

24 May 2006

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

### **Consultation on proposed changes to subsidised asthma products**

PHARMAC is seeking feedback on proposed changes to subsidised asthma products with effect from 1 August 2006. 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 under new Special Authority criteria;
- widening access to salmeterol 50 µg per dose (Serevent Accuhaler) 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; and
- increasing the subsidy for some presentations of fluticasone (Flixotide 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). In addition, we are proposing changes that affect a range of other 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.

PHARMAC is also likely to begin consultation on changes to other related asthma products over the next week; this additional proposal will be consulted on as soon as details are confirmed.

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)

- Eformoterol fumarate 12 µg (Foradil) 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.

### 5. Special Authority criteria for Seretide and Seretide Accuhaler

- 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:

- All of the following:
  - Patient is a child under the age of 12; and
  - All of the following:
    - Has, for 6 months or more, been treated with:
      - An inhaled long-acting beta adrenoceptor agonist; and
      - Inhaled corticosteroids at a dose of at least 400 mcg per day beclomethasone or budesonide, or 200 mcg per day fluticasone; and
    - The prescriber considers that the patient would receive additional clinical benefit from switching to a combination product; or
- All of the following:
  - Patient is over the age of 12; and
  - All of the following:
    - Has, for 6 months or more, been treated with:
      - An inhaled long-acting beta adrenoceptor agonist; and
      - Inhaled corticosteroids at a dose of at least 800 mcg per day beclomethasone or budesonide, or 500 mcg per day fluticasone; and
    - 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:

- The treatment remains appropriate and the patient is benefiting from treatment.
- Patients with current Special Authority approvals for budesonide with eformoterol (Symbicort Turbuhaler) would be eligible for subsidy for fluticasone with salmeterol (Seretide, Seretide Accuhaler).