Special Foods Subcommittee of PTAC
Meeting held 5 December 2013

(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 generally 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 8 & 9 May 2014, the record of which will be available in July 2014.

Record of the Special Foods Subcommittee of PTAC meeting held at PHARMAC on 5 December 2013

1 Record of the previous Subcommittee meeting

1.1 The Subcommittee reviewed the minutes of its previous meeting held on 27 August 2012.

1.2 In relation to the discussion on the Special Authority initial application for extensively hydrolysed formula (section 6 - Hospital Pharmaceuticals), the Subcommittee considered that for chylous ascites and chlyothorax, Monogen or MCT Pepdite should be used (rather than Monogen or Peptamen Junior). Accordingly, the Subcommittee **recommended** the following amendment be made to the minutes (changes marked in bold and strikethrough):

> **SPECIAL AUTHORITY – EXTENSIVELY HYDROLYSED FORMULA**
>
> Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6months for applications meeting the following criteria:
>
> Any of the following:
> 1 Both:
> 1.1 Cows' milk formula is inappropriate due to severe intolerance or allergy to its protein content; and
> 1.2 Either:
> 1.2.1 Soy milk formula has been trialled without resolution of symptoms; or
> 1.2.2 Soy milk formula is considered clinically inappropriate or contraindicated; or
> 2 Severe malabsorption; or
> 3 Short bowel syndrome; or
> 4 Intractable diarrhoea; or
> 5 Biliary atresia; or
> 6 Cholestatic liver diseases causing malabsorption; or
> 7 ~~Chylous ascite; or~~ (Monogen or ~~Peptamen Junior~~ **MCT Pepdite** should be used for this indication)
> 8 ~~Chylothorax; or~~ (Monogen or ~~Peptamen Junior~~ **MCT Pepdite** should be used for this indication)
> 9 Cystic fibrosis; or
> 10 Proven fat malabsorption; or
> 11 Severe intestinal motility disorders causing significant malabsorption; or
> 12 Intestinal failure.

1.3 The remainder of the minute was accepted.

1.4 The Subcommittee also reviewed the minutes of its meetings held on 26 September 2012 and 5 September 2013 and had no comments.

Special Foods, Paediatric Products

1.5 The Subcommittee noted that Standard Supplements listing in the HML has the following restriction:

"For patients who have, or are expected to, eat little or nothing for 5 days"

1.6 The Subcommittee **recommended** that a similar restriction is applied in the HML to the Special Foods, Paediatric Products, to allow children who are expected to eat little or nothing for an extended period of time to access paediatric products.

Infant formula for infants whose mothers are HIV positive

1.7 The Subcommittee reviewed correspondence from the Ministry of Health relating to the subsidisation of standard infant formula for infants whose mothers are HIV positive.

1.8 The Subcommittee considered that in this case, infant formula is a standard food and is not a medical food.

1.9 The Subcommittee considered that no distinction could be made between the mothers with HIV and mothers who were unable to breast feed their infants for other reasons e.g. mothers with double mastectomies and mothers receiving chemotherapy treatment.

1.10 The Subcommittee **recommended** that standard infant formula is not listed on the Pharmaceutical Schedule for use in infants whose mothers cannot breast feed (for any reason).

1.11 The Decision Criteria particularly relevant to these recommendations 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.*

Nutrient modules

1.12 The Subcommittee noted the 1 July 2013 change to the Special Authority criteria for fat modules.

1.13 The Subcommittee considered that the restriction relating to the term 'modular formula' should be amended to better clarify the intent of the restriction. Therefore, the Subcommittee **recommended** that modular formula should be defined as a formula made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule. The Subcommittee noted that patients would be required to meet any Special Authority criteria associated with all of the products used in the modular formula.

Standard supplements

1.14 The Subcommittee reviewed correspondence from the Crohn's Society of New Zealand to PHARMAC relating to the use of exclusive enteral nutrition (EEN) for the remission of Crohn's disease in children. The Subcommittee noted its August 2012 minutes on the use of Standard Supplements as an EEN.

1.15 The Subcommittee considered that Crohn's disease in patients up to age 18 years old tends to be more aggressive when compared with Crohn's disease in adults and that paediatric Crohn's patients have high health need.

1.16 The Subcommittee noted that the majority of evidence supporting the use of an EEN diet to induce the remission of Crohn's disease in children used a ready to drink formulation. The Subcommittee considered that the availability of ready to drink standard supplements for EEN for children with Crohn's disease may be an important contributing factor to compliance with therapy. The Subcommittee considered that compliance was vital to the success of this therapy.

1.17 The Subcommittee noted that the alternative therapy used to induce remission is steroids. The Subcommittee considered that there was an increase chance of sustained remission rate with an EEN diet for 6-8 weeks in children when compared with use of steroids to induce remission. The Subcommittee considered that the available evidence supported a higher chance of complete mucosal healing, and therefore longer remission, in children treated with EEN compared with steroids. The Subcommittee considered that the use of ready to drink standard supplements for EEN in children with Crohn's disease may potentially delay the use of biological treatments (e.g. tumour necrosis factor alpha inhibitors) in these patients. The Subcommittee considered that up to 50 children per year with Crohn's disease would benefit from a 6-8 week course of EEN.

1.18 The Subcommittee **recommended** that the endorsement for full funding of the Standard Supplement liquid oral feeds should be extended to patients aged up to 18 years for use in the remission of Crohn's disease for a 6-8 week period as a sole diet and then for an additional 4 week transition period. The Subcommittee gave this recommendation a high priority.

1.19 The Decision Criteria particularly relevant to these recommendations are: *(iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things, (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, (vi) The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule.*

Infant Formula

1.20 The Subcommittee noted the data presented by PHARMAC staff regarding currently subsidised infant formula. The Subcommittee consider that the number of patients receiving extensively hydrolysed formula (eHF) and amino acid formula (AAF) are high compared to the number of patients reported to have true allergy. Furthermore the Subcommittee questioned whether a soy formula could be used in a proportion of these patients.

1.21 The Subcommittee considered that the indications that are specified in the Special Authority restriction for eHF are difficult diseases to diagnose and could be outside of the scope of a number of the prescriber types authorised to make Special Authority applications. The Subcommittee hypothesised that this may be a contributing factor to the higher than predicted patient numbers and commented that prescriber data may provide insight.

1.22 The Subcommittee noted that the treatment pathway allowed progression to amino acid formula (AAF) following documented intolerance of eHF following a reasonable trial. The Subcommittee noted that the Special Authority for AAF does not include a definition of 'reasonable trial.' The Subcommittee noted its August 2012 recommendation that 'reasonable trial' be defined as being a 2 to 4 week trial. The Subcommittee also noted that a definition relating to a trial of soy formula has not been included in the Special Authority for eHF. The Subcommittee **recommended** that a reasonable trial would be considered as being a 2 to 4 week trial. The Subcommittee considered that this definition was appropriate for both a reasonable trial of eHF for AAF applications and for a reasonable trial of soy formula for eHF applications.

1.23 The Subcommittee considered that stopping criteria had not been clearly defined in the Special Authorities for eHF and AAF. The Subcommittee noted the length of the Special Authority approval for AAF and eHF and commented that an earlier follow up visit to evaluate the treatment may be useful to establish whether treatment is beneficial.

1.24 The Subcommittee **recommended** that the Special Authority criteria for eHF be amended to (changes marked in bold and strikethrough):

> **Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:
> Any of the following:
> 1 Both:
> 1.1 Cows milk formula is inappropriate due to severe intolerance or allergy to its protein content; and
> 1.2 Either:
> 1.2.1 Soy milk formula has been **reasonably** trialled without resolution of symptoms; or
> 1.2.2 Soy milk formula is considered clinically inappropriate or contraindicated; or
> 2 Severe malabsorption; or
> 3 Short bowel syndrome; or
> 4 Intractable diarrhoea; or
> 5 Biliary atresia; or
> 6 Cholestatic liver diseases causing malsorption; or
> 7 Cystic fibrosis; or
> 8 Proven fat malabsorption; or
> 9 Severe intestinal motility disorders causing significant malabsorption; or
> 10 Intestinal failure.
>
> **Note: A reasonable trial is defined as a 2-4 week trial**

1.25 The Subcommittee **recommended** that the Special Authority criteria for AAF be amended to:

> **Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:
> Any of the following:

1. Extensively hydrolysed formula has been reasonably trialled and is inappropriate due to documented severe intolerance or allergy or malabsorption; or
2. History of anaphylaxis to cow's milk protein formula or dairy products; or
3. Eosinophilic oesophagitis.

Note: A reasonable trial is defined as a 2-4 week trial

Infatrini

1.26 The Subcommittee noted the further information requested from PHARMAC staff in relation to a funding application for Infatrini, a high energy (1 kcal/ml), ready to feed, infant formula which is not currently listed on the Pharmaceutical Schedule or Part II of Section H of the Pharmaceutical Schedule. The Subcommittee noted its previous discussion relating to Infatrini and its recommendation that Infatrini is listed on the Pharmaceutical Schedule with a medium/high priority.

1.27 The Subcommittee reviewed the application and considered that infants with faltering growth who are fluid restricted and who had failed every other manoeuvre would be the patient group most likely to gain clinical benefit from Infatrini. The Subcommittee considered that this product would be the sole source of nutrition in this patient group which would be up to 250 children per year. The Subcommittee considered that treatment would be initiated in these patients in hospital and these patients would be under the hospital care of a paediatrician.

1.28 The Subcommittee noted that the alternative treatment option for this patient group is standard formula that had been fortified with a fat module. However the Subcommittee noted that the high osmolality of standard formula fortified with a fat module could result in poor tolerance of the formulation. Therefore the Subcommittee concluded that Infatrini high energy, ready to feed, infant formula offers clinical advantages over standard formula that had been fortified with a fat module in patients who are fluid restricted and who had failed every other manoeuvre. The Subcommittee considered that patients who received treatment with a high energy infant formula may still require a nasogastric tube, noting that these patients may tire of feeding and a high energy infant formula may be administered via a nasogastric tube.

1.29 The Subcommittee **recommended** that Infatrini high energy (1 kcal/ml), ready to feed, infant formula is listed in Section D of the Pharmaceutical Schedule with a medium/high priority under the following Special Authority:

SPECIAL AUTHORITY – HIGH ENERGY READY TO FEED INFANT FORMULA

Initial application - only from a paediatrician or on the recommendation of a paediatrician. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:
1. Patient is fluid restricted and has been diagnosed with faltering growth
2. Patient is under the care of a hospital paediatrician who has recommended treatment with a high energy infant formula

Renewal - only from a paediatrician or on the recommendation of a paediatrician. Approvals valid for 6months for applications meeting the following criteria:

All of the following:

1. Patient is fluid restricted and has been diagnosed with faltering growth
2. Patient is under the care of a hospital paediatrician who has recommended treatment with a high energy infant formula
3. Patient has only received one previous approval for high energy ready to feed infant formula

1.30 The Subcommittee **recommended** that the Infatrini high energy (1 kcal/ml), ready to feed, infant formula be listed on the Part II of Section H of the Pharmaceutical Schedule subject to the following restriction:

Restricted
Paediatrician

Fluid restricted with faltering growth
Patient is fluid restricted and will not meet their nutritional requirements with other formula or has been diagnosed with faltering growth

1.31 The Decision Criteria particularly relevant to these recommendations are: *(iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things, (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, (vi) The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule.*

2 Food/fluid thickeners and pre-thickened fluids

General Recommendations

2.1 The Subcommittee recommended that food/fluid thickeners and pre-thickened fluids should not be listed in Section D of the Pharmaceutical Schedule for use in patients with dysphagia in the community.

2.2 The Subcommittee recommended that community funded food thickeners (Karicare Aptamil) be delisted from Section D of the Pharmaceutical Schedule.

2.3 The Subcommittee recommended that the following currently listed food/fluid thickeners; carob bean gum with maize starch and maltodextrin, maize starch, and maltodextrin with xanthan gum and ascorbic acid, continue to be listed on the HML (Part II of Section H of the Pharmaceutical Schedule) for inpatient use in patients with dysphagia subject to the following restrictions, with specific brand(s) to be determined by PHARMAC with reference to the Subcommittee's additional recommendations:

Restricted
For in-hospital use in patients with dysphagia diagnosed by a speech language therapist, where the speech language therapist has recommended the use of thickened fluids.

2.4 The Subcommittee recommended that nectar-thick (mildly-thick) and honey-thick (moderately-thick) pre-thickened fluids be listed on Part II of Section H of the Pharmaceutical Schedule for inpatient use in patients with dysphagia, with a medium priority, subject to the following restrictions, with specific brand(s) to be

determined by PHARMAC with reference to the Subcommittee's additional recommendations.

> **Restricted**
> For in-hospital use in patients with dysphagia diagnosed by a speech language therapist, where the speech language therapist has recommended the use of thickened fluids.

2.5 The Subcommittee recommended that pudding-thick (extremely thick) pre-thickened fluids are not listed on Part II of Section H the Pharmaceutical Schedule.

2.6 The Decision Criteria particularly relevant to these recommendations are: (iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things, (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, (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

Current Situation

2.7 The Subcommittee noted that Karicare Aptamil Feed Thickener food thickener is currently listed in Section D of the Pharmaceutical Schedule subject to Special Authority criteria restricting its use to patients with motor neurone disease with swallowing disorder. The Subcommittee also noted that fluid/fluid thickeners are listed on Part II of Section H of the Pharmaceutical Schedule (HML) as follows (brand names in brackets are examples only; DHBs can currently use any brand of these products):

> **FOOD/FLUID THICKENERS**
>
> CAROB BEAN GUM WITH MAIZE STARCH AND MALTODEXTRIN
> Powder (Karicare Aptamil Feed Thickener)
>
> GUAR GUM
> Powder (Guarcol)
>
> MAIZE STARCH
> Powder (Resource Thicken Up; Nutilis)
>
> MALTODEXTRIN WITH XANTHAN GUM
> Powder (Instant Thick)
>
> MALTODEXTRIN WITH XANTHAN GUM AND ASCORBIC ACID
> Powder (Easy Thick)

2.8 The Subcommittee noted that while pre-thickened drinks and supplements are not listed on Part II of Section H of the Pharmaceutical Schedule (HML) a note within the HML informs that DHB hospitals may continue to use such products, provided that use was established in the particular DHB hospital prior to 1 July 2013, and that PHARMAC intends to make a further decision in relation to pre-thickened drinks and supplements in the future and will notify of any change to this situation.

2.9 The Subcommittee noted its previous minutes relating to food/fluid thickeners and pre-thickened fluids and its deferral on making a recommendation pending receipt of further information from relevant clinical groups. The Subcommittee noted that information had been requested from the following groups: speech language therapists, geriatricians, neurologists, dietitians, gastroenterologists and otolaryngologists. The Subcommittee noted the recent responses from speech language therapists (including opinion from a lecturer in speech language therapy), dietitians and geriatricians. The Subcommittee noted earlier responses from a neurologist, a gastroenterologist, speech language therapists, dietitians and a geriatrician. The Subcommittee also noted the supporting literature and information provided by two suppliers on this topic along with funding applications for products that fall within this category. The Subcommittee considered that on the basis of the information provided, it was able to progress to making a recommendation in relation to food/fluid thickeners and pre-thickened fluids.

2.10 The Subcommittee noted that the funding applications would be considered individually; however, the Subcommittee considered that discussions relating to food/fluid thickeners and pre-thickened fluids in this agenda item are relevant to the following applications:

- Nutilis - maize starch powder (Nutricia Ltd)
- Instant Thick - maltodextrin with xanthan gum (Flavour Creations)
- Easy Thick - maltodextrin with xanthan gum and ascorbic acid (Flavour Creations)
- Pre –thickened fluids including:
  - Flavour Creations - Thickened Water
  - Flavour Creations - Thickened Hot Beverages
  - Flavour Creations - Thickened Cordials
  - Flavour Creations - Thickened Juices
  - Flavour Creations - Thickened Functional Juices
  - Flavour Creations - Thickened Milk Based Drinks
  - Flavour Creations - Thickened Protein Enriched Products
  - Flavour Creations - Thickened Formulated Meal Replacement Drinks

Clinical use

2.11 The Subcommittee noted that thickened fluids can be made by adding a thickening powder to a fluid or they can be purchased, pre-thickened, from a supplier. The Subcommittee considered that the method of producing a thickened fluid i.e. using a powder or purchasing a pre-thickened fluid, did not impact its therapeutic effect. The Subcommittee noted thickened fluids are used as a compensation technique for patients with dysphagia with an aim of preventing aspiration. The Subcommittee considered that the use of thickened fluids is a contentious subject with conflicting information on the benefits and drawbacks of this technique. The Subcommittee considered that aspiration of fluids can still occur when a patient is receiving thickened fluids and considered that, once aspirated, it may be more difficult to clear the airways of a thickened fluid. The Subcommittee considered that dysphagia alone does not predict the incidence of aspiration. The Subcommittee noted that dysphagia and aspiration are associated with high mortality and morbidity. The Subcommittee noted that dehydration, malnutrition and aspiration pneumonia are common co-morbidities associated with dysphagia. The Subcommittee considered that patients with dysphagia have a high health need.

Evidence of use of thickened fluids in patients with dysphagia

2.12 The Subcommittee reviewed the studies provided by suppliers Nutricia Ltd and Flavour Creations, information provided by clinicians and further information it had sourced. The Subcommittee noted that the relevant information provided related to thickened fluids and therefore considered that it was relevant to the discussion on both powder thickeners and pre-thickened fluids. The Subcommittee considered that generally the quality of evidence to support the use of thickened fluids in patients with dysphagia was weak and of low quality. The Subcommittee considered that the heterogeneity of the patient group with dysphagia can make both the study of treatments and consistent clinical practice difficult. The Subcommittee considered that using non-thickened fluids and the chin down position is the appropriate first line technique in patients with dysphagia. The Subcommittee noted that there is some good strength and quality of evidence for the use of thickened fluids in order to prevent aspiration pneumonia in the acute phase of dysphagia. However the Subcommittee considered that there is no solid evidence for the use of thickened fluids in order to prevent aspiration pneumonia in patients with chronic dysphagia. The Subcommittee noted the systematic review, Andersen et al (e-SPEN Journal, 8:2013:e127-134) supported this conclusion. The Subcommittee considered that the acute phase of dysphagia would be present in a hospital setting. The Subcommittee considered that there are some clinical risks for patients treated with thickened fluids, particularly the risk that patients treated with thickened fluids were unable to meet their hydration needs. Subsequent to its review, the Subcommittee made the following recommendations:

- The Subcommittee **recommended** that powder thickeners and pre-thickened fluids be listed on Part II of Section H of the Pharmaceutical Schedule for patients with dysphagia with a medium priority.

- The Subcommittee **recommended** that powder thickeners and pre-thickened fluids are not listed in Section D of the Pharmaceutical Schedule.

- The Subcommittee **recommended** that Feed Thickener Karicare Aptamil be delisted and removed from Section D of the Pharmaceutical Schedule as there is no evidence to support the use of powder thickeners and pre-thickened fluids in this setting.

2.13 The Subcommittee considered that there was no evidence to suggest that any specific group of patients with dysphagia (e.g. those with dysphagia caused by motor neurone disease) would receive greater benefit from thickened fluids than any other group of patients with dysphagia. The Subcommittee considered that the cause of dysphagia would not predict a patient's clinical response to treatment with a thickened fluid. The Subcommittee considered that a restriction to the use of powder thickeners or a pre-thickened fluid should not be based on an indication.

2.14 The Subcommittee noted that dysphagia can be difficult to diagnose and may involve a bedside swallowing test, videofluroscopy and fibre optic evaluation. The Subcommittee noted that current practice involves trialling patients on different viscosities of thickened fluids and reviewing the outcome of these trials. The Subcommittee considered that a speech language therapist would be involved in making a diagnosis of dysphagia. The Subcommittee considered that the swallowing assessment process is beneficial to patients and considered that this process helped relieve patient anxiety associated with drinking fluids. The

Subcommittee **recommended** that powder thickeners and pre-thickened fluids should be listed on Part II of Section H of the Pharmaceutical Schedule subject to the following restriction:

> **Restricted**
> For in-hospital use in patients with dysphagia diagnosed by a speech language therapist, where the speech language therapist has recommended the use of thickened fluids.

2.15 The Decision Criteria particularly relevant to these recommendations are: *(iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things, (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, (vi) The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule.*

2.16 The Subcommittee noted that thickened fluids are also used for the treatment of gastro-oesophageal reflux disease (GORD) in infants. The Subcommittee considered that the evidence provided to support the use of thickened fluids in infants with GORD is weak and of low quality. The Subcommittee noted that thickened, anti-reflux infant formula is available and is listed on Part II of Section H of the Pharmaceutical Schedule. The Subcommittee considered that the clinical need for these patients had been met.

Which powder thickeners and/or pre-thickened fluids does the Subcommittee recommend?

2.17 The Subcommittee considered that powder thickeners and pre-thickened beverages have the same or similar therapeutic effect when used for dysphagia management. The Subcommittee considered that in certain situations, the use of pre-thickened fluids may be clinically beneficial over powder thickeners. The Subcommittee considered that these situations may include busy ward situations where a number of people would be involved with the care of a patient. The Subcommittee considered that a pre-thickened fluid may be beneficial in this situation to ensure uniform consistency of a thickened fluid. The Subcommittee also noted that there is a cost in terms of staff time present when using a powder thickener which would not occur when using a pre-thickened fluid. The Subcommittee considered in situations where a patient was being cared for primarily by a small number of care givers, or in situations where time pressure is not a factor, consistent provision of uniform treatment would be less of an issue. Therefore the Subcommittee considered in situations where a patient was being primarily cared for by a small number of care givers, or in situations where time pressure is not a factor there is no noticeable clinical benefit in the use of pre-thickened fluids over powder thickeners.

2.18 The Subcommittee considered that the properties of thickeners and pre-thickened products may vary between different chemicals e.g. one type of thickener may dissolve more readily in a cold fluid compared to another powder thickener. The Subcommittee considered that a range of powder thickeners that provided a range of properties would be required for use in different situations. The Subcommittee **recommended** that a range of powder thickeners that offer different properties be available on Part II of Section H of the Pharmaceutical Schedule. The

Subcommittee considered that these different properties may include being suitable for children, suitable for hot fluids, suitable for cold fluids, etc.

2.19 The Subcommittee considered that it would be sufficient to list only one brand of each type of the listed powder thickeners and pre-thickened products based on price.

2.20 The Subcommittee noted that the information provided by clinicians indicates that in New Zealand, two viscosities of thickened fluid are generally used, these being nectar-thick (mildly-thick) fluids and honey-thick (moderately-thick) fluids. The Subcommittee considered that this information indicates that patients requiring a pudding-thick (extremely thick) fluid are placed on an enteral feed rather than receiving extremely thick fluid to ensure their nutritional and fluid status. The Subcommittee therefore considered that there was no clinical need for pudding-thick (extremely thick) pre-thickened products to be available in DHB hospitals. The Subcommittee **recommended** that pudding-thick (extremely thick) pre-thickened fluids are not listed on Part II of Section H the Pharmaceutical Schedule.

3 Nutilis (maize starch powder food/fluid thickener)

Application

3.1 The Subcommittee reviewed an application from Nutricia Ltd for the listing of Nutilis (maize starch) food/fluid thickener in Part II of Section H of the Pharmaceutical Schedule and in Section D of the Pharmaceutical Schedule for patients with dysphagia.

Recommendations

3.2 The Subcommittee **recommended** that the application for Nutilis (maize starch) food/fluid thickener for listing in Section D of the Pharmaceutical Schedule for patients with dysphagia in the community be declined.

3.3 The Subcommittee **recommended** that a maize starch food/fluid thickener be listed on Part II of Section H of the Pharmaceutical Schedule for patients with dysphagia and noted that Nutilis food/fluid thickener falls within this category. The Subcommittee gave this recommendation a medium priority and considered that the following restriction should be applied to this pharmaceutical:

> **Restricted**
> For in-hospital use in patients with dysphagia diagnosed by a speech language therapist, where the speech language therapist has recommended the use of thickened fluids.

3.4 The Decision Criteria particularly relevant to these recommendations are: *(iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things, (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, (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

3.5 The Subcommittee referred to its separate discussion on the use of food/fluid thickeners and pre-thickened fluids at this meeting.

3.6 The Subcommittee considered there to be no clinical reason not to list the Nutilis brand of maize starch on Part II of Section H of the Pharmaceutical Schedule and noted that Nutilis food/fluid thickener is cost saving to other listed powder food/fluid thickeners.

4 Instant Thick (maltodextrin with xanthan gum food/fluid thickener)

Application

4.1 The Subcommittee reviewed an application from Flavour Creations for the listing of Instant Thick (maltodextrin with xanthan gum) food/fluid thickener on Part II of Section H of the Pharmaceutical Schedule and in Section D of the Pharmaceutical Schedule for patients with dysphagia.

Recommendations

4.2 The Subcommittee **recommended** that the application for Instant Thick (maltodextrin with xanthan gum) food/fluid thickener for listing in Section D of the Pharmaceutical Schedule for patients with dysphagia for use in the community be declined.

4.3 The Subcommittee **recommended** that a maltodextrin with xanthan gum and ascorbic acid food/fluid thickener or a maltodextrin with xanthan gum food/fluid thickener be listed on Part II of Section H of the Pharmaceutical Schedule for patients with dysphagia. The Subcommittee considered that it would be sufficient to list only one of maltodextrin with xanthan gum or maltodextrin with xanthan gum with ascorbic acid, based on price. The Subcommittee noted that Instant Thick food/fluid thickener is a maltodextrin with xanthan gum food/fluid thickener. The Subcommittee gave this recommendation a medium priority and considered that the following restriction should be applied to maltodextrin with xanthan gum food/fluid thickener should it be listed:

> **Restricted**
> For in-hospital use in patients with dysphagia diagnosed by a speech language therapist, where the speech language therapist has recommended the use of thickened fluids.

4.4 The Decision Criteria particularly relevant to these recommendations are: *(iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things, (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, (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

4.5 The Subcommittee referred to its separate discussion on the use of food/fluid thickeners and pre-thickened fluids at this meeting.

4.6 The Subcommittee noted the proposed cost of Instant Thick. The Subcommittee considered that there was no clinical reason not to list Instant Thick; however, there was no particular benefit of Instant Thick over the other food/fluid thickening powders available in DHB hospitals that would justify a higher price. The Subcommittee considered that there were no clinically significant differences between maltodextrin with xanthan gum and maltodextrin with xanthan gum and ascorbic acid. The Subcommittee considered that it would be sufficient to list only one of maltodextrin with xanthan gum or maltodextrin with xanthan gum with ascorbic acid, based on price.

5 Easy Thick (maltodextrin with xanthan gum and ascorbic acid food/fluid thickener)

Application

5.1 The Subcommittee reviewed an application from Flavour Creations for the listing of Easy Thick (maltodextrin with xanthan gum and ascorbic acid) food/fluid thickener on Part II of Section H of the Pharmaceutical Schedule and in Section D of the Pharmaceutical Schedule for patients with dysphagia.

Recommendations

5.2 The Subcommittee **recommended** that the application for Easy Thick (maltodextrin with xanthan gum and ascorbic acid) food/fluid thickener for listing in Section D of the Pharmaceutical Schedule for patients with dysphagia for use in the community be declined.

5.3 The Subcommittee **recommended** that a maltodextrin with xanthan gum and ascorbic acid food/fluid thickener or a maltodextrin with xanthan gum food/fluid thickener be listed on Part II of Section H of the Pharmaceutical Schedule for patients with dysphagia. The Subcommittee considered that it would be sufficient to list only one of maltodextrin with xanthan gum or maltodextrin with xanthan gum with ascorbic acid, based on price. The Subcommittee noted that Easy Thick food/fluid thickener is a maltodextrin with xanthan gum and ascorbic acid food/fluid thickener. The Subcommittee gave this recommendation a medium priority and considered that the following restriction should be applied to maltodextrin with xanthan gum and ascorbic acid food/fluid thickener should it be listed:

> **Restricted**
> For in-hospital use in patients with dysphagia diagnosed by a speech language therapist, where the speech language therapist has recommended the use of thickened fluids.

5.4 The Decision Criteria particularly relevant to these recommendations are: *(iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things, (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, (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

5.5 The Subcommittee referred to its separate discussion on the use of food/fluid thickeners and pre-thickened fluids at this meeting.

5.6 The Subcommittee considered there to be no clinical reason not to list the Easy Thick brand of maltodextrin with xanthan gum and ascorbic acid on Part II of Section H of the Pharmaceutical Schedule. The Subcommittee considered that there were no clinically significant differences between maltodextrin with xanthan gum and maltodextrin with xanthan gum and ascorbic acid. The Subcommittee considered that it would be sufficient to list only one of maltodextrin with xanthan gum or maltodextrin with xanthan gum with ascorbic acid, based on price.

6 Ready to Drink Pre-Thickened Fluids

Application

6.1 The Subcommittee reviewed an application from Flavour Creations for the listing of Ready to Drink Pre-Thickened Fluids on Part II of Section H of the Pharmaceutical Schedule and in Section D of the Pharmaceutical Schedule for patients with dysphagia. The application included a range of different products and each of the product categories was discussed separately by the Subcommittee.

Thickened Basic Beverages

Thickened Basic Beverage – Water

Application

6.2 The Subcommittee reviewed an application from Flavour Creations for the listing Flavour Creations - Thickened Water on Part II of Section H of the Pharmaceutical Schedule and in Section D of the Pharmaceutical Schedule for patients with dysphagia. The Subcommittee noted that the application included the following products:

- Flavour Creations – Thickened Water - Mildly Thick Nectar Level 1
- Flavour Creations – Thickened Water - Moderately Thick Honey Level 2
- Flavour Creations – Thickened Water - Extremely Thick Pudding Level 3

Recommendations

6.3 The Subcommittee **recommended** that the application for Flavour Creations - Thickened Water, for listing in Section D of the Pharmaceutical Schedule for patients with dysphagia for use in the community be declined.

6.4 The Subcommittee **recommended** that nectar-thick (mildly-thick) and honey-thick (moderately-thick) pre-thickened fluids, be listed on Part II of Section H of the Pharmaceutical Schedule for patients with dysphagia and noted that Flavour Creations - Thickened Water falls within this category. The Subcommittee gave this recommendation a medium priority and considered that the following restriction should be applied to this pharmaceutical:

> **Restricted**
> For in-hospital use in patients with dysphagia diagnosed by a speech language therapist, where the speech language therapist has recommended the use of thickened fluids.

6.5 The Decision Criteria particularly relevant to these recommendations are: *(iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things, (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, (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

6.6 The Subcommittee referred to its separate discussion on the use of food/fluid thickeners and pre-thickened fluids at this meeting.

6.7 The Subcommittee considered there to be no clinical reason not to list the Flavour Creations - Thickened Water, brand of pre-thickened fluid on Part II of Section H of the Pharmaceutical Schedule.

Flavour Creations – Thickened Hot Beverages

Application

6.8 The Subcommittee reviewed an application from Flavour Creations for the listing of Flavour Creations – Thickened Hot Beverages on Part II of Section H of the Pharmaceutical Schedule and in Section D of the Pharmaceutical Schedule for patients with dysphagia. The Subcommittee noted that the application included the following products:

- Flavour Creations – Thickened Black Tea - Mildly Thick Nectar Level 1
- Flavour Creations – Thickened Black Tea - Moderately Thick Honey Level 2
- Flavour Creations – Thickened Black Tea - Extremely Thick Pudding Level 3
- Flavour Creations – Thickened White Tea - Mildly Thick Nectar Level 1
- Flavour Creations – Thickened White Tea - Moderately Thick Honey Level 2
- Flavour Creations – Thickened White Tea - Extremely Thick Pudding Level 3
- Flavour Creations – Thickened White Coffee - Mildly Thick Nectar Level 1

- Flavour Creations – Thickened White Coffee - Moderately Thick Honey Level 2

- Flavour Creations – Thickened White Coffee - Extremely Thick Pudding Level 3

Recommendations

6.9 The Subcommittee **recommended** that the application for Flavour Creations – Thickened Hot Beverages, for listing in Section D of the Pharmaceutical Schedule for patients with dysphagia for use in the community be declined.

6.10 The Subcommittee **recommended** that nectar-thick (mildly-thick) and honey-thick (moderately-thick) pre-thickened hot beverages be listed on Part II of Section H of the Pharmaceutical Schedule only if they are cost neutral to the cost of using maltodextrin with xanthan gum and ascorbic acid food/fluid thickener to thicken a hot beverage. The Subcommittee noted that Flavour Creations – Thickened Hot Beverages fall within this category.

6.11 The Decision Criteria particularly relevant to these recommendations are*: (iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things, (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, (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

6.12 The Subcommittee referred to its separate discussion on the use of food/fluid thickeners and pre-thickened fluids at this meeting.

6.13 The Subcommittee considered there to be no clinical reason not to list Flavour Creations – Thickened Hot Beverages. However the Subcommittee considered that the powder thickeners available on Part II of Section H of the Pharmaceutical Schedule thicken hot beverages consistently and quickly and that there was no requirement for pre-thickened hot beverages to be listed on Part II of Section H of the Pharmaceutical Schedule.

Flavour Creations – Thickened Cordials

Application

6.14 The Subcommittee reviewed an application from Flavour Creations for the listing Flavour Creations – Thickened Cordials on Part II of Section H of the Pharmaceutical Schedule and in Section D of the Pharmaceutical Schedule for patients with dysphagia. The Subcommittee noted that the application included the following products:

- Flavour Creations – Thickened Diet Lemon Cordial - Mildly Thick Nectar Level 1

- Flavour Creations – Thickened Diet Lemon Cordial - Moderately Thick Honey Level 2
- Flavour Creations – Thickened Diet Lemon Cordial - Extremely Thick Pudding Level 3
- Flavour Creations – Thickened Diet Raspberry Cordial - Mildly Thick Nectar Level 1
- Flavour Creations – Thickened Diet Raspberry Cordial - Moderately Thick Honey Level 2
- Flavour Creations – Thickened Diet Raspberry Cordial - Extremely Thick Pudding Level 3
- Flavour Creations – Thickened Citrus Cordial - Mildly Thick Nectar Level 1
- Flavour Creations – Thickened Citrus Cordial - Moderately Thick Honey Level 2
- Flavour Creations – Thickened Citrus Cordial - Extremely Thick Pudding Level 3
- Flavour Creations – Thickened Lime Cordial - Mildly Thick Nectar Level 1
- Flavour Creations – Thickened Lime Cordial - Moderately Thick Honey Level 2
- Flavour Creations – Thickened Lime Cordial - Extremely Thick Pudding Level 3
- Flavour Creations – Thickened Raspberry Cordial - Mildly Thick Nectar Level 1
- Flavour Creations – Thickened Raspberry Cordial - Moderately Thick Honey Level 2
- Flavour Creations – Thickened Raspberry Cordial - Extremely Thick Pudding Level 3

Recommendations

6.15 The Subcommittee **recommended** that the application for Flavour Creations – Thickened Cordials for listing in Section D of the Pharmaceutical Schedule for patients with dysphagia for use in the community be declined.

6.16 The Subcommittee **recommended** that nectar-thick (mildly-thick) and honey-thick (moderately-thick) pre-thickened fluids, be listed on Part II of Section H of the Pharmaceutical Schedule for patients with dysphagia and noted that Flavour Creations - Thickened Cordials fall within this category. The Subcommittee gave this recommendation a medium priority and considered that the following restriction should be applied to this pharmaceutical:

Restricted
For in-hospital use in patients with dysphagia diagnosed by a speech language therapist, where the speech language therapist has recommended the use of thickened fluids.

6.17 The Decision Criteria particularly relevant to these recommendations are*: (iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things, (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, (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

6.18 The Subcommittee referred to its separate discussion on the use of food/fluid thickeners and pre-thickened fluids at this meeting.

6.19 The Subcommittee considered there to be no clinical reason not to list the Flavour Creations – Thickened Cordials brand of pre-thickened fluid on Part II of Section H of the Pharmaceutical Schedule.

Flavour Creations – Thickened Juices

Application

6.20 The Subcommittee reviewed an application from Flavour Creations for the listing Flavour Creations – Thickened Juices on Part II of Section H of the Pharmaceutical Schedule and in Section D of the Pharmaceutical Schedule for patients with dysphagia. The Subcommittee noted that the application included the following products:

- Flavour Creations – Thickened Apple Juice - Mildly Thick Nectar Level 1
- Flavour Creations – Thickened Apple Juice - Moderately Thick Honey Level 2
- Flavour Creations – Thickened Apple Juice - Extremely Thick Pudding Level 3
- Flavour Creations – Thickened Orange Juice - Mildly Thick Nectar Level 1
- Flavour Creations – Thickened Orange Juice - Moderately Thick Honey Level 2
- Flavour Creations – Thickened Orange Juice - Extremely Thick Pudding Level 3
- Flavour Creations – Thickened Sun Juice - Mildly Thick Nectar Level 1
- Flavour Creations – Thickened Sun Juice - Moderately Thick Honey Level 2
- Flavour Creations – Thickened Sun Juice - Extremely Thick Pudding Level 3

Recommendations

6.21 The Subcommittee **recommended** that the application for Flavour Creations – Thickened Juices for listing in Section D of the Pharmaceutical Schedule for patients with dysphagia for use in the community be declined.

6.22 The Subcommittee **recommended** that nectar-thick (mildly-thick) and honey-thick (moderately-thick) pre-thickened fluids, be listed on Part II of Section H of the Pharmaceutical Schedule for patients with dysphagia and noted that Flavour Creations - Thickened Juices fall within this category. The Subcommittee gave this recommendation a medium priority and considered that the following restriction should be applied to this pharmaceutical:

> **Restricted**
> For in-hospital use in patients with dysphagia diagnosed by a speech language therapist, where the speech language therapist has recommended the use of thickened fluids.

6.23 The Decision Criteria particularly relevant to these recommendations are*: (iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things, (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, (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

6.24 The Subcommittee referred to its separate discussion on the use of food/fluid thickeners and pre-thickened fluids at this meeting.

6.25 The Subcommittee considered there to be no clinical reason not to list the Flavour Creations – Thickened Juices brand of pre-thickened fluid on Part II of Section H of the Pharmaceutical Schedule.

Flavour Creations – Thickened Functional Juices

Application

6.26 The Subcommittee reviewed an application from Flavour Creations for the listing Flavour Creations – Thickened Functional Juices on Part II of Section H of the Pharmaceutical Schedule and in Section D of the Pharmaceutical Schedule for patients with dysphagia. The Subcommittee noted that the application included the following products:

- Flavour Creations – Thickened Cranberry Drink - Mildly Thick Nectar Level 1
- Flavour Creations – Thickened Cranberry Drink - Moderately Thick Honey Level 2

- Flavour Creations – Thickened Cranberry Drink - Extremely Thick Pudding Level 3
- Flavour Creations – Thickened Dark Grape Juice - Mildly Thick Nectar Level 1
- Flavour Creations – Thickened Dark Grape Juice - Moderately Thick Honey Level 2
- Flavour Creations – Thickened Dark Grape Juice - Extremely Thick Pudding Level 3
- Flavour Creations – Thickened Pear Juice - Mildly Thick Nectar Level 1
- Flavour Creations – Thickened Pear Juice - Moderately Thick Honey Level 2
- Flavour Creations – Thickened Pear Juice - Extremely Thick Pudding Level 3

Recommendations

6.27 The Subcommittee **recommended** that the application for Flavour Creations – Thickened Functional Juices for listing in Section D of the Pharmaceutical Schedule for patients with dysphagia for use in the community be declined.

6.28 The Subcommittee **recommended** that nectar-thick (mildly-thick) and honey-thick (moderately-thick) Flavour Creations – Thickened Functional Juices be listed on Part II of Section H of the Pharmaceutical Schedule only if they were no more expensive than other available pre-thickened fluids.

6.29 The Decision Criteria particularly relevant to these recommendations are*: (iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things, (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, (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

6.30 The Subcommittee referred to its separate discussion on the use of food/fluid thickeners and pre-thickened fluids at this meeting.

6.31 The Subcommittee noted the proposed cost of Flavour Creations – Thickened Functional Juices. The Subcommittee considered that there was no clinical reason not to list Flavour Creations – Thickened Functional Juices; however, there was no particular benefit of Flavour Creations – Thickened Functional Juices over other pre-thickened fluids that would justify a higher price. The Subcommittee recommended that, should other pre-thickened fluids be available, it would be reasonable to not list Flavour Creations – Thickened Functional Juices based on price.

Flavour Creations – Thickened Milk Based Beverages

Application

6.32 The Subcommittee reviewed an application from Flavour Creations for the listing Flavour Creations – Thickened Milk Based Beverages on Part II of Section H of the Pharmaceutical Schedule and in Section D of the Pharmaceutical Schedule for patients with dysphagia. The Subcommittee noted that the application included the following products:

- Flavour Creations – Thickened Creamy Strawberry - Mildly Thick Nectar Level 1
- Flavour Creations – Thickened Creamy Strawberry - Moderately Thick Honey Level 2
- Flavour Creations – Thickened Creamy Strawberry - Extremely Thick Pudding Level 3
- Flavour Creations – Thickened Creamy Vanilla - Mildly Thick Nectar Level 1
- Flavour Creations – Thickened Creamy Vanilla - Moderately Thick Honey Level 2
- Flavour Creations – Thickened Creamy Vanilla - Extremely Thick Pudding Level 3
- Flavour Creations – Thickened Creamy Banana - Mildly Thick Nectar Level 1
- Flavour Creations – Thickened Creamy Banana - Moderately Thick Honey Level 2
- Flavour Creations – Thickened Creamy Banana - Extremely Thick Pudding Level 3
- Flavour Creations – Thickened Creamy Chocolate - Mildly Thick Nectar Level 1
- Flavour Creations – Thickened Creamy Chocolate - Moderately Thick Honey Level 2
- Flavour Creations – Thickened Creamy Chocolate - Extremely Thick Pudding Level 3
- Flavour Creations – Thickened Creamy Dairy - Mildly Thick Nectar Level 1
- Flavour Creations – Thickened Creamy Dairy - Moderately Thick Honey Level 2
- Flavour Creations – Thickened Creamy Dairy - Extremely Thick Pudding Level 3

Recommendations

6.33 The Subcommittee **recommended** that the application for Flavour Creations – Thickened Milk Based Beverages for listing in Section D of the Pharmaceutical Schedule for patients with dysphagia for use in the community be declined.

6.34 The Subcommittee **recommended** that nectar-thick (mildly-thick) and honey-thick (moderately-thick) Flavour Creations – Thickened Milk Based Beverages, be listed on Part II of Section H of the Pharmaceutical Schedule only if they were no more expensive than other available pre-thickened fluids.

6.35 The Decision Criteria particularly relevant to these recommendations are*: (iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things, (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, (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

6.36 The Subcommittee referred to its separate discussion on the use of food/fluid thickeners and pre-thickened fluids at this meeting.

6.37 The Subcommittee noted the proposed cost of Flavour Creations – Thickened Milk Based Beverages. The Subcommittee considered that there was no clinical reason not to list Flavour Creations – Thickened Milk Based Beverages; however, there was no particular benefit of Flavour Creations – Thickened Milk Based Beverages over the other pre-thickened fluids that would justify a higher price. The Subcommittee noted that the primary purpose of this pharmaceutical was to provide hydration. The Subcommittee recommended that, should other pre-thickened fluids be available, it would be reasonable to not list Flavour Creations – Thickened Milk Based Beverages based on price.

Flavour Creations - Thickened Protein Enriched Products

Application

6.38 The Subcommittee reviewed an application from Flavour Creations for the listing Flavour Creations – Thickened Protein Enriched Products on Part II of Section H of the Pharmaceutical Schedule and in Section D of the Pharmaceutical Schedule for patients with dysphagia. The Subcommittee noted that the application included the following products:

- Flavour Creations – Thickened Pro Caramel - Mildly Thick Nectar Level 1
- Flavour Creations – Thickened Pro Caramel - Moderately Thick Honey Level 2
- Flavour Creations – Thickened Pro Caramel - Extremely Thick Pudding Level 3

- Flavour Creations – Thickened Pro Lemon Lime - Mildly Thick Nectar Level 1
- Flavour Creations – Thickened Pro Lemon Lime - Moderately Thick Honey Level 2
- Flavour Creations – Thickened Pro Lemon Lime - Extremely Thick Pudding Level 3

Recommendations

6.39 The Committee **recommended** that the application for Flavour Creations – Thickened Protein Enriched Products for listing in Section D of the Pharmaceutical Schedule for patients with dysphagia for use in the community be declined.

6.40 The Committee **recommended** that a nectar-thick (mildly-thick) and honey-thick (moderately-thick) pre-thickened high protein oral feed be listed on Part II of Section H of the Pharmaceutical Schedule and noted that Flavour Creations – Thickened Protein Enriched Products fall within this category. The Subcommittee gave this recommendation a medium priority and considered that the following restriction should be applied to this pharmaceutical:

Restricted:
Speech language therapist; and.

1. Patient requires thickened fluids; and
2. Any of the following:

2.1 Decompensating liver disease without encephalopathy; or
2.2 Protein losing enteropathy; or
2.3 Patient has substantially increased metabolic requirements.

6.41 The Decision Criteria particularly relevant to these recommendations are*: (iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things, (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, (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

6.42 The Subcommittee referred to its separate discussion on the use of food/fluid thickeners and pre-thickened fluids at this meeting.

6.43 The Subcommittee considered there to be no clinical reason not to list the Flavour Creations - Thickened Protein Enriched Products brand of pre-thickened fluid on Part II of Section H of the Pharmaceutical Schedule.

6.44 The Subcommittee considered that suitable comparators for pre-thickened protein enriched products are the High Protein oral feeds available on Part II of Section H of the Pharmaceutical Schedule. The Subcommittee considered it appropriate that a similar restriction to the High Protein products restriction be attached to Flavour Creations – Thickened Protein Enriched Products.

Flavour Creations - Thickened Formulated Meal Replacement Drinks

Application

6.45 The Subcommittee reviewed an application from Flavour Creations for the listing Flavour Creations - Thickened Formulated Meal Replacement Drinks on Part II of Section H of the Pharmaceutical Schedule and in Section D of the Pharmaceutical Schedule for patients with dysphagia. The Subcommittee noted that the application included the following products:

- Flavour Creations – FMR Iced Coffee - Mildly Thick Nectar Level 1
- Flavour Creations – FMR Iced Coffee - Moderately Thick Honey Level 2
- Flavour Creations – FMR Iced Coffee - Extremely Thick Pudding Level 3
- Flavour Creations – FMR Chocolate - Mildly Thick Nectar Level 1
- Flavour Creations – FMR Chocolate - Moderately Thick Honey Level 2
- Flavour Creations – FMR Chocolate - Extremely Thick Pudding Level 3

Recommendations

6.46 The Subcommittee **recommended** that the application for Flavour Creations - Thickened Formulated Meal Replacement Drinks for listing in Section D of the Pharmaceutical Schedule for patients with dysphagia for use in the community be declined.

6.47 The Subcommittee **recommended** that a nectar-thick (mildly-thick) and honey-thick (moderately-thick) pre-thickened standard supplement be listed on Part II of Section H of the Pharmaceutical Schedule and noted that Flavour Creations - Thickened Formulated Meal Replacement Drinks fall within this category. The Subcommittee gave this recommendation a medium priority and considered that the following restriction should be applied to this pharmaceutical:

Restricted:
Speech language therapist; and.

1. Patient requires thickened fluids; and

Any of the following:
2 For patients with malnutrition, defined as any of the following:
2.1 BMI < 18.5;
2.2 Greater than 10% weight loss in the last 3-6 months; or
2.3 BMI < 20 with greater than 5% weight loss in the last 3-6 months; or
3. For patients who have, or are expected to, eat little or nothing for 5 days; or
4. For patients who have a poor absorptive capacity and/or high nutrient losses and/or increased nutritional needs from causes such as catabolism; or
5. For use pre- and post-surgery; or

6. For any other conditions that meet the community Special Authority criteria for Standard Supplements.

6.48 The Decision Criteria particularly relevant to these recommendations are*: (iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things, (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, (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

6.49 The Subcommittee referred to its separate discussion on the use of food/fluid thickeners and pre-thickened fluids at this meeting.

6.50 The Subcommittee considered that suitable comparators Flavour Creations - Thickened Formulated Meal Replacement Drinks are the Standard Supplements available on Part II of Section H of the Pharmaceutical Schedule. The Subcommittee considered it appropriate that a similar restriction to the Standard Supplements restriction be attached to Flavour Creations - Thickened Formulated Meal Replacement Drinks.

7 PKU Lophlex Sensation 20 Supplement

Application

7.1 The Subcommittee reviewed an application from Nutricia Ltd for listing of a concentrated phenylalanine-free protein substitute (PKU Lophlex Sensation 20) for use in the dietary management of proven phenylketonuria (PKU) on Part II of Section H of the Pharmaceutical Schedule and in Section D of the Pharmaceutical Schedule.

Recommendations

7.2 The Subcommittee **recommended** listing PKU Lophlex Sensation 20 on Part II of Section H of the Pharmaceutical Schedule and in Section D of the Pharmaceutical Schedule for patients with PKU only if cost neutral to PKU Lophlex LQ.

7.3 The Decision Criteria particularly relevant to this recommendation is: *(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

7.4 The Subcommittee noted that phenylketonuria (PKU) and related forms of hyperphenylalinaemia, are autosomal recessive disorders. Members noted that PKU has an incidence of 1 in 15,000 births in New Zealand, and that it is likely that

there are approximately 4 infants per year born with this disease in New Zealand (based on 60,000 births per year) (Frank et al NZMJ 2007, Vol 120 No 1262). The Subcommittee noted that in New Zealand life-long adherence to the PKU diet is recommended to all patients (Frank 2007).

7.5 The Subcommittee noted that dietary compliance in PKU is challenging due to the restrictive nature of the diet, which consists of a restricted protein diet (from foods) and phenylalanine-free protein sources. Members noted that PKU Lophlex Sensation 20 is a semisolid, ready-to-eat product. Members considered that PKU Lophlex Sensation 20 may aid compliance due to the fact that the product does not require reconstitution.

7.6 Members considered that the availability of a range of phenylalanine-free protein substitute products might be useful to extend the range of eating experiences for patients but there would be a requirement for such products to demonstrate cost effectiveness.

7.7 The Subcommittee considered that the appropriate comparator to PKU Lophlex Sensation 20 is PKU Lophlex LQ 20.The Subcommittee noted that the difference between these two products that PKU Lophlex Sensation 20 is semi-solid and PKU Lophlex LQ 20 is a liquid formulation. The Subcommittee noted that semisolid presentations had shown high patient acceptability in a survey performed by the National Metabolic Service. The Subcommittee considered that, should PKU Lophlex Sensation 20 be listed on the Pharmaceutical Schedule, patients would use a combination of both of these products to achieve their daily protein requirement.

7.8 The Subcommittee considered that PKU Lophlex Sensation 20 might provide additional health benefits over PKU Lophlex LQ 20 alone due to increased compliance. Members considered the supplier's estimate of ten patients to be low.

7.9 Members considered that better adherence and patient acceptability may lead to increase usage and, therefore, increased costs to the Pharmaceutical Budget.

8 Cubitan (oral feed 1.25kcal/ml)

Application

8.1 The Subcommittee reviewed an application received from Nutricia Ltd for the listing of Cubitan (oral feed 1.25kcal/ml) for patients with pressure ulcers on Part II of Section H of the Pharmaceutical Schedule and in Section D of the Pharmaceutical Schedule.

Recommendation

8.2 The Subcommittee **deferred** making a recommendation on this product pending review of the published version of a recently completed study by Cereda et al and receipt of advice from the Dermatology Subcommittee of PTAC.

Discussion

8.3 The Subcommittee noted that Cubitan is a ready-to-drink food product with high levels of arginine, zinc, vitamin C, and other components considered to aid in the recovery of pressure ulcers. The Subcommittee noted that this product was not intended to help prevent the development of pressure sores nor was it intended to treat patients with malnutrition.

8.4 The Subcommittee noted its previous discussions on this product in October 2003 and in August 2012. The Subcommittee noted the minutes from the Hospital Pharmaceuticals Subcommittee of PTAC meeting held December 2011 discussing this product.

8.5 The Subcommittee considered that the literature provided to support the application was of poor quality and noted that the citations were generally small, un-blinded studies, often with no comparators. The Subcommittee noted that duration of the studies provided was not long enough to show complete healing rates. The Subcommittee considered that the appropriate comparator for this product would be good nutrition and wound care and noted that the studies provided did not use this comparator.

8.6 The Subcommittee noted a study by Cereda et al. on Cubitan has recently been completed, but is yet to be published. The Subcommittee expressed an interest in reviewing this study and its findings.

8.7 The Subcommittee considered that advice on this product should be sought from the Dermatology Subcommittee of PTAC.

9 Calogen Extra

Application

9.1 The Subcommittee reviewed an application from Nutricia Ltd to list Calogen Extra (fat and protein nutrient module) on Part II of Section H of the Pharmaceutical Schedule and in Section D of the Pharmaceutical Schedule for patients with malnutrition.

Recommendation

9.2 The Subcommittee **recommended** that the application for Calogen Extra (fat and protein nutrient module) on Part II of Section H of the Pharmaceutical Schedule and in Section D of the Pharmaceutical Schedule for patients with malnutrition be declined.

9.3 The Decision Criteria particularly relevant to this recommendation is*: (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

9.4 The Subcommittee noted that Calogen Extra is a high energy (4 kcal/ml), long chain triglyceride fat emulsion with added protein, vitamins and minerals. Members noted that Calogen Extra can be used as a supplement to the diet or to fortify the diet of patients who are unable to meet their energy, protein and vitamin and mineral requirements from normal dietary intake alone. The Subcommittee noted that Calogen Extra is designed for the dietary management of disease-related malnutrition, malabsorption states or other conditions requiring fortification with a high fat and protein, vitamin and mineral supplement. Members noted that it may be used in situations where patients cannot tolerate standard oral nutritional supplements or nutrition targets could not be met using these products due to lack of adequate intake of volume.

9.5 The Subcommittee noted that the supplier provided one randomised control trial specifically related to Calogen Extra (Hubbard et al, 2009 Calogen ESPEN poster), which compared the effects of Calogen Extra versus dietary advice on nutrient intakes and appetite in elderly patients at risk of malnutrition. Forty five community-based elderly patients (mean age: 83±7years, mean BMI: 20.8±3.4 kg/m2), at risk of malnutrition were randomised to receive either; 400 kcal/day (in 3 daily doses) of a 4 kcal/ml energy supplement containing a complete range of micronutrients (Calogen Extra, n=22), or dietary advice (n=23), for 4 weeks. Dietary and total energy & nutrient intake, appetite (using visual analogue scales) and compliance with supplementation were assessed. Members noted that supplementation with Calogen Extra increased total mean energy intake (from 1325±550 kcal/d to 1935±624 kcal/d, p=0.0001). Members noted that a significant increase in mean voluntary dietary intake over time (+251 kcal/d, p=0.014) with no significant effect on appetite scores was also observed with supplementation. Members noted that total intakes of K, Ca, Mg, PO4, Fe, Zn, Se, folate, vitamins D, E, B6, B1 and B2 increased significantly in the supplementation group over time ($p<0.05$), which was not observed in the dietary advice group. Members noted that compliance with the supplement was 92% and that it was well accepted and tolerated.

9.6 The Subcommittee noted that the supplier also provided general literature related to this therapeutic area.

9.7 The Subcommittee considered that the evidence for Calogen Extra was limited in relation to the recommended product indications such as cancer, cystic fibrosis, patients with human immunodeficiency virus and chronic obstructive pulmonary disease.

9.8 The Subcommittee noted that the supplier considers that Calogen Extra would be used primarily in patients over 20 and particularly in patients over 65 years of age. Members noted that the supplier has provided comparisons to Nutrient Reference Values for Australia and New Zealand for some age groups, but not for the over 20 and over 65 year age groups.

9.9 The Subcommittee considered that it was unclear which patients group would benefit from Calogen Extra. The Subcommittee considered that there was a need for more evidence to demonstrate clinical benefit such as decreases in mortality, morbidity, functional decline and maintenance of the elderly in a domiciliary setting.

10 Nutrini Drink

Application

10.1 The Subcommittee reviewed an application from Nutricia Ltd to list NutriniDrink (paediatric oral feed) on Part II of Section H of the Pharmaceutical Schedule and in Section D of the Pharmaceutical Schedule for paediatric patients.

Recommendation

10.2 The Subcommittee **recommended** that the application for NutriniDrink (paediatric oral feed powder) be listed on Part II of Section H of the Pharmaceutical Schedule, under the Paediatric Products restriction, and on Section D of the Pharmaceutical Schedule, under the Paediatric Products Special Authority, only if it was no more expensive than Pediasure (paediatric oral feed powder).

10.3 The Decision Criteria particularly relevant to these recommendations 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

10.4 The Subcommittee reviewed a funding application from Nutricia LTD for the listing of NutriniDrink paediatric oral feed powder, on Part II of Section H of the Pharmaceutical Schedule and in Section D of the Pharmaceutical Schedule.

10.5 The Subcommittee noted that the subject of the application was different from the previously funded product called NutriniDrink, which changed its brand name to Fortini and remains funded and listed on the Pharmaceutical Schedule.

10.6 The Subcommittee compared NutriniDrink against the currently funded paediatric oral feed powder (Pediasure) and noted the differences in the nutritional content between the two products. The Subcommittee noted that the currently funded brand, Pediasure, contains higher levels of protein and fat and considered that these higher protein levels were clinically beneficial.

10.7 The Subcommittee considered that there was no clinical reason not to list NutriniDrink; however, the Subcommittee considered that there would be no justification for listing it at a higher price than Pediasure.