Special Foods Subcommittee meeting held 6 June 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.

Some material has been withheld, in accordance with the Official Information Act 1982 (OIA) in order to protect the privacy of natural persons (section 9(2)(a)).

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.

Contents

1 PKU Anamix Junior LQ

Application

1.1 The Subcommittee reviewed an application from Nutrica for the replacement on the Pharmaceutical Schedule of its PKU product Minaphlex with PKU Anamix Junior.

Recommendation

1.2 The Subcommittee **recommended** that PKU Anamix Junior LQ is listed on the Pharmaceutical Schedule with a high priority.

1.3 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; (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 PKU Anamix Junior LQ and Minaphlex powder are clinically equivalent and are used by the same aged patients.

1.5 The Subcommittee considered that PKU Anamix Junior LQ had a number of advantages over Minaphlex including that it is a liquid rather than a powder and that it is a follow-on product to PKU Anamix Infant.

1.6 The Subcommittee noted that PKU Anamix Junior LQ and Minaphlex had the same cost on a per gram of protein basis and that both were cheaper than XP Maxamaid. The Subcommittee considered that listing PKU Anamix Junior would be cost neutral to cost saving depending upon any patient switch from XP Maxamaid.

1.7 The Subcommittee considered that currently the product range was acceptable but that PKU Anamix Junior LQ tastes better than Minaphlex powder and that this may result in better compliance and therefore better clinical outcomes.

1.8 The Subcommittee considered that there was no clinical reason not to list PKU Anamix Junior LQ on the Pharmaceutical Schedule.

2 Infatrini

Application

2.1 The Subcommittee reviewed an application from Nutrica for the listing on the Pharmaceutical Schedule of a high energy (1 kcal/ml) infant formula in a 100 ml Ready to Feed bottle (Infatrini).

Recommendation

2.2 The Subcommittee **recommended** that Infatrini is listed on the Pharmaceutical Schedule with a medium/high priority.

2.3 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

2.4 The Subcommittee noted that currently infants who require a high energy formula concentrate a standard unfunded formula and that additives may be added.

2.5 The Subcommittee noted that the protein content of Infatrini was high with more than 10% of the energy being from protein. The Subcommittee considered that the protein content was high and that this created a risk that infants would be given too much protein. The Subcommittee noted that the application recommended up to 160 ml per kg however the Subcommittee considered that this was too high and that the amount of Infatrini per kg of weight would need to be limited.

2.6 The Subcommittee considered that mixing errors would be reduced with Infatrini and that it was more convenient than concentrating a standard unfunded formula.

2.7 The Subcommittee noted that as Infatrini was sterile it could be hung as a continuous tube feed for 8 hours while standard concentrated formula could only be hung for 4 hours. The Subcommittee noted that this would reduce the frequency of overnight cares for parents.

2.8 The Subcommittee considered that Infatrini would be useful in a small niche group of patients such as fluid restricted children who were either in cardiac or intensive care wards. The Subcommittee considered that there was a disproportionate burden on these children and their families.

2.9 The Subcommittee noted that there were about 5-10 children on Infatrini at any one time in Starship Children's Hospital and that the supplier estimated that there would be about 130 children who required this product at any one time. The Subcommittee considered that the number of patients that this product would be used in would be small.

2.10 The Subcommittee noted that the proposed cost of Infatrini of $2.50 per 100 ml bottle was high and considered that the supplier should reduce the cost per unit.

2.11 The Subcommittee considered that by 6 months the infants could start to be transferred to standard formula and that by 12 months there would be other options available including solids, Nutrini drink and standard formula.

2.12 The Subcommittee considered that Infatrini should be restricted to:

2.12.1 patients that would otherwise concentrate a standard formula

2.12.2 not more than 150 ml per kg

2.12.3 a 6 month initial Special Authority approval period

2.12.4 only one 6 month Special Authority renewal

2.13 The Subcommittee considered that Infatrini was an expensive product that would be in a new therapeutic group and that there was a place for Infatrini as a niche product, that would be useful for a small patient group on the basis of convenience. The Subcommittee also considered that Infatrini would not meet a great unmeet clinical need.

3 Nutrini Energy Multi-fibre

Application

3.1 The Subcommittee reviewed an application from Nutrica for the listing on the Pharmaceutical Schedule of a Ready to Hang 1.5 kcal/ml paediatric enteral feed with fibre (Nutrini Energy Multi-fibre).

Recommendation

3.2 The Subcommittee **recommended** that Nutrini Energy Multi-fibre is listed on the Pharmaceutical Schedule with a high priority subject to Nutrica maintaining the availability of Nutrini Energy RTH (1.5 kcal/ml paediatric eneteral feed).

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; (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

3.3 The Subcommittee noted that Nutrini Energy Multifibre is the same product as Nutrini Energy but with fibre added.

3.4 The Subcommittee noted that there is currently no fibre enriched 1.5 kcal/ml paediatric enteral feed and that currently either Nutrini Energy is being used or Nutrini drink with fibre is being decanted.

3.5 The Subcommittee noted that there is no evidence that the addition of fibre reduces constipation or diarrhoea. However, the Subcommittee considered that anecdotally fibre products do significantly reduce constipation. The Subcommittee therefore considered that the use of Nutrini Energy Multifibre would reduce the use of laxatives such as lactulose and movical.

3.6 The Subcommittee noted that previously when Nutrison Energy with Multifibre was listed the supplier delisted Nutrison Energy (the non-fibre version of the product). The Subcommittee therefore recommended that prior to any listing of Nutrini Energy Multifibre the supplier must agree that Nutrini Energy would remain available.

4 Nutrini Low Energy Multi-fibre

Application

4.1 The Subcommittee reviewed a reapplication from Nutrica for the listing on the Pharmaceutical Schedule of a Ready to Hang 0.75 kcal/ml paediatric enteral feed with fibre (Nutrini Low Energy Multi-fibre).

Recommendation

4.2 The Subcommittee recommended that Nutrini Low Energy Multi-fibre is listed on the Pharmaceutical Schedule with a high priority for children with a low energy requirement who also have neurodevelopmental disability.

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; (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

4.4 The Subcommittee noted that Nutrini Low Energy Multi-fibre was considered by the Subcommittee in 2006 and recommended for decline.

4.5 The Subcommittee noted that Nutrini Low Energy Multi-fibre was targeted to children (1 to 10 years of age) with a low energy requirement but maintained normal protein and micronutritient requirements. The Subcommittee considered that most of these children would be tube-feed.

4.6 The Subcommittee noted that currently patients would reduce the volume taken of the standard feed and may take additional vitamins and minerals to meet their requirements.

4.7 The Subcommittee noted that there is a significant amount of evidence regarding child growth and micronutrients including an increased risk of oestopenia if load bearing does not occur. The Subcommittee also noted that tube feed children have to be lifted by their carers and therefore the weight of the child can be an issue.

4.8 The Subcommittee noted that the patient population that would benefit most from Nutrini Low Energy Multi-fibre would be those who maintain their growth on a lower energy product rather than obese patients.

4.9 The Subcommittee considered that there is no similar product available and that if Nutrini Low Energy Multi-fibre was listed on the Pharmaceutical Schedule then it would replace Nutrini RTH (paediatric enteral feed 1 kcal/ml) and Pediasure (paediatric oral feed 1 kcal/ml). The Subcommittee considered that perhaps 25% to 33% of children currently on Nutrini could switch to Nutrini Low Energy Multi-fibre. The Subcommittee also considered that it would be unlikely for Nutrini Low Energy Multi-fibre to be misused.

4.10 The Subcommittee considered that Nutrini Low Energy Multi-fibre should be restricted to children with low energy requirements who have neurodevelopmental disability.

5 Modulen

Application

5.1 The Subcommittee reviewed additional information regarding Modulen IBD for the treatment of Crohn's disease.

Recommendation

5.2 The Subcommittee **recommended** that Modulen IBD is listed on the Pharmaceutical Schedule if cost-neutral to standard nutritional therapy such as Fortisip and Ensure Plus. The Subcommittee also recommended that should studies be performed comparing Modulen with standard nutritional therapy then Modulen should be reconsidered.

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; (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 the minutes from November 2008 when the Subcommittee previously reviewed the application. The Subcommittee also noted an opinion on exclusive enteral nutrition and Modulen IBB in Crohn's disease from [withheld under s9(2)(a) of the OIA] a Paediatric Gastroenterologist.

5.5 The Subcommittee considered that nutritional therapy is an appropriate treatment for children with Crohn's disease for the induction of remission, either initially or following a relapse from remission.

5.6 The Subcommittee noted that compliance with nutritional therapy is good as it is only used as a short-term treatment and that it provides an alternative to steriods which have a less favourable side-effect profile.

5.7 The Subcommittee noted that the currently available nutritional therapy treatments included standard oral feeds such as Fortisip and Ensure Plus.

5.8 The Subcommittee noted that Modulen is a complete feed which contains TGF- ß2 (transforming growth factor).

5.9 The Subcommittee noted that there is no strong evidence comparing Modulen with Fortisip or Ensure Plus and that appropriate trials to do this are required.

5.10 The Subcommittee noted that while there is no comparative evidence both current nutritional therapy options and Modulen provide a good clinical outcome. However, the Subcommittee noted that the cost of Modulen is significantly higher than the cost of standard nutritional therapy.