

5.24 SALBUTAMOL,

Pressurised inhalation 100 micrograms (as sulfate) per dose with dose counter, 200 doses (CFC-free formulation),

Ventolin[®],

GlaxoSmithKline Australia Pty Ltd.

1 Purpose of Application

- 1.1 The minor submission requested an Unrestricted Benefit listing of a new presentation of salbutamol (Ventolin[®]) metered dose inhaler (MDI) 100 micrograms per dose with an integrated dose counter (DC) (hereafter referred to as Ventolin DC). The current presentation of Ventolin MDI on the PBS does not have a dose counter. The submission requested an agreed ex-manufacturer price (AEMP) of \$ [REDACTED] higher than the current presentation of Ventolin MDI.

2 Requested listing

- 2.1 The submission requested the same restriction as the existing listings of Ventolin MDI. Asmol[®] MDI is listed on the PBS and that, all three presentations (i.e. Ventolin MDI, Asmol MDI and Ventolin DC) be considered equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule).
- 2.2 Suggestions and additions proposed by the Secretariat to the requested listing are in italics and deletions are in strikethrough.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
SALBUTAMOL 100 microgram/actuation inhalation with dose counter, 200 actuations	2	5	\$ [REDACTED]	Ventolin GlaxoSmithKline Australia Pty Ltd

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Administrative Advice:	<i>Pharmaceutical benefits that have the form salbutamol 100 microgram/actuation inhalation with dose counter, 200 actuations and pharmaceutical benefits that have the form salbutamol 100 microgram/actuation inhalation, 200 actuations are equivalent for the purposes of substitution.</i>

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Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
SALBUTAMOL 100 microgram/actuation inhalation with dose counter, 200 actuations	1	0	\$ [REDACTED]	Ventolin GlaxoSmithKline Australia Pty Ltd

Category / Program:	GENERAL – General Schedule (Code DB Prescribers Bag)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Administrative Advice:	<i>Pharmaceutical benefits that have the form salbutamol 100 microgram/actuation inhalation with dose counter, 200 actuations and pharmaceutical benefits that have the form salbutamol 100 microgram/actuation inhalation, 200 actuations are equivalent for the purposes of substitution.</i>

For more detail on PBAC’s view, see section 6 PBAC outcome.

3 Background

- 3.1 Two brands of salbutamol pressurised inhalation 100 micrograms (as sulfate) per dose, 200 doses (CFC-free formulations) are currently listed on the PBS and are also available over-the-counter (Ventolin and Asmol). Asmol inhaler, is manufactured by the sponsor (GlaxoSmithKline Australia Pty Ltd) on behalf of Alphapharm Pty Ltd. The current presentations of Ventolin and Asmol MDIs do not have a dose counter.
- 3.2 Airomir® Autohaler, a salbutamol pressurised inhalation in breath actuated device 100 micrograms (as sulfate) per dose, 200 doses (CFC-free formulation) is also currently listed on the PBS as a Restricted Benefit for patients unable to achieve co-ordinated use of other MDIs containing this drug. The current presentation of Airomir Autohaler does not have a dose counter.
- 3.3 Ventolin DC was TGA registered on 31st July 2019 for the relief of bronchospasm in patients with asthma or COPD, and for acute prophylaxis against exercise-induced asthma and other stimuli known to induce bronchospasm. The ARTG Summary specifies the product as Ventolin inhaler CFC-Free Salbutamol 100 microgram (as sulfate) pressurised inhaler metered dose (with counter). The TGA approval letter states ‘Ventolin (with counter) (AUST R – 317221) is also supplied as Ventolin (AUST R – 62695). The two products are the same, apart from their container, which will not affect rate and extent of absorption. On this basis, they are bioequivalent.’
- 3.4 The submission argued that for MDIs without a reliable and practical means of gauging how many effective doses are left, patients have relied on various methods to estimate remaining medication. These include shaking or canister flotation, which

have been shown to be unreliable (Connor 2013)¹. The submission stated that many patients are not aware that with continued use beyond the labelled number of doses, the amount of drug delivered per actuation becomes inaccurate as the MDI begins to run out of formulation – a phenomenon known as ‘tail off’ (Schultz 1994)(Schultz, 1994)². Consequently, the submission argued that patients are placed at potential risk of having sub-therapeutic or negligible drug being available at a critical time of acute bronchospasm.

- 3.5 The submission stated that in February 2017, the TGA initiated dialogue with the sponsor to understand the potential for Ventolin DC to be marketed in Australia. The submission stated that the TGA was concerned with the issue of ‘inadvertent non-adherence’, where patients continue to use their salbutamol MDI despite their MDI being without any effective doses remaining. In their correspondence with the sponsor, the TGA referred to a review by Connor et al (2013)¹, which estimated that the extent of this inadvertent non-adherence with MDIs to be up to 40%.

For more detail on PBAC’s view, see section 6 PBAC outcome.

4 Current situation

- 4.1 The submission requested listing of a new presentation of salbutamol MDI 100 micrograms per dose (Ventolin DC), which the submission stated would replace the current Ventolin inhaler. The submission stated that a phasing-in approach to supply is required, which would see both presentations being available on the PBS concurrently in Year 1 (2020), followed by 100% supply of Ventolin DC from Year 2 (2021) and beyond. The submission stated that Ventolin MDI will be de-listed as of Year 2. The submission anticipated that a DC version of the Asmol MDI will also become available.
- 4.2 The submission requested that all three presentations (i.e. Ventolin MDI, Asmol MDI and Ventolin DC) be considered equivalent for the purposes of substitution (i.e., ‘a’ flagged) to facilitate transition of patients to Ventolin DC, given the imminent removal of Ventolin MDI from the Schedule.

5 Consideration of the evidence

Sponsor hearing

- 5.1 There was no hearing for this item as it was a minor submission.

¹ Connor J., et al. Improving Asthma Management: The Case for Mandatory Inclusion of Dose Counters on All Rescue Bronchodilators. *Journal of Asthma*, 2013; 50(6): 658–663.

² Schultz RK. Drug delivery characteristics of metered-dose inhalers. *Journal of Allergy and Clinical Immunology*, 1994; 96:284-7

Consumer comments

- 5.2 The PBAC noted and welcomed the input from individuals (7) and organisations (2) via the Consumer Comments facility on the PBS website. The comments described a range of benefits of treatment with salbutamol including improved quality of life. The comments of Asthma Australia and The Lung Foundation highlighted the importance of patients receiving accurate metered doses of salbutamol when required to relieve bronchoconstriction and suggested the addition of a dose counter may assist patients to understand and monitor medication use and act as a reminder to replace medication.

Clinical trials

- 5.3 As a minor submission, no clinical trials were presented in the submission.
- 5.4 The submission conducted a literature review to provide evidence relating to the implementation of a dose counter in an MDI device and the consequent outcomes on patient safety, patient satisfaction and the impact on clinical outcomes such as healthcare utilisation. One study (Wasserman 2006³) related to patient satisfaction and four studies (Chipps 2017⁴, Kerwin 2017⁵, Lachmann 2018⁶, Price 2016⁷) referring to healthcare utilisation were identified. Two of the studies were in abstract form only (Chipps 2017, Lachmann 2018). As a minor submission an independent search to identify other relevant studies was not conducted.
- 5.5 Patient satisfaction was assessed as one of the secondary endpoints in an open-label single-arm study that included 268 patients aged ≥ 4 years with asthma or chronic obstructive pulmonary disease (COPD) (Wasserman 2006). Patients who required a short-acting beta2-agonist for relief of respiratory symptoms at least 3 times per week over the two weeks before the study were eligible to participate. After screening, patients were assigned to receive a fixed twice-daily dose regimen from a Ventolin MDI with a dose counter until completion of 200 doses. The submission stated that after use of the Ventolin DC at study completion, 80% of patients were more satisfied

³ Wasserman, R. Real-world assessment of a metered-dose inhaler with integrated dose counter. *Allergy Asthma Proc*, 2006;27: 486–492.

⁴ Chipps B., et al. Impact of integrated dose counter on healthcare utilization and disease control in medicare patients with asthma and/or chronic obstructive pulmonary disease using albuterol sulfate inhalation aerosol (ProAir® HFA). *American Journal of Respiratory and Critical Care Medicine*, 2017; 195.

⁵ Kerwin E., et al. Real-world health care utilization in asthma patients using albuterol sulfate inhalation aerosol (ProAir® HFA) with and without integrated dose counters. *Journal of Asthma and Allergy* 2017;10: 171–179.

⁶ Lachman B.S. Effect of rescue inhaler dose counters on ER utilization, asthma admissions and health care claims costs in a population of children in medicaid managed care. *Journal of Allergy and Clinical Immunology*, 2018; 141:2 Supplement 1 (AB225).

⁷ Price D.B., et al. Historical cohort study examining comparative effectiveness of albuterol inhalers with and without integrated dose counter for patients with asthma or chronic obstructive pulmonary disease. *Journal of Asthma and Allergy*, 2016; 9: 145-154.

with the MDI with a dose counter when compared with other MDI devices without a dose counter used in the past and 93% agreed that the MDI with a dose counter would let them know when to refill medication.

- 5.6 Four retrospective claims-based studies conducted in the United States were identified in the literature review to evaluate the impact of introducing a dose counter to the salbutamol MDI on asthma control and healthcare resource utilisation (Table 1).
- 5.7 The submission noted that while Chipps 2017 identified a significantly higher proportion of patients who experienced no severe exacerbations in the dose counter group compared with no dose counter group, this difference was not observed in Price 2016, where the rates of severe exacerbations were similar between dose counter and no dose counter groups. The submission stated that, notwithstanding the limitations of observational retrospective studies, the consistency of results across the four studies suggest that the introduction of a dose counter to salbutamol MDI is associated with a reduction in respiratory-related ED visits.

Table 1: Overview of studies evaluating the impact of DC on asthma control and healthcare resource utilisation.

Reference Design/Location	N Patient population	Outcomes	Key Results
Chipps 2017 (Abstract only) Retrospective claims study (USA)	13,339 (No DC) 13,339 (DC) <ul style="list-style-type: none"> Aged ≥65 years ≥1 prescription claim for albuterol† inhalation aerosol (ProAir HFA*, with or without dose counter) over Jan 1 2011- Dec 31 2013 ≥1 diagnostic medical claim for asthma and/or COPD Continuous enrolment for 12 months pre- and post- index date 	<ul style="list-style-type: none"> Moderate exacerbations Severe exacerbations All-cause healthcare utilisation Respiratory healthcare utilisation 	<ul style="list-style-type: none"> Significantly higher proportion with no severe exacerbations in DC vs. no DC (60.15% vs. 55.99%, p<0.0001) Significantly lower proportion with DC vs. no DC for 2-3 (14.24% vs. 15.93%, p=0.0001) or ≥4 (8.08% vs. 9.78%, p<0.0001) severe exacerbations Significantly lower risk of all-cause inpatient services (DC vs. no DC, RR 0.84, 95% CI 0.81-0.87) and ED services (RR 0.98 (0.95-1.01)) Significantly lower risk of respiratory-related inpatient utilisation (RR 0.84, 95% CI 0.81-0.87) and ED visits (RR 0.90, 95% CI 0.87-0.93)
Kerwin 2017 Retrospective claims study (USA)	287,243 (No DC) 135,305 (DC) <ul style="list-style-type: none"> Aged 4-64 years ≥1 prescription claim for albuterol inhalation aerosol (ProAir HFA, with or without dose counter) over Jan 1 2011 – Jul 31 2014 ≥1 nonrule-out diagnosis indicative of asthma 	<ul style="list-style-type: none"> Respiratory-related hospitalisations ED visits 	<ul style="list-style-type: none"> Significantly lower odds of experiencing a respiratory-related hospitalisation (DC vs. no DC, adjusted OR 0.92; 95% CI 0.88-0.96) and ED visit (adjusted OR 0.92; 95% CI 0.90-0.94) Significantly lower number of respiratory-related hospitalisations (DC vs. no DC, adjusted per-patient no. of respiratory-related hospitalisations 0.024 vs. 0.026, p<0.05) and ED visits (adjusted per-patient number of ED visits (0.082 vs. 0.088, p<0.05))

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Reference Design/Location	N Patient population	Outcomes	Key Results
	<ul style="list-style-type: none"> Continuous enrolment for 6 months pre- and post- index date 		
Lachman 2018 (Abstract only) Retrospective claims study (USA)	Not reported <ul style="list-style-type: none"> Medicaid children 	<ul style="list-style-type: none"> Hospital admission ER visits Health care costs 	<ul style="list-style-type: none"> Lower number of hospital admissions (DC vs. no DC, 4.36 per 1000 vs. 7.91 per 1000) Lower number of ED visits (101.44 per 1000 vs. 149.36 per 1000)
Price 2016 Retrospective claims study (USA)	26,729 (No DC) 67,251 (DC) Asthma subpopulation 21,823 (No DC) 75,787 (DC) <ul style="list-style-type: none"> Aged 4-64 years ≥1 prescription claim for albuterol inhalation aerosol (Ventolin HFA with dose counter or ProAir HFA/Proventil HFA without dose counter) over Jan 1 2010 – Sept 30 2011 Diagnosis of asthma and/or COPD and/or exercise-induced bronchospasm Continuous insurance coverage for 1 year pre- and post-index date Asthma subpopulation <ul style="list-style-type: none"> ≥1 consultation, inpatient admission, or ED visit for asthma recorded at any time during the study period 	Primary endpoint: <ul style="list-style-type: none"> Incidence rate of respiratory-related ED visits Secondary endpoints: <ul style="list-style-type: none"> Incidence rate of severe exacerbations Incidence rate of acute respiratory events 	<ul style="list-style-type: none"> Significantly lower risk of respiratory-related ED visits (DC vs. no DC, adjusted RR 0.55, 95% CI 0.47-0.65) Asthma subpopulation <ul style="list-style-type: none"> Significantly lower incidence of respiratory-related ED visits (adjusted RR 0.49; 95% CI 0.41-0.59) Rates of severe exacerbations were similar between DC vs. no DC Rates of acute respiratory events were similar between DC vs. no DC

*ProAir HFA (with a dose counter) is a generic of Ventolin HFA (with a dose counter) in the US. The devices for both are similar. †albuterol sulfate is another name for salbutamol sulfate.

Abbreviations: ED, Emergency Department; RR, Risk Ratio; HFA, Hydrofluoroalkane

Source: Table 6, pp18-19 of submission

5.8 The submission claimed that the evidence from the literature review suggested that from a patient perspective, the DC enables monitoring on inhaler use and provides reassurance that medication will not run out in the time of need. In addition, the submission claimed that compared with salbutamol MDIs with no DC, salbutamol MDIs with DC are associated with reduced respiratory-related ED visits, which

highlights the benefit of having a DC that enables patients to accurately determine when their inhaler is depleted of active drug.

Pricing considerations

- 5.9 The proposed AEMP for Ventolin DC is higher than the current AEMP for Ventolin MDI. The submission stated that the manufacture of Ventolin DC is more complex and hence has a higher cost than the non-DC MDI such that to ensure supply a \$█ higher AEMP is necessary.
- 5.10 The proposed price for Ventolin DC is shown in comparison to the other salbutamol MDIs in Table 2.

Table 2: Current and proposed prices for salbutamol MDIs

Product	PBS code	Schedule	AEMP	Price to pharmacy	DPMQ
Ventolin	3495Y	DB	\$3.90	\$6.02	\$17.50
Ventolin*	8288F	GE	\$3.90	\$4.19	\$19.87
Asmol	3495Y	DB	\$3.90	\$4.19	\$15.67
Asmol	8288F	GE	\$3.90	\$4.19	\$19.87
Airomir autohaler	8354Q	GE	\$13.01	\$13.99	\$39.47
Ventolin DC	new	DB	\$█	\$█	\$█
Ventolin DC	new	GE	\$█	\$█	\$█

DB = Prescriber Bag, GE = Generally Available Pharmaceutical Benefits

*claimed AEMP and claimed DPMQ differ for Ventolin (General Schedule) due to existence of brand price premium (BPP) of \$1.83 per unit. Therefore, claimed DPMQ for Ventolin GE is \$23.53

- 5.11 Section 85C of the National Health Act 1953 provides that the AEMP of each listed brand of a pharmaceutical item containing a drug must be the same; “If there are 2 or more listed brands of a pharmaceutical item, then the Minister must ensure, when agreeing an amount under subsection 85AD (1) or determining an amount under subsection 85B (2), that the approved ex-manufacturer price of each listed brand of the pharmaceutical item is the same.” The submission requested a separate pharmaceutical item acknowledging the dose counter component of Ventolin DC.
- 5.12 The PBAC could only recommend listing salbutamol MDI with a dose counter at a higher price than the alternative therapy or therapies if it is satisfied that it provides, for some patients, a significant improvement in efficacy or reduction of toxicity over the alternative therapy or therapies (National Health Act 1953, Section 101(3B)). The alternative therapies in this case should include salbutamol MDI without a dose counter.
- 5.13 The pre-PBAC response (p2) acknowledged that the submission had not presented an economic evaluation to support the requested higher AEMP. The pre-PBAC response (p2) provided a cost-effectiveness analysis based on utilisation data derived from one of the retrospective claim-based studies identified in the submission (Kerwin 2017) to ascertain cost per ED visit avoided. The pre-PBAC response stated that based on the results of the cost-effectiveness analysis, Ventolin DC is associated with an

incremental cost of \$ [REDACTED] per ED visit avoided. The PBAC noted that this analysis was not evaluated. The PBAC also noted that differences in baseline inhaled corticosteroid (ICS) use (DC 20.5%, no DC 17.5%) and the proportion of patients using no asthma therapy at baseline (DC 59.8%, no DC 66.5%) may have biased the results in favour of Ventolin DC.

Estimated PBS usage & financial implications

5.14 The submission used a market share approach to generate utilisation and financial estimates for listing Ventolin DC with the key inputs reported in Table 3.

Table 3: Key inputs for financial estimates

Model parameter		Value	Reference and/or justification
Market shares for current Salbutamol MDI market	VENTOLIN (salbutamol sulfate 100 mcg)	[REDACTED]%	Market share based on GSK sales data reported for 2018 (GSK commercial-in-confidence), assumption is the [REDACTED] split is consistent across both private and PBS markets.
	ASMOL (salbutamol sulfate 100 mcg)	[REDACTED]%	
Average growth rate of the total Salbutamol MDI market.		-1%	Based on annual average growth rate 2016-2018 from historical script data. A scenario analysis using a flat growth assumption is included.
Uptake of Ventolin DC into potentially substitutable salbutamol market		Year 1: [REDACTED] % Year 2: 100% Year 3: 100% Year 4: 100% Year 5: 100% Year 6: 100%	GSK projections based on entry to market of Ventolin DC is based on the phasing out of the non-dose counter versions salbutamol MDIs.

Source: Table 8, p23 of the submission.

5.15 The submission stated that the introduction of this product is not expected to increase the overall size of the salbutamol MDI market (Ventolin and Asmol MDIs) but rather Ventolin DC is expected to replace these medicines by the second year of listing (2021). The PBAC noted a review by Stein 2014 which stated that MDI with DC are designed in such a way that the dose counter may over-count if the canister is depressed with enough force or displacement to advance the counter but insufficient force or displacement to fire a dose.⁸

5.16 The minor submission estimated a net cost to the PBS/RPBS of \$10 - \$20 million in Year 6 of listing, with a total net cost to the PBS/RPBS of \$30 - \$60 million over the first 6 years of listing. This is summarised in the table below.

⁸ Stein SW, et al. Advances in metered dose inhaler technology: hardware development. AAPS PharmSciTech. 2014 Apr 1;15(2):326-38.

Table 4: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts dispensed	██████	██████	██████	██████	██████	██████
Estimated financial implications of Ventolin DC						
Cost to PBS/RPBS	██████	██████	██████	██████	██████	██████
Copayments	██████	██████	██████	██████	██████	██████
Cost to PBS/RPBS less copayments	██████	██████	██████	██████	██████	██████
Estimated financial implications for Ventolin and Asmol MDI						
Cost to PBS/RPBS	██████	██████	██████	██████	██████	██████
Copayments	██████	██████	██████	██████	██████	██████
Cost to PBS/RPBS less copayments	██████	██████	██████	██████	██████	██████
Net financial implications						
Net cost to PBS/RPBS	██████	██████	██████	██████	██████	██████

Source: Table 10 pg 26, Table 11 pg 27, Table 12 pg 28 of the submission.

- 5.17 The submission presented a sensitivity analysis using a flat growth assumption of the Ventolin DC market (i.e. 0% growth rate, instead of -1%). Based on this analysis over the first six years of listing there would be an estimated cost of \$30-\$60 million to the PBS/RPBS, an increase of less than \$10 million from the base case.
- 5.18 The approach to the financial estimates taken by the submission assumed that Asmol MDI will be delisted by 2021 and that any Asmol MDI with dose counter will have an AEMP of \$██████ higher than the current presentation.
- 5.19 As a minor submission, the financial estimates have not been independently evaluated. The PBAC noted that the financial estimates would need to be recalculated based on the final agreed price.

For more detail on PBAC’s view, see section 5 PBAC outcome.

6 PBAC Outcome

- 6.1 The PBAC recommended the Unrestricted Benefit listing of salbutamol, in the form of pressurised inhalation 100 micrograms (as sulfate) per dose with dose counter, 200 doses (CFC-free formulation) and hereafter referred to as Ventolin DC. The PBAC’s recommendation for listing was based on, among other matters, the potential health benefits related to the likely risk of having sub-therapeutic or negligible drug being available at a time of acute bronchoconstriction and the role of a DC in this specific context to act as a reminder to replace medication. The PBAC considered that the cost-effectiveness of Ventolin DC would be acceptable if it was priced with a small premium (██████%) over the current Ventolin MDI price.
- 6.2 The PBAC welcomed the input from individuals and organisations and noted the input described the importance of patients receiving accurate metered doses of salbutamol

when required to relieve bronchoconstriction and will provide a reminder to patients to replace the medication.

- 6.3 The PBAC noted the studies identified by the submission to provide evidence on the impact of a dose counter in an MDI device on patient satisfaction (Wasserman 2006) and healthcare utilisation (Chipps 2017, Kerwin 2017, Lachman 2018, Price 2016). The PBAC considered the risk of bias to be high and in favour of Ventolin DC in the non-controlled, unblinded patient satisfaction study.
- 6.4 In addition, the PBAC noted that all four healthcare utilisation studies were conducted in the United States and considered that differences in healthcare settings may limit applicability to the Australian setting. The PBAC also considered that despite the large sample size (n=422,548) in the Kerwin 2017 study the differences were small for the odds of experiencing a respiratory-related hospitalisation (DC vs no DC, adjusted OR 0.92; 95% CI 0.88-0.96) or emergency department visit (adjusted OR 0.92; 95% CI 0.90-0.94) with the upper 95% confidence intervals close to the null value. The PBAC also noted that Price 2016 reported no differences in the rates of severe exacerbations or the rates of acute respiratory events between DC versus no DC MDI use. The PBAC noted the remaining two studies (Chipps 2017, Lachmann 2018) were provided in abstract form only. The PBAC considered that the evidence supporting a reduction in healthcare utilisation as a result of an integrated DC was limited. However, the PBAC acknowledged the potential risk of having sub-therapeutic or negligible drug being available at a time of acute bronchoconstriction and the role of a DC in this specific context to act as a reminder to replace medication.
- 6.5 The PBAC noted that the submission requested an agreed ex-manufacturer price (AEMP) of \$ [REDACTED] higher than the current presentation of Ventolin MDI, i.e. a price increase of [REDACTED]. The PBAC noted the cost-effectiveness analysis provided in the pre-PBAC response based on the Kerwin 2017 study to ascertain cost per ED visit avoided (see paragraph 5.13). In addition to the concerns raised in paragraph 6.4 regarding the applicability of the Kerwin 2017 study to the Australian setting, the PBAC considered that differences in baseline inhaled corticosteroid use and the proportion using no asthma therapy likely favoured Ventolin DC in this study. The PBAC considered the evidence provided in the submission was insufficient to support the AEMP requested in the submission. However, the PBAC pragmatically advised that a [REDACTED] over the existing Ventolin MDI price would be acceptable.
- 6.6 In considering the financial estimates, the PBAC noted the potential for devices like Ventolin DC to over count doses (see paragraph 5.15) and advised that this may result in an increase in utilisation in clinical practice. Accordingly, the PBAC considered that the submission had underestimated total utilisation for the salbutamol MDI market but considered that any increase in the market as a result of listing Ventolin DC was likely to be relatively small.

- 6.7 The PBAC considered the potential health benefits related to the likely risk of having sub-therapeutic or negligible drug being available at a time of acute bronchoconstriction and the role of a DC in this specific context to act as a reminder to replace medication meant that Ventolin DC and currently listed salbutamol MDI (Ventolin MDI, Asmol MDI) should not be considered equivalent for the purposes of substitution under Section 101 (4AACD) of the *National Health Act 1953*.
- 6.8 The PBAC advised that Ventolin DC is suitable for prescribing by nurse practitioners, as applies to the current PBS listing for salbutamol MDI.
- 6.9 The PBAC advised that Ventolin DC should be exempt from the Early Supply Rule, as applies to the current PBS listing for salbutamol MDI.
- 6.10 The PBAC recommended that salbutamol should not be treated as interchangeable with any other drugs on an individual patient basis.
- 6.11 The PBAC found that the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* for Pricing Pathway A were not met. Specifically the PBAC found that in the circumstances of its recommendation for Ventolin DC:
- a. The treatment is not expected to provide a substantial and clinically relevant improvement in efficacy, over alternative therapies, as Ventolin DC is a new presentation of salbutamol MDI with the improvements limited to those outlined in paragraph 6.4.
 - b. The treatment is not expected to address a high and urgent unmet clinical need because other subsidised therapies are available.
 - c. It was not necessary to make a finding in relation to whether it would be in the public interest for the subsequent pricing application to be progressed under Pricing Pathway A because one or more of the preceding tests had failed.
- 6.12 The PBAC advised that this submission would not meet the criteria for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

- 7.1 Add new item:

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Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer		
SALBUTAMOL 100 microgram/actuation inhalation with dose counter, 200 actuations	2	5	Ventolin	GlaxoSmithKline Pty Ltd	Australia

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer		
SALBUTAMOL 100 microgram/actuation inhalation with dose counter, 200 actuations	1	0	Ventolin	GlaxoSmithKline Pty Ltd	Australia

Category / Program:	GENERAL – General Schedule (Code DB Prescribers Bag)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives

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

GSK is working with the PBAC to list Ventolin DC on the PBS.