

**5.20 HYDROCORTISONE,
Capsule containing granules 0.5 mg
Capsule containing granules 1.0 mg
Capsule containing granules 2.0 mg
Capsule containing granules 5.0 mg,
Alkindi[®],
Chiesi Australia.**

1 Purpose of Application

- 1.1 The Category 3 submission requested an Authority Required (STREAMLINED) listing for hydrocortisone 0.5 mg, 1 mg, 2 mg and 5 mg granules in capsules (Alkindi[®]) for replacement therapy of adrenal insufficiency for patients aged six or younger.
- 1.2 The submission also requested consideration of listing for patients older than 6 years of age with swallowing difficulties or tablet phobia for whom treatment compliance is an ongoing issue. The submission indicated that a very small number of patients would fall in this category.

2 Background

- 2.1 Alkindi was registered in the ARTG by the TGA on 18 August 2020 for replacement therapy of adrenal insufficiency and was granted an orphan drug status by the TGA.
- 2.2 Hydrocortisone 0.5 mg, 1 mg, 2 mg and 5 mg granules in capsules have not been considered by the PBAC previously.
- 2.3 Hydrocortisone 4 mg and 20 mg tablets are currently listed on the PBS under the General Schedule as Unrestricted Benefits.

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

3 Requested listing

- 3.1 The submission requested the following new listing.
- 3.2 Suggested additions are in italics and deletions are in strikethrough.

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MEDICINAL PRODUCT Medicinal Product Pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
HYDROCORTISONE hydrocortisone 500 microgram granules, 50 capsules	NEW	32	450 100	2	Alkindi
hydrocortisone 1 mg granules in capsules, 50 capsules	NEW	32	450 100	2	Alkindi
hydrocortisone 2 mg granules in capsules, 50 capsules	NEW	32	450 100	2	Alkindi
hydrocortisone 5 mg granules in capsules, 50 capsules	NEW	32	450 100	2	Alkindi

Restriction Summary [New] / Treatment of Concept: [New]	
	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 [new code]
	Indication: Replacement therapy of adrenal insufficiency
	Population criteria:
	Patient must have been diagnosed and initiated on treatment for this condition at an age of 6 years of age or less; or
	Patient must be 6 years of age or older with must have difficulty swallowing hydrocortisone tablets resulting in poor treatment compliance.
	Administrative Advice: Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners

- 3.3 The Pre-PBAC response maintained that a listing with a maximum quantity of three packs was reasonable particularly in the context of maintaining adequate supplies of medication for ‘stress dosing’ that is required when a patient experiences non-adrenal insufficiency related illness or trauma. However, the pre-PBAC response indicated the sponsor would accept the suggested maximum quantity of two packs.

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

4 Comparator

- 4.1 The submission nominated hydrocortisone 4 mg and 20 mg tablets (Hydrocortisone Mylan 4[®] and Hysone 4[®], PBS code 1499X; Hydrocortisone Mylan 20[®] and Hysone 20[®], PBS code 1500Y) as the main comparators. This is appropriate.
- 4.2 In accordance with section 101(3B) of the *National Health Act 1953* (the Act), when the proposed therapy is substantially more costly than an alternative therapy or therapies, the PBAC cannot make a positive recommendation unless it is satisfied that, for some patients, the proposed medicine provides a significant improvement in efficacy or reduction of toxicity over the alternative therapy or therapies.

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

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 individuals (20), health care professionals (6) and organisations (4) via the Consumer Comments facility on the PBS website. The comments noted that many parents and carers find measuring lower doses with the existing tablets to be difficult and that the uncertainty around whether correct dosing has been administered causes significant stress. The comments also noted that administering treatment to young children was difficult due to the bitter taste associated with hydrocortisone tablets. The comments indicated many parents considered that Alkindi would allow for more accurate dosing and therefore prevent the negative side effects associated with under or over dosing.
- 5.3 The Congenital Adrenal Hyperplasia (CAH) Support Group UK, Australasian Paediatric Endocrine Group, Endocrine Nurses Society of Australia and the CAH Support Group Australia supported listing Alkindi on the PBS, noting the lower doses required for paediatric patients would be more easily and accurately prepared from the available strengths for Alkindi. The input from these groups emphasised that for parents and carers, preparing the small doses required for paediatric patients from the existing 4 mg tablets was challenging and added to the existing stress of caring for a child with a medical condition.

Clinical trials

- 5.4 The submission presented the following 3 studies:
- A single centre, open label bioequivalence study (Infacort 001) evaluating the pharmacokinetics of Alkindi and immediate release hydrocortisone in healthy adult volunteers.
 - A phase 3, single centre, open-label, single-dose, single-arm study (Infacort 003) evaluating absorption, safety and palatability of Alkindi in paediatric patients aged less than 6 years with adrenal insufficiency.
 - A phase 3b, open-label, single-arm follow up study of Infacort 003 (Infacort 004) evaluating the safety of Alkindi. Key secondary end points were longitudinal assessment of height and weight (growth velocity) and assessment of Tanner Development Stage.
- 5.5 These studies were part of the submission to TGA for the registration of Alkindi.
- 5.6 As a Category 3 submission, the clinical evidence has not been independently evaluated.

Clinical claim

- 5.7 The submission claimed that Alkindi is therapeutically equivalent to hydrocortisone tablets but superior in effectiveness in usual clinical practice due to more precise dosing which should reduce the risk of under or overdosing in paediatric patients with the currently listed 4 mg and 20 mg hydrocortisone tablets. No bioequivalence data to Australian hydrocortisone products was presented to support this claim. Overall, there is a lack of comparative data to support these claims.
- 5.8 The submission claimed that the adverse events reported for Alkindi were consistent with that expected for patients on hormone replacement therapy and that Alkindi is effective in preventing potentially life-threatening development of adrenal crisis. The claim with respect to prevention of adrenal crisis was based on no adverse events of adrenal crisis events being reported in Infacort 003 and Infacort 004.
- 5.9 An economic analysis was not presented in the submission. The submission stated that a cost-effectiveness versus hydrocortisone tablets is not appropriate given the lack of comparative studies evaluating the long-term outcomes associated with Alkindi and modelling the longer-term costs and effectiveness based on the single arm studies Infacort 003 and Infacort 004 would result in highly uncertain cost-effectiveness.

Price consideration

- 5.10 The submission's requested prices for each capsule strength was based on an AEMP of \$[REDACTED] for a pack (50 units) of 1 mg granules in capsules. The submission stated this price was based on licencing company Diurnal's mean price across European countries where the product is commercially available. The proposed price for Alkindi (\$[REDACTED] per mg) is substantially higher than the current price for 4 mg (\$0.067 per mg) and 20 mg (\$0.016 per mg) hydrocortisone tablets.
- 5.11 The proposed AEMP and DPMQ for each strength of Alkindi is presented in Table 1.

Table 1: Proposed Pricing for Alkindi

Product	Maximum amount (packs)	Maximum amount (units)	No. of repeats	AEMP	DPMQ
Alkindi					
Hydrocortisone 0.5 mg granules in capsules	3	150	2	\$ [REDACTED]	\$ [REDACTED]
Hydrocortisone 1 mg granules in capsules	3	150	2	\$ [REDACTED]	\$ [REDACTED]
Hydrocortisone 2 mg granules in capsules	3	150	2	\$ [REDACTED]	\$ [REDACTED]
Hydrocortisone 5 mg granules in capsules	3	150	2	\$ [REDACTED]	\$ [REDACTED]
Hydrocortisone Mylan 4 and Hysone 4					
Hydrocortisone 4 mg tablet	1	50	4	\$13.45	\$26.48
Hydrocortisone Mylan 20 and Hysone 20					
Hydrocortisone 20 mg tablet	1	60	4	\$19.20	\$32.66

Source: Table 4, p19; p38 of the submission

Abbreviations: AEMP = approved ex-manufacturer price; DPMQ = dispensed price for maximum quantity

Consideration of an exempt item under Section 84AH

5.12 The submission requested Alkindi be determined as an ‘exempt item’ under Section 84AH of the Act. Section 84AH of the Act provides that the Minister may, by legislative instrument, determine a pharmaceutical item to be an exempt item if:

- (a) there is only one listed brand of the relevant item; and
- (b) there are no listed brands of other pharmaceutical items that are bioequivalent or biosimilar to the listed brand of the relevant item; and
- (c) the relevant item and at least one listed brand of another pharmaceutical item have the same drug; and
- (d) the Minister is satisfied, having regard to advice (if any) given to the Minister by the Pharmaceutical Benefits Advisory Committee (whether before or after the commencement of this section), that:
 - i. the listed drug in the relevant item represents suitable therapy for a particular patient population; and
 - ii. the relevant item is suitable for use by a particular subgroup of that population because of either or both of the form and manner of administration of the drug in the item; and
 - iii. no other pharmaceutical item that has that drug is suitable for use by that subgroup because of either or both of the form and manner of administration of the drug in that other item.

- 5.13 The submission made the request for Alkindi to be determined as an ‘exempt item’ on the basis that:
- Alkindi satisfies criterion d(i) as it is TGA-approved as a therapy for patients with adrenal insufficiency.
 - Compared with brands of hydrocortisone in F2, Alkindi is suitable for use by a particular subgroup (paediatric patients) because of both the form (lower strength presentations) and manner of administration (taste masked granules for oral administration without compounding or parent/carer manipulation) which satisfies criterion d(ii).
 - There are no other presentations of hydrocortisone listed on the PBS suitable for use in paediatric patients due to form (adult strengths of 4 mg and 20 mg) and manner of administration (cannot be used in paediatric patients without pharmacy compounding or parent/carer manipulation) which satisfies criterion (d)(iii).

Drug cost/patient/year: \$ [REDACTED]

- 5.14 The cost/patient/year for treatment with Alkindi is difficult to determine as it would vary based on patient body surface area and the dose/m²/day. Based on a body surface area of 0.582 m² (average body surface area in Infacort 004) and assuming the maximum daily dose of 15 mg/m² (assuming each day, a patient takes two 2 mg capsules and one 0.5 mg capsule in the morning and one 2 mg capsule for lunch and dinner doses), the cost/patient/year would be \$ [REDACTED] (\$ [REDACTED] (DPMQ of 2 mg) x 10 packs of 2 mg + \$ [REDACTED] (DPMQ of 0.5 mg) x 3 packs of 0.5 mg).
- 5.15 The cost/patient/year for a patient using 4 mg hydrocortisone tablets (assuming the morning dose was made up with two 4 mg capsules and lunch and dinner doses were made up with a 4 mg tablet each) would be \$767.92 (\$26.48 (DPMQ) x 29 packs of 4 mg).

Estimated PBS utilisation and financial implications

- 5.16 The submission used an epidemiological approach to estimate PBS utilisation and financial implications for the eligible PBS population. The submission noted that the 4 mg tablet would most likely be substituted by Alkindi if it was PBS listed as the 20 mg tablet would most likely be used by adults.
- 5.17 The submission did not account for the additional requested population of patients older than 6 years of age with swallowing difficulties in the financial estimates on the basis that this is a very small patient population.
- 5.18 The estimated extent of use, cost of Alkindi to the PBS and the net financial implications to the PBS are shown in Table 2. The financial impact to Services Australia will be determined by that agency as part of the post PBAC process.
- 5.19 A total of 500 to < 5,000 patients are estimated to be supplied Alkindi over the first six years of listing (< 500 patients in Year 1 to < 500 patients in Year 6).

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- 5.20 The cost of Alkindi to the PBS is expected to be \$0 to < \$10 million over six years (\$0 to < \$10 million in Year 1 to \$0 to < \$10 million in Year 6).
- 5.21 Alkindi is expected to have an impact of net cost saving of \$0 to < \$10 million on the utilisation of existing hydrocortisone 4mg tablets over six years.
- 5.22 The submission estimated an overall net cost for the listing of Alkindi to the PBS of \$0 to < \$10 million over six years \$0 to < \$10 million in Year 1 to \$0 to < \$10 million in Year 6).

Table 2: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of patients treated	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Total days on therapy ^a	29,996	45,413	53,013	63,302	72,409	81,609
Number of packs dispensed for 0.5 mg	█ ² (28%)	█ ² (27%)	█ ² (30%)	█ ² (31%)	█ ² (33%)	█ ² (31%)
Number of packs dispensed for 1.0 mg	█ ² (38%)	█ ² (35%)	█ ² (32%)	█ ² (30%)	█ ² (27%)	█ ² (28%)
Number of packs dispensed for 2.0 mg	█ ² (33%)	█ ² (38%)	█ ² (39%)	█ ² (37%)	█ ² (37%)	█ ² (37%)
Number of packs dispensed 5.0 mg	0 (0%)	0 (0%)	0 (0%)	█ ¹ (2%)	█ ¹ (3%)	█ ¹ (4%)
Total number of packs	█ ²	█ ²	█ ³	█ ³	█ ³	█ ³
Drug costs						
Cost of Alkindi to PBS (excl. patient copayments)	\$█ ⁴	\$█ ⁴	\$█ ⁴	\$█ ⁴	\$█ ⁴	\$█ ⁴
Cost of Alkindi to PBS (less patient copayments)	\$█ ⁴	\$█ ⁴	\$█ ⁴	\$█ ⁴	\$█ ⁴	\$█ ⁴
Cost of hydrocortisone 4 mg tablets (excl. patient copayments) ^b	\$█ ⁴	\$█ ⁴	\$█ ⁴	\$█ ⁴	\$█ ⁴	\$█ ⁴
Cost of hydrocortisone 4 mg tablets (less patient copayments)	\$█ ⁴	\$█ ⁴	\$█ ⁴	\$█ ⁴	\$█ ⁴	\$█ ⁴
Estimated net financial implications						
Net cost PBS	\$█ ⁴	\$█ ⁴	\$█ ⁴	\$█ ⁴	\$█ ⁴	\$█ ⁴

Source: p47 to p49 of the submission.

^a Assuming that 1/6 of patients initiate in each month over 6 months (i.e. 1/6 of patients have 6 months of therapy, 1/6 have 5 months of therapy etc.)

^b Assuming 3 hydrocortisone 4 mg tablets are used per day for current patients.

The redacted values correspond to the following ranges:

¹ < 500

² 500 to < 5,000

³ 5,000 to < 10,000

⁴ \$0 to < \$10 million

- 5.23 The estimated number of packs for each strength of Alkindi is estimated based Alkindi dosing guidance developed by Diurnal. The dosing guidance equates patient age with an average body weight and resulting body surface area in m² based on

WHO Child Growth Standards and provides the recommended daily dose (assumed to be 10 mg/m² divided into three doses).

- 5.24 The estimated financial implication of listing Alkindi include the following assumptions:
- In Year 1 of listing, uptake for newborns is ■% and ■% of prevalent patients 0.5 to 6 years of age switch to Alkindi from hydrocortisone tablets.
 - That there is 100% compliance.
- 5.25 The submission acknowledged that the estimates are uncertain and if the above assumptions are not met, the financial impact of listing may be overestimated.
- 5.26 There is a risk of use outside the target population in adult patients that the submission did not address. The pre-PBAC response considered there was no rationale for clinicians to prescribe Alkindi paediatric formulations to adults given the typical daily dose for adults of 30 mg specified in the TGA Product Information, could be achieved using the 4 mg and 20 mg tablets. The pre-PBAC response also noted that data from other markets where Alkindi is available indicates that use in adults is limited.
- 5.27 The submission also presented sensitivity analyses to evaluate the impact of variable changes to the estimated net financial implications. The variables tested include changing the mean dose per day to 15 mg/m², the incidence of congenital adrenal hyperplasia in newborns and assuming that current patients use two hydrocortisone 4 mg tablets daily. The results of the sensitivity analyses are presented in Table 3.

Table 3: Sensitivity analysis

Assumption	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Total
15 mg/m ² /day dosing	\$ ■ ¹	\$ ■ ¹	\$ ■ ¹	\$ ■ ¹	\$ ■ ¹	\$ ■ ¹	\$ ■ ¹
CAH incidence: 1:18,034 births	\$ ■ ¹	\$ ■ ¹	\$ ■ ¹	\$ ■ ¹	\$ ■ ¹	\$ ■ ¹	\$ ■ ¹
CAH incidence: 1:14,869 births	\$ ■ ¹	\$ ■ ¹	\$ ■ ¹	\$ ■ ¹	\$ ■ ¹	\$ ■ ¹	\$ ■ ¹
Assume current patients use 2 hydrocortisone 4mg tablets per day	\$ ■ ¹	\$ ■ ¹	\$ ■ ¹	\$ ■ ¹	\$ ■ ¹	\$ ■ ¹	\$ ■ ¹

Source: Table 28 of the submission,
 CAH= congenital adrenal hyperplasia
 The redacted values correspond to the following ranges:
¹ \$0 to < \$10 million

- 5.28 As a Category 3 submission, the financial estimates have not been independently evaluated.
- 5.29 The Department conducted utilisation analyses on the total number of patients aged 6 years or under who were supplied the 4 mg or 20 mg hydrocortisone tablets and scrips dispensed for the 4 mg and 20 mg hydrocortisone tablets in the years 2016 to 2020. The results of these analyses are presented below.

Table 4: Analyses on utilisation of hydrocortisone 4 mg and 20 mg tablets

	2016	2017	2018	2019	2020
Number of patients					
4 mg hydrocortisone tablet	364	344	349	338	321
20 mg hydrocortisone tablet	40	44	39	34	29
Total	404	388	388	362	350
Number of scrips					
4 mg hydrocortisone tablet	3030	3098	3058	2908	2818
20 mg hydrocortisone tablet	280	305	245	235	232
Total	3310	3403	3303	3143	3050
Drug costs (less patient copayments)					
4 mg hydrocortisone tablet	\$54,234.51	\$55,828.96	\$54,120.38	\$51,384.89	\$50,542.77
20 mg hydrocortisone tablet	\$2,816.63	\$3,823.94	\$2,870.45	\$3,326.93	\$2,742.85
Total	\$57,051.14	\$59,652.90	\$56,990.83	\$54,711.82	\$53,285.62

Based on date of supply data

Quality use of Medicines

- 5.30 The submission indicated that Alkindi would result in improved quality use of medicines by reducing dosing inaccuracies for paediatric patients which result from manipulation of adult formulations of hydrocortisone (hydrocortisone 4mg and 20 mg tablets). The submission stated that inconsistent and inaccurate dosing of hydrocortisone in paediatric patients with adrenal insufficiency places patients at risk of not achieving optimal disease control which can lead to short and long-term adverse consequences such as Cushing’s syndrome, adrenal crises and compromised growth.

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

6 PBAC Outcome

- 6.1 The PBAC recommended the Authority Required (STREAMLINED) listing of Alkindi for replacement therapy of adrenal insufficiency in patients aged 6 years or under. The PBAC made its recommendation on the basis that Alkindi would be acceptably cost-effective if listed with a modest price advantage over the currently listed hydrocortisone 4 mg tablets for this population.
- 6.2 The PBAC acknowledged there was a high demand for a formulation of hydrocortisone more suitable for paediatric dosing than the currently listed 4 mg and 20 mg tablets.

- 6.3 The PBAC considered that Alkindi was therapeutically equivalent to hydrocortisone tablets on a mg to mg basis.
- 6.4 The PBAC noted that paediatric patients require small doses which may be difficult to achieve with hydrocortisone tablets. The PBAC considered that Alkindi would facilitate accurate dosing in paediatric patients and may be easier to administer to paediatric patients than hydrocortisone tablets, which need to be crushed prior to administration. However, the PBAC considered there was insufficient evidence to establish that treatment with Alkindi would reduce the incidence of adverse effects associated with inadequately managed adrenal insufficiency such as adrenal crises.
- 6.5 The PBAC noted the requested price represented a significant increase in cost per mg of drug compared to the currently listed tablets (\$█████ per mg for Alkindi versus \$0.067 per mg for 4 mg tablets and \$0.016 per mg for 20 mg tablets). The PBAC considered a price of this magnitude to be unjustified although a modest price advantage for facilitating accurate dosing and ease of administration in paediatric patients would be reasonable.
- 6.6 The PBAC considered that Alkindi should be cost-minimised against the currently available hydrocortisone 4 mg tablets with a modest price advantage to be negotiated between the Sponsor and Department.
- 6.7 The PBAC considered that use of Alkindi should be limited to patients aged 6 years or under. The PBAC considered that this patient population would most likely require dose titrations at intervals difficult to achieve with the currently available hydrocortisone tablets.
- 6.8 The PBAC considered that a maximum quantity of 2 packs with 2 repeats would be sufficient for around three months of treatment noting that patients would likely be prescribed more than one strength of Alkindi.
- 6.9 The PBAC noted there was some uncertainty around the financial estimates with respect to the assumed compliance and uptake rate. However, the PBAC considered that many prescribers would switch paediatric patients to Alkindi if it becomes available on the PBS.
- 6.10 The PBAC did not consider that the circumstances exist in relation to the pharmaceutical item to advise the Minister that Section 101(4AB) (a) to (c) of the *National Health Act 1953* should apply to Alkindi. The PBAC noted that Alkindi represented a suitable therapy for a particular patient population with adrenal insufficiency (criterion i) of Section 101(4AB)(d)) and that Alkindi is suitable for use by paediatric patients (criterion ii) of Section 101(4AB)(d)). However, the PBAC considered that the existing hydrocortisone tablets are a suitable alternative therapy for paediatric patients and therefore considered that criterion iii) of Section 101(4AB)(d) was not met.

- 6.11 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because Alkindi is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over hydrocortisone tablets, 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 2009* for Pricing Pathway A were not met.
- 6.12 PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

- 7.1 Add new item as follows:

MEDICINAL PRODUCT Medicinal Product Pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
HYDROCORTISONE hydrocortisone 500 microgram granules in capsules, 50 capsules	NEW	2	100	2	Alkindi
hydrocortisone 1 mg granules in capsules, 50 capsules	NEW	2	100	2	Alkindi
hydrocortisone 2 mg granules in capsules, 50 capsules	NEW	2	100	2	Alkindi
hydrocortisone 5 mg granules in capsules, 50 capsules	NEW	2	100	2	Alkindi
Restriction Summary [New] / Treatment of Concept: [New]					
	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 [new code]				
	Indication: Replacement therapy of adrenal insufficiency				
	Population criteria:				
	Patient must be 6 years of age or less				
	Administrative Advice: Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners				

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 10 Sponsor's Comment

Chiesi Australia welcomes the PBAC positive recommendation to approve and list Alkindi® (Hydrocortisone)- Granules (in Capsules) on the Pharmaceutical Benefits Scheme. Chiesi Australia looks forward to working with the PBAC and the Department of Health to move forward on securing access to Alkindi on the Schedule of Pharmaceutical Benefits.