Special Foods Subcommittee meeting held 27 August 2012

(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 9 & 10 May 2013, the record of which is available on the PHARMAC website.

Contents

1 Naming and Descriptions for Special Foods

Application

1.1 The Committee reviewed a memorandum from PHARMAC discussing what information would be useful in the hospital formulary and Section D of the Pharmaceutical Schedule to assist prescribers.

Recommendation

1.2 The Committee **recommended** that the information presented in the British National Formulary regarding Special Foods would be most appropriate for inclusion in the hospital formulary and Section D of the Pharmaceutical Schedule.

Discussion

1.3 The Subcommittee noted that as part of the establishment of the hospital formulary the information presented in the Pharmaceutical Schedule is being reviewed in order to improve the way in which nutritional products are described.

1.4 The Subcommittee noted the information and presentation of nutritional products in Section D of the Pharmaceutical Schedule, New Zealand Formulary, New Zealand Universal List of Medicines, BNF, PBS, MIMS and the Dietician Clinical Handbook.

1.5 The Subcommittee considered that the Pharmaceutical Schedule, New Zealand Formulary, and New Zealand Universal List of Medicines do not contain sufficient information to differentiate or describe products to prescribers.

1.6 The Subcommittee noted that the BNF includes a Special Characteristics field and that the Dietician Clinical Handbook has a similar feature which summarises the features of each product. The Subcommittee considered these useful although it considered that the overall information in the Dietician Handbook to be too comprehensive.

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 for infants with food allergies be deferred pending further information, specifically additional growth data for infants and wider use in infants outside of the limited study populations to date.

Discussion

2.3 The Subcommittee reviewed the 2010 application, the May 2010 meeting minute, the April 2010 World Allergy Organisation (WAO) Diagnosis and Rationale for Action

against Cow's Milk Allergy (DRACMA) Guidelines, reviews of the application from two members of the Paediatric Society, and additional information provided by the Supplier regarding Risolac's use in Europe and its international role-out.

2.4 The Subcommittee noted that the composition of Risolac hydrolysed rice protein formula meets the infant formula requirements.

2.5 The Subcommittee noted a number of studies including Fiocchi et al (2003), Fiocchi et al (2006), D'Auria et al (2003), Agostoni et al (2007), and Terracciano et al (2010).

2.6 The Subcommittee considered that while these studies supported the use of hydrolysed rice protein formula in the treatment of cows and soy milk allergy they only included a small number of patients similar to the New Zealand target population (infants under 2 years old with cow's milk allergy). The Subcommittee also considered that there is a lack of data to indicate the hydrolysed rice protein formula results in appropriate growth rates in infants under 2 years old and as it is a new product clinician experience of growth rates is not available as is available for other funded formulae.

2.7 The Subcommittee noted that as theoretically Risolac does not include cow's or soy milk it may: reduce the number of patients requiring an amino acid based formula due to cows' milk and soy milk intolerance; that it could be used as an alternative to amino acid formula for infants with anaphylaxis to cows' milk; and that it may result in symptom resolution earlier than currently funded formula.

2.8 The Subcommittee considered that Risolac may be preferred by parents for infants with cows' milk allergy due to it not containing any cows' milk products unlike currently funded formula.

2.9 The Subcommittee considered that given the information available hydrolysed rice protein formula would most likely have the same or similar therapeutic effect to extensively hydrolysed cows' milk formula.

2.10 The Subcommittee concluded that hydrolysed rice protein formula showed significant promise, that it would welcome additional evidence supporting its use, and that the supplier should be encouraged to supply this.