

**5.06 FLUTICASONE PROPIONATE WITH SALMETEROL,
Powder for oral inhalation in breath actuated device
containing fluticasone propionate 250 micrograms
with salmeterol 50 micrograms (as xinafoate) per
dose, 60 doses,
Powder for oral inhalation in breath actuated device
containing fluticasone propionate 500 micrograms
with salmeterol 50 micrograms (as xinafoate) per
dose, 60 doses,
Salflumix[®] Easyhaler[®],
Orion Pharma (Aus) Pty Limited**

1 Purpose of Submission

1.1 The Category 4 submission requested General Schedule Authority Required (STREAMLINED) Pharmaceutical Benefits Scheme (PBS) listings for fluticasone propionate with salmeterol, under the same circumstances as the PBS listings for Seretide[®] Accuhaler[®] 250/50 and 500/50 and 'a'-flagged generic brands, for the following forms:

- powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses (herein referred to as Salflumix[®] Easyhaler[®] 250/50), for the treatment of asthma.
- powder for oral inhalation in breath actuated device containing fluticasone propionate 500 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses (herein referred to as Salflumix Easyhaler 500/50), for the treatment of asthma and chronic obstructive pulmonary disease (COPD).

2 Background

2.1 Seretide Accuhaler 250/50 and 500/50 are currently listed on the PBS as Authority Required (STREAMLINED) listings for asthma (both strengths) and COPD (500/50 strength only).

2.2 In addition to Seretide Accuhaler, the following generic brands are also included under the same PBS-listings and are marked as equivalent for the purposes of substitution ('a'-flagged):

- Fluticasone Salmeterol Ciphaler
- Pavtide® Accuhaler.

Registration status

2.3 Salflumix Easyhaler was Therapeutic Goods Administration (TGA) registered on 28 October 2022 for:

- the regular treatment of asthma, where the use of a combination product is appropriate. This may include:
 - patients on effective maintenance doses of long-acting beta-2 agonists and inhaled corticosteroids
 - patients who are symptomatic on current inhaled corticosteroid therapy.
- the symptomatic treatment of patients with severe COPD (forced expiratory volume in 1 second (FEV1) <50% predicted normal) and a history of repeated exacerbations who have significant symptoms despite regular beta-2 agonist bronchodilator therapy.

Salflumix Easyhaler is not indicated for the initiation of bronchodilator therapy in COPD.

2.4 Seretide Accuhaler, Fluticasone Salmeterol Ciphaler and Pavtide Accuhaler are registered for these same indications.

2.5 The submission noted that Seretide Accuhaler and Pavtide Accuhaler are also TGA registered for the following indication:

- the regular treatment of asthma, where the use of a combination product is appropriate. This may include initiation of maintenance therapy in those patients with moderate persistent asthma not adequately controlled on ‘as needed’ reliever medication, and who have moderate/severe airway limitation and daily symptoms requiring reliever medication every day.

The submission stated that Salflumix Easyhaler, in addition to Fluticasone Salmeterol Ciphaler, are not TGA-registered for this indication due to these brands not having the 100/50 dose form, which is the recommended dose for initiation of maintenance therapy. The PBAC noted that the requested listings for Salflumix Easyhaler did not include initiation of treatment in asthma.

2.6 The submission further stated that Seretide Accuhaler and Pavtide Accuhaler are TGA-registered for use in children ≥4 years of age and adults, while Salflumix Easyhaler (and Fluticasone Salmeterol Ciphaler) are only TGA-registered for use in children ≥12 years of age and adults. The submission stated this was due to Seretide Accuhaler and Pavtide Accuhaler being the only brands with the 100/50 dose form, which is the

recommended dose for children ≥ 4 years of age. The recommended dose for children ≥ 12 years of age and adults is 100/50 to 500/50 twice daily for all brands.

- 2.7 The submission noted the Salflumix Easyhaler Product Information states ‘For dosages which cannot be achieved with Salflumix Easyhaler (i.e. 100 micrograms fluticasone propionate and 50 micrograms salmeterol) other fixed-dose combination products containing these two active ingredients are available.’ The submission claimed this supported quality use of medicines, and prescribers are directed to switch brands for patients who would benefit from a lower strength than what is available in the Salflumix Easyhaler products.

Previous PBAC consideration

- 2.8 Salflumix Easyhaler 250/50 and 500/50 have not been considered by the PBAC previously.

3 Requested listing

- 3.1 The submission requested Salflumix Easyhaler 250/50 be listed under the same circumstances as Seretide Accuhaler 250/50 and generic brands for asthma in patients aged 4 years or older, and that Salflumix Easyhaler 500/50 be listed under the same circumstances as Seretide Accuhaler 500/50 and generic brands for asthma in patients aged 4 years or older and COPD.
- 3.2 The submission requested Salflumix Easyhaler 250/50 and 500/50 be marked as equivalent in the Schedule of Pharmaceutical Benefits for the purposes of substitution (‘a’-flagged) to the currently PBS-listed Seretide Accuhaler, Fluticasone Salmeterol Ciphalel and Pavtide Accuhaler in the 250/50 and 500/50 strengths respectively.
- 3.3 The current listings of fluticasone propionate with salmeterol 250/50 and 500/50 for asthma have the population criteria ‘Patient must be aged 4 years or older’. At its July 2014 meeting, the PBAC recommended the restriction for PBS listings for Seretide for asthma include a population criteria stating patients must be aged 4 years or over. The PBAC was concerned about the small number of very young children < 4 years prescribed fixed dose combination inhaled corticosteroid (ICS)/long-acting beta₂-agonist (LABA) products, where there was no evidence available regarding safety and efficacy. The PBAC also noted inconsistencies in the age recommendations provided in the Product Information and Australian asthma guidelines (i.e. National Asthma Council Australian Asthma Handbook (Asthma Handbook)). For some strengths of Seretide, the age restriction in the Product Information was older than the age recommendation in the Asthma Handbook (i.e. for Seretide 250/50 and 500/50 the Product Information restricted use to patients ≥ 12 years, compared to ≥ 6 years in the Asthma Handbook). In contrast, the Asthma Handbook recommended Seretide 100/50 in patients ≥ 6 years, compared to ≥ 4 years in the Product Information (Post-market review of PBS medicines used to treat asthma in children Minutes, July 2014 PBAC meeting).

- 3.4 The current Asthma Handbook recommends a low-dose ICS/LABA combination may be used in some children aged 6-11 years and considers fluticasone propionate 100-200 micrograms daily to be low dose, and >200 micrograms daily to be high dose. The Asthma Handbook does not recommend ICS/LABA combination treatment in the management of asthma in patients aged 1-5 years (see Table 1).

Table 1: Fluticasone propionate + salmeterol current PBS listings and recommended age groups

PBS Listed Brands (and proposed PBS listed brand)	Product Information recommended ages	National Asthma Council Australian Asthma Handbook recommended ages
Fluticasone propionate 100 microgram/actuation + salmeterol 50 microgram/actuation Current PBS Population Criteria: Patient must be aged 4 years or older		
Seretide Accuhaler 100/50 Pavtide Accuhaler 100/50	≥4 years	ICS/LABA combination treatment not recommended for the management of asthma in patients aged 1-5 years. Low-dose ICS/LABA combination may be used in some children aged 6-11 years (for children fluticasone propionate 100-200 micrograms daily considered to be low dose)
Fluticasone propionate 250 microgram with salmeterol 50 microgram Current PBS Population Criteria: Patient must be aged 4 years or older		
Salfumix Easyhaler 250/50 Fluticasone Salmeterol Ciphaler 250/50 Pavtide Accuhaler 250/50 Seretide Accuhaler 250/50	≥12 years	For adults, fluticasone propionate 100-200 micrograms daily considered to be low dose, 250-500 micrograms daily considered to be medium dose, >500 micrograms daily considered to be high dose. Low-dose ICS/LABA combination may be used in some adolescents* and adults, few patients may require medium to high-dose ICS/LABA combination
Fluticasone propionate 500 microgram with salmeterol 50 microgram Current PBS Population Criteria: Patient must be aged 4 years or older		
Salfumix Easyhaler 500/50 Fluticasone Salmeterol Ciphaler 500/50 Pavtide Accuhaler 500/50 Seretide Accuhaler 500/50	≥12 years	As above

Source: Product Information for Salfumix Easyhaler, Fluticasone Salmeterol Ciphaler, Pavtide Accuhaler, Seretide Accuhaler; National Asthma Council Australian Asthma Handbook.

*N.B. 'adolescents' in the Asthma Handbook refers to approximately 12–18 years of age. The Asthma Handbook advises that for 'younger adolescents, the general guidance for diagnosing and managing asthma in children will apply in most situations.

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By mid-adolescence (around 14–16 years), the general guidance for diagnosing and managing asthma in adults will apply in most situations.'

3.5 Add new medicinal product pack as follows:

Suggestions and additions proposed by the Secretariat are added in italics.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
FLUTICASONE PROPIONATE + SALMETEROL					
fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations	8431R	1	1	5	<i>Salflumix Easyhaler 250/50^a</i> Fluticasone Salmeterol Ciphaler 250/50 ^a Pavtide Accuhaler 250/50 ^a Seretide Accuhaler 250/50 ^a
Restriction Summary / Treatment of Concept					
	Category / Program: GENERAL – General Schedule (Code GE)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined) [4930]				
	Indication: Asthma				
	Clinical criteria:				
	Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids				
	Population criteria:				
	Patient must be aged 4 years or older				
	Administrative Advice: This product is not indicated for the initiation of treatment in asthma				
	Administrative Advice: This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).				
	Administrative Advice: The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)				
	Administrative Advice: A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.				
	Administrative Advice: Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.				

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
FLUTICASONE PROPIONATE + SALMETEROL					

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fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations	8432T	1	1	5	Salflix Easyhaler 500/50 ^a Fluticasone Salmeterol Ciplhaler 500/50 ^a Pavide Accuhaler 500/50 ^a Seretide Accuhaler 500/50 ^a
Restriction Summary/ Treatment of Concept					
	Category / Program: GENERAL – General Schedule (Code GE)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined) [4930]				
	Indication: Asthma				
	Clinical criteria:				
	Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids				
	Population criteria:				
	Patient must be aged 4 years or older				
	Administrative Advice: This product is not indicated for the initiation of treatment in asthma				
	Administrative Advice: The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)				
	Administrative Advice: A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.				
	Administrative Advice: Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.				
Restriction Summary / Treatment of Concept					
	Category / Program: GENERAL – General Schedule (Code GE)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (STREAMLINED) [10121]				
	Indication: Chronic obstructive pulmonary disease (COPD)				
	Clinical criteria:				
	Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy				
	AND				
	Clinical criteria:				
	Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months				
	Administrative Advice: This product is not indicated for the initiation of bronchodilator therapy in COPD.				
	Administrative Advice: The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.				
	Administrative Advice: A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.				

Administrative Advice: Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.
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4 Comparator

- 4.1 The submission nominated Seretide Accuhaler 250/50 and 500/50 as the main comparators. This was appropriate, however any of the brands of fluticasone propionate + salmeterol powder for inhalation, 250/50 and 500/50, that are currently PBS-listed could also be considered comparators. This includes Fluticasone Salmeterol Ciphaler and Pavtide Accuhaler.
- 4.2 As part of its evaluation for registration, the TGA was satisfied that Salflumix Easyhaler 250/50 and 500/50 could be considered to be bioequivalent to Seretide Accuhaler 250/50 and 500/50 respectively.
- 4.3 The submission noted the Easyhaler is a new device which is different from the Accuhaler and Ciphaler devices that are currently PBS-listed.

5 Consideration of the evidence

Sponsor hearing

- 5.1 There was no hearing for this item.

Consumer comments

- 5.2 The PBAC noted and welcomed the input from organisations (2) via the Consumer Comments facility on the PBS website. The comments noted the high burden of disease and costs to the healthcare system due to asthma and COPD. Comments also noted that correct inhaler technique was essential and poor technique can lead to worsening of symptoms. Asthma Australia noted that there is a high proportion of patients who use their inhaler devices incorrectly. Comments considered that the PBS listings of a new device could provide an option for patients who have difficulty using other inhaler devices.
- 5.3 The PBAC noted the consumer comments stated that there are multiple inhaler devices available, and the availability of a new device has the potential to cause confusion in practice. Both Asthma Australia and Lung Foundation Australia considered it was important to have adequate education, and education materials, available for both health care professionals and patients on how to appropriately use the Easyhaler device.
- 5.4 Asthma Australia stated that the carbon emissions of Salflumix Easyhaler are estimated to be lower compared to some other dry powder inhalers, and lower than metered dose inhalers. It noted that climate change can contribute to increasing triggers for people with asthma, and having low carbon emission alternatives for asthma management is beneficial.

Clinical trials

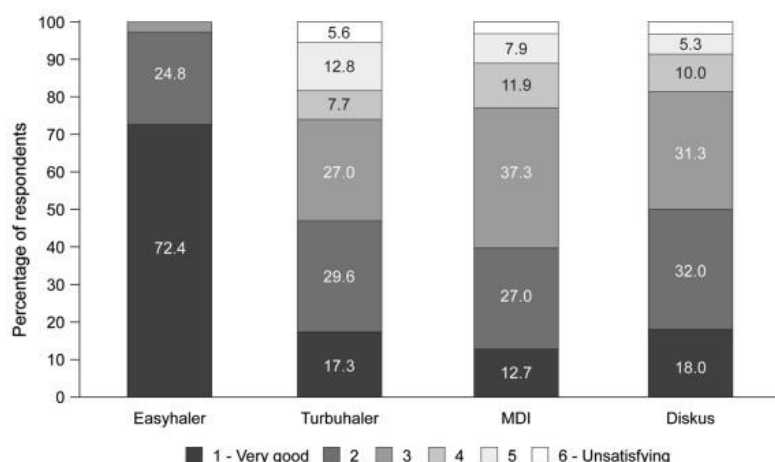
5.5 The submission provided evidence from the published papers outlined in Table 2.

Table 2: Publications provided in the submission.

Trial ID	Publication title	Publication citation
Publication 1	Chrystyn H, Lavorini F. The dry powder inhaler features of the Easyhaler that benefit the management of patients.	Expert Rev Respir Med 2020; 14(4): 345-51.
Publication 2	Lavorini F, Chudek J, Gálffy G, et al. Switching to the dry-powder inhaler Easyhaler®: A narrative review of the evidence.	Pulm Ther 2021; 7(2): 409-27.
Publication 3 Trial registration no: OGYÉI/13,942- 5/2016	Tamási L, Szilasi M, Gálffy G. Clinical effectiveness of budesonide/formoterol fumarate Easyhaler® for patients with poorly controlled obstructive airway disease: a real-world study of patient-reported outcomes.	Adv Ther 2018; 35(8): 1140-52.

- 5.6 The submission stated the Easyhaler is a multi-dose dry powder inhaler (DPI) and releases the drug dose by force generated by the patient’s inhalation, which leads to consistent high drug delivery. It claimed that dose emission is consistent irrespective of the inhalation flow used by each patient.
- 5.7 The submission claimed an advantage of DPIs is that they mitigate the clinical consequences of poor coordination since the drug release relies on inhalation, rather than the pressurised release of an aerosol (Lavorini et al, 2021).
- 5.8 The submission stated the Easyhaler differs from other DPIs available in appearance, mechanism of action and usability.
- 5.9 The submission claimed the use of the Easyhaler is associated with high patient satisfaction and acceptance, is easy to learn and teach, and is associated with patient adherence (Lavorini et al, 2021).
- 5.10 The submission cited a study conducted in 1,043 patients with asthma or COPD who switched to the Easyhaler (Tamasi et al, 2018). It claimed 72.4% of patients self-reported very high satisfaction with the Easyhaler (score of one on a six-point scale) compared with 18% with the Accuhaler (also known as Diskus) (Figure 1). In addition, more than 90% of physicians described the Easyhaler as easy to teach, with 73.8% of their patients having learned the technique within 5 minutes and 98.9% within 10 minutes of teaching.

Figure 1: Patient satisfaction by inhaler type



Source: Submission main body, Figure 2 page 8

Note: The Easyhaler was assessed following 12 weeks' treatment, whereas the other inhalers were assessed at baseline

Note: The Accuhaler is also called the Diskus

MDI = metered dose inhaler

5.11 As a Category 4 submission, no evaluation of the clinical evidence was undertaken.

Clinical claim

5.12 The submission claimed non-inferior comparative effectiveness and non-inferior comparative safety of Salflumix Easyhaler 250/50 and 500/50 compared with Seretide Accuhaler 250/50 and 500/50.

5.13 The PBAC considered that the claims of non-inferior comparative effectiveness and non-inferior comparative safety were reasonable.

Economic analysis

5.14 The submission presented a cost-minimisation analysis of Salflumix Easyhaler 250/50 and 500/50 compared with current PBS-listed brands of fluticasone with salmeterol 250/50 and 500/50 (Table 3).

Table 3: Cost Minimisation Analysis

	Salflumix Easyhaler	Fluticasone propionate and salmeterol (Fluticasone Salmeterol Ciphaler, Pavtide Accuhaler, Seretide Accuhaler)
Salflumix Easyhaler 250/50 versus fluticasone propionate and salmeterol 250/50		
AEMP	\$30.50	\$30.50
Administrations per day	2	2
Cost of medicine per day	\$1.02 [[\$30.50/60] x 2]	\$1.02 [[\$30.50/60] x 2]
Total medicine cost per month	\$30.94 [\$1.02 x [365.25/12]]	\$30.94 [\$1.02 x [365.25/12]]
Difference in cost per month	\$0.00	
Salflumix Easyhaler 500/50 versus fluticasone propionate and salmeterol 500/50		
AEMP	\$41.29	\$41.29
Administrations per day	2	2
Cost of medicine per day	\$1.38 [[\$41.29/60] x 2]	\$1.38 [[\$41.29/60] x 2]
Total medicine cost per month	\$41.89 [\$1.38 x [365.25/12]]	\$41.89 [\$1.38 x [365.25/12]]
Difference in cost per month	\$0.00	

Source: Submission main body

AEMP = Approved ex-manufacturer price

5.15 As a Category 4 submission, the economic analysis has not been independently evaluated.

Drug cost/patient/year: \$549.36 for Salflumix Easyhaler 250/50 and \$688.68 for Salflumix Easyhaler 500/50

5.16 The estimated drug cost/patient per year would be \$549.36 for Salflumix Easyhaler 250/50 and \$688.68 for Salflumix Easyhaler 500/50, based on a Dispensed Price for Maximum Quantity (DPMQ) of \$45.78 and \$57.39 respectively and 12 prescriptions per year for ongoing treatment.

Estimated PBS usage and financial implications

5.17 The requested price was based on the AEMP of Seretide Accuhaler 250/50 and 500/50 listed in the PBS in August 2023.

5.18 Refer to Table 4 which presents the estimated extent of use, cost of Salflumix Easyhaler 250/50 and 500/50 to the PBS/RPBS and the net financial implications to the PBS/RPBS.

5.19 The submission claimed that the cost of Salflumix Easyhaler 250/50 to the PBS/RPBS is expected to be \$20 million to < \$30 million over six years (Year 1 \$0 to < \$10 million to Year 6 \$0 to < \$10 million). The submission claimed that the cost of Salflumix Easyhaler 500/50 to the PBS/RPBS is expected to be \$10 million to < \$20 million over six years (Year 1 \$0 to < \$10 million to Year 6 \$0 to < \$10 million). This would be completely offset by reductions in currently PBS-listed medicines, resulting in an estimated nil financial impact to the PBS/RPBS for the listing of Salflumix Easyhaler over six years.

Table 4: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Substituted prescriptions						
Prescriptions	1	1	1	1	1	1
Salflumix Easyhaler						
Cost to R/PBS	2	2	2	2	2	2
Patient co-pay	3	3	3	3	3	3
Total R/PBS	2	2	2	2	2	2
Fluticasone propionate with salmeterol (Fluticasone Salmeterol Ciphaler, Pavtide Accuhaler, Seretide Accuhaler)						
Cost to R/PBS	3	3	3	3	3	3
Patient co-pay	2	2	2	2	2	2
Total R/PBS	3	3	3	3	3	3
Net impact to the R/PBS						
Cost to R/PBS	2	2	2	2	2	2
Patient co-pay	2	2	2	2	2	2
Total R/PBS	2	2	2	2	2	2

Source: Submission main body

PBS = Pharmaceutical Benefits Schedule, RPBS = Repatriation Pharmaceutical Benefits Schedule

The redacted values correspond to the following ranges:

¹ 100,000 to < 200,000

² \$0 to < \$10 million

³ net cost saving

Quality Use of Medicines

5.20 To ensure quality use of medicines and that patients can effectively use the new device, the sponsor plans to liaise with peak health bodies (e.g. Asthma Australia, National Asthma Council Australia and the Lung Foundation Australia), and industry organisations (e.g. the Pharmacy Guild of Australia and Pharmaceutical Society of Australia) to develop suitable resources consistent with those available for existing inhalers. These will include:

- consumer resources to ensure the correct and safe use of the new device, including a package insert, a patient education website and patient information booklets.
- resources for health care professionals to assist in appropriate patient education, including demonstration devices and information booklets.

6 PBAC Outcome

6.1 The PBAC recommended the listing of the following new forms of fluticasone propionate with salmeterol, under the same circumstances as the current PBS listings for Seretide Accuhaler 250/50 and 500/50:

- powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses (Salflumix Easyhaler 250/50), for the treatment of asthma.

- powder for oral inhalation in breath actuated device containing fluticasone propionate 500 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses (Salflumix Easyhaler 500/50), for the treatment of asthma and COPD.
- 6.2 The PBAC recommended listing Salflumix Easyhaler 250/50 and 500/50 on a cost-minimisation basis to the lowest cost PBS-listed fluticasone propionate + salmeterol powder for inhalation 250/50 and 500/50 items, respectively.
 - 6.3 The PBAC noted the PBS listing of Salflumix Easyhaler 250/50 and 500/50 is expected to have no net cost to the PBS.
 - 6.4 The PBAC noted the TGA considered Salflumix Easyhaler 250/50 and 500/50 to be bioequivalent to Seretide Accuhaler 250/50 and 500/50, respectively.
 - 6.5 The PBAC considered Seretide Accuhaler 250/50 and 500/50 and currently listed generic brands to be appropriate comparators.
 - 6.6 The PBAC advised the equi-effective doses were: Salflumix Easyhaler 250/50 = Seretide Accuhaler 250/50, and Salflumix Easyhaler 500/50 = Seretide Accuhaler 500/50.
 - 6.7 The PBAC noted the consumer comments highlighting the need for adequate education for both patients and health care professionals on the use of a new inhaler device, and the high proportion of patient who use their inhalers incorrectly. The PBAC noted the sponsor's plans to liaise with peak health bodies and industry organisations to develop suitable education resources.
 - 6.8 The PBAC noted that Salflumix Easyhaler 250/50 and 500/50, as well as Seretide Accuhaler 250/50 and 500/50 and PBS-listed generic brands, are currently TGA-registered for use in children aged 12 years of age and older, and adults. The PBAC noted the inconsistencies in the age recommendations between the TGA Product Information, PBS population criteria and Australian Asthma Handbook for these items, as shown in Table 1. The PBAC recommended not including an age restriction for the listings of Salflumix Easyhaler 250/50 and 500/50 for asthma. It requested this also be flowed on to the restrictions for the currently listed fluticasone propionate with salmeterol 250/50 microgram and 500/50 microgram items for asthma, by removing the population criteria 'Patient must be aged 4 years or older' from these listings.
 - 6.9 The PBAC advised, under Section 101 (4AACD) of the *National Health Act*, that Salflumix 250/50 and 500/50 and Seretide Accuhaler 250/50 and 500/50 respectively and other PBS-listed generic brands should be considered equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule).
 - 6.10 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because Salflumix Easyhaler 250/50 and 500/50 are not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over Seretide Accuhaler 250/50 and 500/50, or not expected to address a high

and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.

- 6.11 The PBAC noted that this submission is not eligible for an Independent Review because it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

- 7.1 Add new medicinal product pack:
Amend existing listing as follows:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
FLUTICASONE PROPIONATE + SALMETEROL					
fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations	8431R	1	1	5	<i>Salfumix</i> <i>Easyhaler</i> 250/50 ^a Fluticasone Salmeterol <i>Ciphaler</i> 250/50 ^a <i>Pavtide</i> <i>Accuhaler</i> 250/50 ^a <i>Seretide</i> <i>Accuhaler</i> 250/50 ^a
Restriction Summary / Treatment of Concept					
	Category / Program: GENERAL – General Schedule (Code GE)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined) [4930]				
	Indication: Asthma				
	Clinical criteria:				
	Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids				
	Population criteria:				
	Patient must be aged 4 years or older				
	Administrative Advice: This product is not indicated for the initiation of treatment in asthma				
	Administrative Advice: This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).				
	Administrative Advice: The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)				
	Administrative Advice: A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.				

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	Administrative Advice: Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.
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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
FLUTICASONE PROPIONATE + SALMETEROL					
fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations	8432T	1	1	5	<i>Salflumix Easyhaler</i> 500/50 ^a Fluticasone Salmeterol Ciplhaler 500/50 ^a Pavtide Accuhaler 500/50 ^a Seretide Accuhaler 500/50 ^a

Restriction Summary / Treatment of Concept

	Category / Program: GENERAL – General Schedule (Code GE)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined) [4930]
	Indication: Asthma
	Clinical criteria:
	Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids
	Population criteria:
	Patient must be aged 4 years or older
	Administrative Advice: This product is not indicated for the initiation of treatment in asthma
	Administrative Advice: The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)
	Administrative Advice: A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
	Administrative Advice: Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Restriction Summary / Treatment of Concept

	Category / Program: GENERAL – General Schedule (Code GE)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (STREAMLINED) [10121]
	Indication: Chronic obstructive pulmonary disease (COPD)
	Clinical criteria:
	Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy
	AND
	Clinical criteria:
	Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months

	Administrative Advice: This product is not indicated for the initiation of bronchodilator therapy in COPD.
	Administrative Advice: The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.
	Administrative Advice: A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.
	Administrative Advice: Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

This restriction may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

9 Sponsor's Comment

The sponsor had no comment.