

30 August 2011

## Proposal on subsidy changes for some respiratory inhalation products and access restrictions to combination inhalers.

As notified on 16 June 2011, PHARMAC has been considering options for managing the funding of the inhaled corticosteroids (ICS) and long-acting beta-adrenoceptor agonists (LABA) and their combination products.

PHARMAC is now seeking feedback on the following proposals which would take effect on 1 February 2012:

1. Removal of the requirement for patients to be on separate ICS and LABA inhalers for at least three months prior to being eligible for funded combination inhalers.
2. Full funding of fluticasone powder for inhalation (Flixotide Accuhaler).
3. Reducing the subsidies (through parity pricing) payable for:
  - a. budesonide with eformoterol ICS and LABA combination inhalers to the level of subsidy for the individual fluticasone ICS and salmeterol LABA inhalers; and
  - b. eformoterol fumarate LABA inhalers to the level of subsidy for the salmeterol LABA inhalers.

The reduction in subsidy would result in manufacturer's surcharges for Symbicort Turbuhaler, Vannair, Oxis Turbuhaler and Foradil should the suppliers not reduce their prices to match the subsidies. Alternative fully funded products would include fluticasone with salmeterol (Seretide, Seretide Accuhaler) and salmeterol (Serevent and Serevent Accuhaler).

To assist in the implementation of these changes Symbicort Turbuhaler and Oxis Turbuhaler will remain fully funded for existing patients (patients dispensed Symbicort Turbuhaler or Oxis Turbuhaler prior to 1 July 2011) until 1 February 2012. Repeat dispensings for prescriptions with a first dispensing before 1 February 2012 will also be fully funded. This will give clinicians and patients time to effect a change to fully funded pharmaceuticals in the event that the suppliers do not reduce their prices and patients wish to receive a fully funded product.

Further details of the proposal can be found below.

### Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Friday, 15 September 2011** to:

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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

### ***In relation to the removal of the requirement that individual inhalers are used for three months prior to the funding of combination inhalers***

It is proposed that from 1 February 2012 the Special Authority for the inhaled corticosteroids with long-acting beta-adrenoceptor agonists combination inhalers (SA0958) will be amended as follows (changes in bold and strike-through):

Initial Application from any relevant 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 Both:~~

~~Has, for 3 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~~

**1.2 Has been treated with inhaled corticosteroids 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 Both:~~

~~Has, for 3 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~~

**2.2 Has been treated with inhaled corticosteroids 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 practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

### ***In relation to fully funding fluticasone powder for inhalation***

PHARMAC has entered into a provisional agreement with GlaxoSmithKline to:

- reduce the price of fluticasone 100 µg and 250 µg (Flixotide Accuhaler) in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 February 2012 as follows (prices are ex-manufacturer, exclusive of GST):

Pharmaceutical	Brand	Presentation	Pack size	Current subsidy and price	Proposed price and subsidy
Fluticasone 100 µg	Flixotide Accuhaler	Powder for inhalation, breath activated 100 µg	60 dose OP	\$7.50 (\$13.87)	\$7.50
Fluticasone 250 µg	Flixotide Accuhaler	Powder for inhalation, breath activated 250 µg	60 dose OP	\$13.60 (\$24.51)	\$13.60

- increase the subsidy of fluticasone 50 µg (Flixotide Accuhaler), so that it is fully funded in Section B of the Pharmaceutical Schedule from 1 February 2012 as follows (prices are ex-manufacturer, exclusive of GST):

Pharmaceutical	Brand	Presentation	Pack size	Current subsidy and price	Proposed price and subsidy
Fluticasone 50 µg	Flixotide Accuhaler	Powder for inhalation, breath activated 50 µg	60 dose OP	\$5.10 (\$7.50)	\$7.50

- note that the provisional agreement with GlaxoSmithKline includes additional confidential rebates for Seretide and Seretide Accuhaler.

***In relation to the reduction in subsidy for Symbicort Turbuhaler, Vannair, Oxis Turbuhaler and Foradil.***

It is proposed that, effective from 1 February 2012 and 1 July 2012, the subsidies of budesonide with eformoterol (Symbicort Turbuhaler and Vannair) and eformoterol fumarate (Oxis Turbuhaler and Foradil) are reduced to the level of the subsidies for fluticasone and salmeterol. If the suppliers do not reduce the prices of their products to match the new subsidies, a manufacturer's surcharge would apply. (Note: all prices are current ex-manufacturer prices exclusive of GST. A mark-up, including GST, would apply to any manufacturer's surcharge.)

Pharmaceutical	Brand	Presentation	Pack size	Proposed Subsidies (Current prices)	
				From 1 Feb 2012	From 1 July 2012
Budesonide 100 µg with eformoterol 6 µg	Symbicort Turbuhaler 100/6	Powder for inhalation	120 dose OP	\$29.54 (\$55.00)	\$26.49 (\$55.00)
Budesonide 200 µg with eformoterol 6 µg	Symbicort Turbuhaler 200/6	Powder for inhalation	120 dose OP	\$34.85 (\$60.00)	\$31.25 (\$60.00)
Budesonide 400 µg with eformoterol 12 µg	Symbicort Turbuhaler 400/12	Powder for inhalation	60 dose OP	\$34.85 (\$60.00)	\$31.25 (\$60.00)
Budesonide 100 µg with eformoterol 6 µg	Vannair	Aerosol inhaler	120 dose OP	\$29.52 (\$33.96)	\$26.49 (\$33.96)
Budesonide 200 µg with eformoterol 6 µg	Vannair	Aerosol inhaler	120 dose OP	\$34.85 (\$40.06)	\$31.25 (\$40.06)
Eformoterol fumarate 6 µg	Oxis Turbuhaler	Powder for inhalation	60 dose OP	\$11.51 (\$16.90)	\$10.32 (\$16.90)
Eformoterol fumarate 12 µg	Foradil	Powder for Inhalation	60 dose	\$23.02 (\$35.80)	\$20.64 (\$35.80)

This proposal would result in the following products being fully funded:

**Inhaled Corticosteroids**

Beclomethasone dipropionate aerosol inhalers (Beclazone)  
Budesonide powder for inhalation (Budenocort and Pulmicort Turbuhaler)  
Fluticasone aerosol inhaler (Flixotide) and  
Fluticasone powder for inhalation (Flixotide Accuhaler)

**Long-acting Beta-adrenoceptor Agents**

Salmeterol aerosol inhaler (Serevent) and  
Salmeterol powder for inhalation (Serevent Accuhaler).

**Combination Inhaled Corticosteroid with Long-acting Beta-adrenoceptor Agents**

Fluticasone with salmeterol aerosol inhalers (Seretide) and  
Fluticasone with salmeterol powder for inhalation (Seretide Accuhaler).

We propose to extend the current additional subsidy for existing patients (patients who had been dispensed Symbicort Turbuhaler or Oxis Turbuhaler prior to 1 July 2011) to 1 February 2012. In the event that the suppliers do not reduce the prices of Symbicort Turbuhaler, Vannair, Oxis Turbuhaler and/or Foradil, PHARMAC will fully fund repeat prescriptions where a first dispensing has been before 1 February 2012 - this will assist in the transition to fully funded products by allowing patients time to obtain a new prescription should they wish to have a fully funded product.

**Background**

**Removal of three month requirement from the Special Authority applicable to combination inhalers.**

In 2010 the US Food and Drug Administration issued new safety requirements for long-acting beta-adrenoceptor agonists (LABAs) in the treatment of asthma. The FDA recommended that LABAs should only be used in combination with an asthma controller medication and only for the shortest duration of time required to achieve control of asthma symptoms. The FDA recommended that LABAs should only be used long-term in patients whose asthma cannot be controlled on an asthma controller and that paediatric and adolescent patients should use a combination product if the addition of a LABA is required.

The current Special Authority for combination inhalers requires the concomitant prescribing of an ICS inhaler with a LABA inhaler. As a result some concern has been raised that patients may not comply with prescribing guidelines and may use LABA monotherapy, rather than using both of the individual LABA and ICS inhalers.

An application for the removal of the three month trial period was received from GlaxoSmithKline NZ Limited in August 2010 and was reviewed by the Pharmacology and Therapeutic Advisory Committee (PTAC) at its November 2010 meeting. The full minute from this meeting can be found on the PHARMAC website [www.pharmac.govt.nz/healthpros/PTAC/PTACminutes](http://www.pharmac.govt.nz/healthpros/PTAC/PTACminutes). The relevant excerpt of the minute is as follows:

The Committee noted that Professor Beasley's group (Beasley et al, Lancet 2010; 376:750-1) had called for the withdrawal of LABA monotherapy use in asthma, and that the British Asthma Guidelines stress the importance of taking a LABA with an inhaled corticosteroid.

The Committee noted that it had last considered the issue of combination inhalers in 2007, and that since then there have been significant developments in quantifying the risks with using sole LABA devices alone in asthma, particularly in younger patients.

The Committee noted issues with non-compliance and sub-optimal ICS use. Consequently, members noted that it is becoming increasingly harder to justify a period of separate LABA and ICS prescriptions to asthma patients who, by guideline recommendations, merit combination LABA and ICS treatment.

The Committee **recommended** the removal of the three month trial period from the Special Authority pertaining to prescriptions for combination inhaled corticosteroids with Long-acting Beta-Adrenoceptor Agents with a medium priority.

### **Full funding of fluticasone powder for inhalation (Flixotide Accuhaler)**

Flixotide Accuhaler is currently listed in Section B and Part II of Section H of the Pharmaceutical Schedule under an agreement between PHARMAC and GlaxoSmithKline dated 28 April 2009.

This proposal amends the current agreement with GlaxoSmithKline and would result in Flixotide Accuhaler becoming fully subsidised. Additional confidential rebates for Seretide and Seretide Accuhaler would apply.

### **Changes to the subsidy for Symbicort Turbuhaler, Vannair, Oxis Turbuhaler, and Foradil**

On 16 June 2011, PHARMAC notified that under a 2006 Agreement prices at which Symbicort Turbuhaler, Oxis Turbuhaler and Vannair are supplied were to be reduced from 12 June 2011 and subsidies would be reduced in accordance with decisions taken in 2006. As notified on 16 June 2011, AstraZeneca met its contractual obligation in relation to Vannair but not Symbicort Turbuhaler or Oxis Turbuhaler.

At that time, PHARMAC provided an additional subsidy for patients who had been dispensed Symbicort Turbuhaler or Oxis Turbuhaler prior to 1 July 2011 (current patients) while the available options were reviewed. A part-charge currently applies to all patients who were first dispensed Symbicort Turbuhaler or Oxis Turbuhaler on or after 1 July 2011.

Parity pricing budesonide with eformoterol (Symbicort Turbuhaler and Vannair) and eformoterol fumarate (Oxis Turbuhaler and Foradil) to fluticasone (Flixotide) and salmeterol (Serevent) would result in significant savings to the Pharmaceutical Budget.