

31 May 2006

To All Pharmaceutical Suppliers, Hospital Pharmacists, Medical Groups and Interested Parties

Further consultation on proposed changes to subsidised asthma products

Further to our letter of 24 May 2006 regarding proposed changes to subsidised asthma products, PHARMAC is seeking feedback on additional proposed changes, arising out of an agreement with AstraZeneca relating to Symbicort and Oxis. Please note that all proposed changes are now included in this letter. The key changes proposed are:

- listing a range of inhalers containing fluticasone and salmeterol, supplied by GlaxoSmithKline under the brand names Seretide and Seretide Accuhaler;
- widening access to salmeterol 50 µg per dose (Serevent Accuhaler), eformoterol 6 µg per dose (Oxis) and eformoterol 12 µg per dose (Foradil);
- listing a CFC-free version of the salmeterol 25 µg per dose aerosol inhaler (Serevent), and delisting the CFC-containing version;
- increasing the subsidy for some presentations of fluticasone (Flixotide Accuhaler);
- listing a new presentation of budesonide with eformoterol (Symbicort Turbuhaler), with a possible future listing of an aerosol inhaler formulation (Symbicort Rapihaler); and
- modifying the Special Authority criteria that relate to combination inhaled corticosteroid and long-acting beta-adrenoceptor agonist devices (Symbicort Turbuhaler, Seretide and Seretide Accuhaler).

PHARMAC has entered into a provisional agreement with GlaxoSmithKline regarding the listing of salmeterol (Serevent and Serevent Accuhaler) and fluticasone with salmeterol (Seretide and Seretide Accuhaler), and into a provisional agreement with AstraZeneca regarding the listing of eformoterol (Oxis) and budesonide with eformoterol (Symbicort Turbuhaler, Symbicort Rapihaler). In addition, we are proposing changes that affect other related asthma products.

There are a number of specific proposals on which we are seeking comment, and these are outlined in the appendix to this letter. We anticipate that a recommendation will be made to PHARMAC's Board in June 2006. PHARMAC welcomes your comments on these proposals. All comments submitted to PHARMAC by **5 pm on Friday, 16 June 2006** will be considered by the Board.

Yours sincerely,



Sean Dougherty
Therapeutic Group Manager

Appendix: Details of proposed changes to the Pharmaceutical Schedule

1. Salmeterol (Serevent, Serevent Accuhaler)

- PHARMAC would list salmeterol aerosol inhaler, 25 µg per dose CFC-free (Serevent) in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 April 2007 at a price and subsidy of \$26.46 per 120 doses.
- PHARMAC would de-list the CFC-containing salmeterol 25 µg aerosol inhaler (Serevent) from Section B of the Pharmaceutical Schedule from 1 October 2007.
- The price and subsidy for salmeterol 50 µg per dose, powder for inhalation (Serevent Accuhaler) would be reduced to \$26.46 from 1 August 2006.
- Salmeterol 50 µg (Serevent Accuhaler) would no longer require Special Authority approval for subsidy, and listing in Section B of the Pharmaceutical Schedule would be subject to the Prescribing Guideline that currently applies to salmeterol (Serevent) aerosol inhaler.
- Serevent aerosol inhaler would be protected from delisting and reference pricing until 1 November 2008. Serevent Accuhaler would be protected from delisting and reference pricing until 1 August 2009.

2. Fluticasone with salmeterol (Seretide, Seretide Accuhaler)

- PHARMAC would list fluticasone with salmeterol (Seretide, Seretide Accuhaler) in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 August 2006 at the following prices and subsidies:

Chemical	Presentation	Brand	Strength	Pack size	Price / subsidy
Fluticasone with salmeterol	Aerosol inhaler	Seretide	50 µg fluticasone with 25 µg salmeterol	120 dose OP	\$37.48
Fluticasone with salmeterol	Aerosol inhaler	Seretide	125 µg fluticasone with 25 µg salmeterol	120 dose OP	\$49.69
Fluticasone with salmeterol	Powder for inhalation, breath activated	Seretide Accuhaler	100 µg fluticasone with 50 µg salmeterol	60 dose OP	\$37.48
Fluticasone with salmeterol	Powder for inhalation, breath activated	Seretide Accuhaler	250 µg fluticasone with 50 µg salmeterol	60 dose OP	\$49.69

- A confidential rebate would apply to reduce the effective cost of Seretide and Seretide Accuhaler to the combined price set by fluticasone and salmeterol as individual inhalers.
- Seretide would be protected from delisting and reference pricing until 1 August 2009.

3. Fluticasone (Flixotide Accuhaler)

- PHARMAC would increase the subsidy applying to the following strengths of fluticasone (Flixotide Accuhaler) from 1 August 2006:

Chemical	Presentation	Strength	Pack size	Price	Current subsidy	Proposed subsidy
Fluticasone	Powder for inhalation, breath activated	100 µg per dose	60 dose OP	\$13.87	\$5.70	\$7.50
Fluticasone	Powder for inhalation, breath activated	250 µg per dose	60 dose OP	\$24.51	\$12.00	\$13.60

4. Eformoterol fumarate (Foradil, Oxis Turbuhaler)

- Eformoterol fumarate 12 µg (Foradil) would no longer require Special Authority approval for subsidy, and eformoterol 6 µg (Oxis Turbuhaler) would no longer be subject to the current endorsement criteria. Both presentations of eformoterol fumarate would be subject to the Prescribing Guideline that currently applies to salmeterol (Serevent) aerosol inhaler.
- The price and subsidy of Oxis Turbuhaler would decrease to \$16.90 from 1 August 2006.
- Oxis Turbuhaler would be subject to a confidential rebate arrangement between PHARMAC and AstraZeneca. This rebate arrangement would be replaced by a further price reduction prior to expiry of the agreement with AstraZeneca.
- Oxis Turbuhaler would be protected from delisting and subsidy reduction until 1 August 2011.

5. Budesonide with eformoterol (Symbicort Turbuhaler)

- The prices and subsidies for Symbicort Turbuhaler would decrease from 1 August 2006 as follows

Chemical	Presentation	Brand	Strength	Pack size	Current price / subsidy	Proposed price / subsidy
Budesonide with eformoterol	Powder for inhalation, breath activated	Symbicort Turbuhaler	100 µg budesonide with 6 µg eformoterol	120 dose OP	\$74.10	\$55.00
Budesonide with eformoterol	Powder for inhalation, breath activated	Symbicort Turbuhaler	200 µg budesonide with 6 µg eformoterol	120 dose OP	\$90.80	\$60.00

- A new presentation of Symbicort Turbuhaler would be listed with effect from 1 August 2006:

Chemical	Presentation	Brand	Strength	Pack size	Price / subsidy
Budesonide with eformoterol	Powder for inhalation, breath activated	Symbicort Turbuhaler	400 µg budesonide with 12 µg eformoterol	60 dose OP	\$60.00

- Symbicort Turbuhaler would be subject to a confidential rebate arrangement between PHARMAC and AstraZeneca. This rebate arrangement would be replaced by a price reduction prior to expiry of the agreement with AstraZeneca.
- Symbicort Turbuhaler would be protected from delisting and subsidy reduction until 1 August 2011.

6. Budesonide with eformoterol (Symbicort Rapihaler)

- A new presentation of budesonide with eformoterol may be listed in Section B of the Pharmaceutical Schedule, subject to gaining all necessary regulatory consents, at the following prices and subsidies:

Chemical	Presentation	Brand	Strength	Pack size	Price / subsidy
Budesonide with eformoterol	Aerosol inhaler	Symbicort Rapihaler	100 µg budesonide with 6 µg eformoterol	120 dose OP	\$55.00
Budesonide with eformoterol	Aerosol inhaler	Symbicort Rapihaler	100 µg budesonide with 6 µg eformoterol	120 dose OP	\$60.00

- Symbicort Rapihaler would be subject to a confidential rebate arrangement between PHARMAC and AstraZeneca. This rebate arrangement would be replaced by a price reduction prior to expiry of the agreement with AstraZeneca.
- Symbicort Rapihaler would be protected from delisting and subsidy reduction until 1 August 2011.

7. Special Authority criteria for ICS/LABA combination inhalers

- All presentations of budesonide with eformoterol (Symbicort Turbuhaler, Symbicort Rapihaler) and fluticasone with salmeterol (Seretide, Seretide Accuhaler) would, from 1 August 2006, be subject to the following Special Authority restriction:

Initial Application only from a relevant specialist or General Practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

1 All of the following:

1.1 Patient is a child under the age of 12; and

1.2 All of the following:

Has, for 6 months or more, been treated with:

1.2.1 An inhaled long-acting beta adrenoceptor agonist; and

1.2.2 Inhaled corticosteroids at a dose of at least 400 mcg per day beclomethasone or budesonide, or 200 mcg per day fluticasone; and

1.3 The prescriber considers that the patient would receive additional clinical benefit from switching to a combination product; or

2 All of the following:

2.1 Patient is over the age of 12; and

2.2 All of the following:

Has, for 6 months or more, been treated with:

2.2.1 An inhaled long-acting beta adrenoceptor agonist; and

2.2.2 Inhaled corticosteroids at a dose of at least 800 mcg per day beclomethasone or budesonide, or 500 mcg per day fluticasone; and

- 2.3 The prescriber considers that the patient would receive additional clinical benefit from switching to a combination product.

Renewal only from a relevant specialist or General Practitioner. Approvals valid for 2 years for applications meeting the following criteria:

- 3 The treatment remains appropriate and the patient is benefiting from treatment.
- Existing Special Authority approvals for budesonide with eformoterol (Symbicort Turbuhaler) would continue to be valid, and would be interchangeable between all presentations of budesonide with eformoterol and fluticasone with salmeterol.