

Special Foods Subcommittee meeting held 21 May 2010

(minutes for web publishing)

Special Foods Subcommittee minutes are published in accordance with the *Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) and PTAC Subcommittees 2008*.

Note that this document is not necessarily a complete record of the Special Foods Subcommittee meeting; only the relevant portions of the minutes relating to Special Foods Subcommittee discussions about an Application or PHARMAC staff proposal that contain a recommendation are published.

The Special Foods Subcommittee may:

- (a) recommend that a pharmaceutical be listed by PHARMAC on the Pharmaceutical Schedule and the priority it gives to such a listing;
- (b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or
- (c) recommend that PHARMAC decline to list a pharmaceutical on the Pharmaceutical Schedule.

These Subcommittee minutes were reviewed by PTAC at its meeting on 4 & 5 November 2010, the record of which is available on the PHARMAC website.

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1 Extensively hydrolysed formula (Alfare) for the treatment of cow's milk protein allergy, food intolerance and hypersensitivity

Application

- 1.1 The Subcommittee reviewed an application from Nestle Healthcare Nutrition for the listing of its extensively hydrolysed infant formula (Alfare) on the Pharmaceutical Schedule for the treatment of cow's milk protein allergy, food intolerance and hypersensitivity.

Recommendation

- 1.2 The Subcommittee **recommended** that Alfare is listed on the Pharmaceutical Schedule with a high priority.
- 1.3 The Decision Criteria particularly relevant to this recommendation are: *(i) The health needs of all eligible people within New Zealand; (iv) The clinical benefits and risks of pharmaceuticals; (v) The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services, and (vi) The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule.*

Discussion

- 1.4 The Subcommittee noted that it had previously requested the supplier submit a funding application for Alfare. Members noted that Pepti Junior Gold was the only currently funded extensively hydrolysed formula funded on the Pharmaceutical Schedule.
- 1.5 The Subcommittee noted that Alfare is currently used in Australia although uptake is surprisingly low. The Subcommittee noted that its contents are clinically appropriate, and that currently the majority of patients who could use Alfare were using the more expensive Neocate.
- 1.6 The Subcommittee noted that Alfare was an appropriate clinical alternative to Neocate for the majority of patients and that as it was significantly cheaper it would be cost-saving.

2 Hydrolysed rice protein formula (Risolac) for the treatment of infants with food allergies

Application

- 2.1 The Subcommittee reviewed an application from Heinz Wattie's Ltd for the listing of hydrolysed rice protein formula (Risolac) on the Pharmaceutical Schedule for the treatment of infants with food allergies.

Recommendation

- 2.2 The Subcommittee **recommended** that the Application for hydrolysed rice protein formula (Risolac) be referred to the Paediatric Society or a similar special interest group for an opinion regarding its potential use and place in therapy.

Discussion

- 2.3 The Subcommittee noted that the supplier considered that hydrolysed rice protein formula could fit into the infant formula treatment algorithm that was consulted upon in the January 2010 Special Foods Consultation Document as follows:
- 2.3.1 for infants over 6 months - following failure on soy formula and before trial of hydrolysed formula.
 - 2.3.2 for infants under 6 months – prior to the use of extensively hydrolysed formula.
- 2.4 The Subcommittee considered that hydrolysed rice protein formula has a reasonably similar profile to the extensively hydrolysed formulae Pepti Junior Gold and Alfare.
- 2.5 The Subcommittee noted that the duration of a patient's allergies appeared to be shorter when Risolac was used instead of alternative products and that the taste of Risolac was acceptable.
- 2.6 The Subcommittee noted that the World Allergy Organisation (WAO) Diagnosis and Rationale for Action against Cow's Milk Allergy (DRACMA) Guidelines (Fiocchi et al, *WAO Journal*, 2010 Apr: 57-161) indicated that rice hydrolyzed formula was not available when a number of guidelines, including the Australian Consensus Panel Guidelines for the use of infant formulas to treat cows milk protein allergy (Kemp et al, 2008 MJA; 188:2 p109-112), were formulated.
- 2.7 The Subcommittee noted that rice hydrolyzed formula is being considered for use in Australia and considered that PHARMAC staff should obtain a copy of any recommendations when they are finalised.
- 2.8 The Subcommittee considered that New Zealand data comparing rice hydrolyzed formula to other relevant formula including soy, extensively hydrolysed and amino acid based formula would be useful.

3 Premature infant post discharge formula (S-26 Gold Premgro)

Application

- 3.1 The Subcommittee reviewed an application from Wyeth Australia Pty Limited for the listing of a new premature infant post discharge formula powder S-26 GOLD PREMGRO on the Pharmaceutical Schedule.

Recommendation

- 3.2 The Subcommittee **recommended** that S-26 GOLD PREMGRO be listed in the Pharmaceutical Schedule with a high priority subject to advice from neonatologists.

- 3.3 The Decision Criteria particularly relevant to this recommendation are: *(iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things.*

Discussion

- 3.4 The Subcommittee noted that S-26 GOLD PREMGRO is designed to be used as a transitional product between low-birth weight (LBW) formula which is used in hospitals and standard term formula which is used in the community when breast feeding is not possible.
- 3.5 The Subcommittee noted that currently infants are using fully funded S-26 GOLD LBW RTF 100 ml liquid (a pre-term formula used post term), a standard formula, or concentrating a standard formula. The Subcommittee noted that a number of additives may also be added to the concentrated standard formula including maltodextrin, calogen, duocal, Vitadol C, iron, alpha calcidiol, sodium and zinc.
- 3.6 The Subcommittee considered that the use of a preterm formula such as S-26 GOLD LBW RTF may provide excessive kcal, that a standard formula may be insufficient, and that adding additives to a formula is not ideal.
- 3.7 The Subcommittee noted that no randomised control trial evidence was supplied supporting the use of S-26 GOLD PREMGRO, however the Subcommittee noted that experts supported its use and that the components of S-26 GOLD PREMGRO - including the protein to energy ratio, the calcium to phosphate ratio, and the amounts of iron, zinc and vitamins A, D, and E - were more appropriate for the intended patient group than the components of the current products. The Subcommittee considered that no similar products were currently listed on the Pharmaceutical Schedule and that if S-26 GOLD PREMGRO was listed it would not be used in conjunction with other products.
- 3.8 The Subcommittee noted that the supplier suggested a Special Authority which would restrict the use of S-26 GOLD PREMGRO to premature infants born at less than 30 (or 33 weeks) gestation for whom breastfeeding is not possible and that the Special Authority should last for a period of 6 months. The Subcommittee noted that currently S-26 GOLD LBW RTF is restricted to infants weighing less than 1.5 kg.
- 3.9 The Subcommittee recommended that advice is sought from Neonatologists from the Perinatal Society of New Zealand regarding the use of S-26 GOLD PREMGRO and what restrictions would be appropriate.
- 3.10 The Subcommittee considered that if S-26 GOLD PREMGRO is listed on the Pharmaceutical Schedule then S-26 GOLD LBW RTF should be delisted because S-26 GOLD PREMGRO would be clinically more appropriate.
- 3.11 The Subcommittee considered that listing S-26 GOLD PREMGRO on the Pharmaceutical Schedule would result in increased expenditure as currently usage of S-26 GOLD LBW RTF is limited due to the high calorie content, although this would be offset by a possible reduction in the use of additives (i.e. vitamin and mineral supplements and Duocal and Polycal).

4 Powder oral supplement (Enprocal)

Application

- 4.1 The Subcommittee reviewed an application from Prime Nutrition for the listing of Enprocal a powder oral supplement on the Pharmaceutical Schedule.

Recommendation

- 4.2 The Subcommittee **recommended** that the Application for Enprocal be declined.
- 4.3 The Decision Criteria particularly relevant to this recommendation are: *(iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things.*

Discussion

- 4.4 The Subcommittee noted that Enprocal was a protein based, high energy, and nutrient dense powder oral supplement. The Subcommittee noted that the evidence supporting its use was limited.
- 4.5 The Subcommittee noted that Enprocal can be used in both hospital and aged care environments to supplement the diets of those who are frail and malnourished as it assists with maintaining and increasing weight.
- 4.6 The Subcommittee noted that Enprocal could be mixed in food or drinks or used as a sprinkle.
- 4.7 The Subcommittee noted that Enprocal was high in vitamin A and protein and therefore would be relatively contraindicated for those with renal impairment.
- 4.8 The Subcommittee considered that the role of Enprocal was ideally as a food fortifier.
- 4.9 The Subcommittee considered that Enprocal was not nutritionally complete and that currently there was a reasonable range of alternatives.

5 Gluten Free Bread Mix (Multi-seed) for gluten enteropathy or dermatitis herpetiformis

Application

- 5.1 The Subcommittee reviewed an application from New Zealand Bakels for the listing of a Multi-Seed gluten free bread mix on the Pharmaceutical Schedule for the treatment of gluten enteropathy or dermatitis herpetiformis.

Recommendation

- 5.2 The Subcommittee **recommended** that there were no clinical reasons not to fund Multi-Seed gluten free bread mix on the Pharmaceutical Schedule, and that any listing should be cost-neutral.
- 5.3 The Decision Criteria particularly relevant to this recommendation are: *(iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things; (v) The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services, and (vi) The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule.*

Discussion

- 5.4 The Subcommittee noted that there are a number of gluten free bread mixes already funded on the Pharmaceutical Schedule.
- 5.5 The Subcommittee noted that a Multi-Seed gluten free bread mix would increase the variety of products available and that it would provide a mixed grain and higher fibre bread mix option.

6 Elemental powder custard-style supplement (Neocate Nutra) for severe cows milk and multiple food protein intolerance

Application

- 6.1 The Subcommittee reviewed an application from Nutrica for the listing of Neocate Nutra, an amino acid based elemental powder which mixes into a custard like consistency, for use in weaning infants from liquids to solids in the treatment of infants with cow's milk allergy or multiple food protein intolerance who require an amino acid based product.

Recommendation

- 6.2 The Subcommittee **recommended** that the Application for Neocate Nutra be declined.
- 6.3 The Decision Criteria particularly relevant to this recommendation are: *(iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things;*

Discussion

- 6.4 The Subcommittee noted that the application was for the use of Neocate Nutra, a 400 g powder which mixes into a custard like consistency, as a weaning product for infants suffering from cow's milk allergy or, multiple food protein intolerance when switching from a liquid to a solid diet.
- 6.5 The Subcommittee considered that currently there are appropriate weaning options available such as a custard made with Neocate formula and baby rice which can be

mixed with water or Neocate formula. The Subcommittee therefore considered that there is no unmet health need for essentially what is a weaning pudding.

- 6.6 The Subcommittee noted that Neocate Nutra had a high cost per day and would be used in addition to standard Neocate.

7 Ketogenic diet formula (Ketocal)

Application

- 7.1 The Subcommittee reviewed an application from Nutricia for the listing of its ketogenic diet formula (Ketocal) on the Pharmaceutical Schedule.

Recommendation

- 7.2 The Subcommittee **recommended** that Ketocal be listed in the Pharmaceutical Schedule with a high priority for use by patients requiring a ketogenic diet.
- 7.3 The Decision Criteria particularly relevant to this recommendation are: *(i) The health needs of all eligible people within New Zealand; (iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things; and (v) The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services.*

Discussion

- 7.4 The Subcommittee noted that the application was for a nutritionally complete easy to use powdered ketogenic diet formula (Ketocal) which could be used as a sole diet or as a supplement/meal replacement in the dietary management of intractable epilepsy and other conditions requiring a Ketogenic Diet (KD).
- 7.5 The Subcommittee noted that Ketocal had a 4:1 ratio (4 g fat for every 1 g carbohydrate and protein) and that it was not suitable for children under 1 year of age.
- 7.6 The Subcommittee noted a case study which reported that Ketocal was well tolerated by 16 of 17 children it was trialed on.
- 7.7 The Subcommittee estimated that there were about 7 children in New Zealand who are currently on a ketogenic diet but that the potential patient number could be greater than this as currently some patients who require a ketogenic diet are not adhering to one.
- 7.8 The Subcommittee noted that currently when patients are initiated onto a ketogenic diet in hospital, a ketogenic formula is calculated by dietitians and provided to patients while the child's metabolism adapts to the diet and patients/parents learn how to make it themselves. A number of products are mixed together including Protifar and Calogen when making oral formula, and Protifar, Calogen, Maltodextrin, Metabolic Mineral Mix, Ketovite tablets and liquid or more recently crushed or effervescent OTC vitamin and mineral preparations. The child follows the Ketogenic diet for 3 months while the medical

team and family assess its effectiveness and consider whether they will continue with the diet.

- 7.9 The Subcommittee considered that Ketocal would be useful for those with the need for tube feeding due to disability or for patients' sick at home and who cannot eat. The Subcommittee considered that patients who are able to eat would not use Ketocal as a full time diet replacement as they would prefer to eat solid food.
- 7.10 The Subcommittee considered that Ketocal could be restricted by Special Authority to Metabolic Physicians or Paediatric Neurologists and patients over 1 year of age. The Subcommittee considered that an initial Special Authority approval of 3 months with 2 yearly renewals would be appropriate. Members noted that Ketocal would be used first line however it would likely be cost-saving to the health-sector.

8 2.4 kcal/ml liquid oral feed (Fortisip Compact)

Application

- 8.1 The Subcommittee reviewed an application from Nutrica for the listing of its 2.4 kcal/ml liquid oral feed (Fortisip Compact) on the Pharmaceutical Schedule.

Recommendation

- 8.2 The Subcommittee noted that there were no clinical reasons not to fund the product, and **recommended** that Fortisip Compact only be listed on the Pharmaceutical Schedule if cost-saving to the Pharmaceutical Schedule.
- 8.3 The Decision Criteria particularly relevant to this recommendation are: *(iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things; (v) The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services, (vi) The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule.*

Discussion

- 8.4 The Subcommittee noted that the application was for a 2.4 kcal/ml liquid oral feed (Fortisip Compact) which was available in a 125 ml bottle which provided 300 kcal.
- 8.5 The Subcommittee noted that standard 1.5 kcal/ml Fortisip and Ensure Plus products provided 300 kcal's or 355 kcal's in 200 ml or 237 ml packs respectively, and that the standard Two Cal HN 2.0 kcal/ml product provided 474 kcal's in a 237 ml pack.
- 8.6 The Subcommittee noted that Fortisip Compact was a concentrated oral feed which provided a high energy and protein content. The Subcommittee considered the viscosity of Fortisip Compact to be acceptable.

- 8.7 The Subcommittee noted that patients would require additional fluids in addition to Fortisip Compact to meet their fluid requirements and therefore an alternative would be to use other less concentrated products such as Two Cal HN.
- 8.8 The Subcommittee noted that there was no evidence provided that indicated that Fortisip Compact provided a health benefit over current available products and the Subcommittee considered that there were no problems with the access to or availability of the current products. The Subcommittee concluded that there was no unmet clinical need for Fortisip Compact however it considered that it could be listed on the Pharmaceutical Schedule if it would be a saving to the Pharmaceutical Budget.