	\$49.50	\$38.77

- The "Retail pharmacy-Specialist" restriction on mesalazine 400 mg tablets, mesalazine 500 mg long-acting tablets and mesalazine 1 g per 100 ml enemas in Section B of the Pharmaceutical Schedule would be removed from 1 December 2008.

Background

In relation to solifenacin

The Pharmacology and Therapeutics Advisory Committee (PTAC) has recommended funding solifenacin for patients with a documented intolerance of oxybutynin, noting that there are no alternative agents listed in the Pharmaceutical Schedule for these patients.

In relation to mesalazine

PTAC has previously considered that mesalazine 400 mg tablets (Asacol) and mesalazine 500 mg long-acting tablets (Pentasa) have the same, or similar therapeutic effect in inflammatory bowel disease and Crohn's disease. As a result these two brands have previously been referenced priced based on an average daily cost (ADC).

PTAC has also considered the Specialist restriction requirement for mesalazine preparations and recommended that they be removed.